



# Supplementary Criteria for Accreditation **PET-CT**



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Tohu Matatau Aotearoa

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# Supplementary Criteria for Accreditation

## Medical Imaging Services Accreditation Programme

### PET-CT

### AS MIS C1.5

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## 1 Introduction

IANZ Supplementary Criteria amplify or particularise the general accreditation criteria for specific fields of technology or for specific types of business activity.

A list of all Specific and Supplementary Criteria publications are available at [www.ianz.govt.nz](http://www.ianz.govt.nz) or from IANZ on request. This Supplementary Criteria AS MIS C1.5 defines specific technical requirements for the accreditation of medical imaging services performing positron emission tomography (PET) CT procedures.

This publication must be read in conjunction with the following IANZ publications:

- (a) *The relevant Supplementary Criteria document for the conjoint modality*
- (b) *The New Zealand Code of Radiology Management Practice (NZCRMP)*
- (c) *Procedures and Conditions for Accreditation (PCA; AS 1)*

The latter document describing the organisation and operation of the IANZ Accreditation Programmes also applies to the accreditation of medical imaging services.

*Note: The New Zealand Code of Radiology Management Practice is developed from the 2007 edition of ISO 15189 Medical Laboratories - Particular requirements for quality and competence*

The IANZ Medical Imaging Services Accreditation Programme offers accreditation in nine separate imaging modalities, as follows:

- (a) Bone Densitometry
- (b) CT Scanning
- (c) DSA
- (d) General Radiography
- (e) MR Imaging
- (f) Mammography
- (g) Nuclear Medicine
- (h) PET-CT
- (i) Ultrasound

Medical Imaging services, including those offering PET-CT, are assessed fully over a cycle of four years. Technical Assessments and Reassessments are carried out at years 2 & 4 in the cycle and Surveillance Assessments are carried out in the intervening years. Advice and technical review is provided by the IANZ Medical Imaging Services Professional Advisory Committee (MISPAC) and the IANZ Accreditation Advisory Committee (AAC).

This Supplementary Criteria provides information on scope of accreditation, staff, accommodation, equipment and other aspects of good medical imaging service management considered to be a minimum standard for medical imaging services PET-CT activities.

## 2 Acronyms

|         |  |
|---------|--|
| 3D      | Three Dimensional  |
| AAC     | Accreditation Advisory Committee   |
| AANMS   | Australasian Association of Nuclear Medicine Specialists                         |
| AAPM    | American Association of Physicists in Medicine                                   |
| ACPSEM  | Australasian College of Physical Scientists & Engineers in Medicine              |
| ACR     | American College of Radiology  |
| ACRIN   | American College of Radiology Imaging Network                                    |
| ANZHSN  | Australia and New Zealand Horizon Scanning Network                               |
| ANZSNM  | Australian and New Zealand Society of Nuclear Medicine Limited                   |
| ARSAC   | Administration of Radioactive Substances Advisory Committee                      |
| BMI     | Body Mass Index  |
| CSP     | Code of Safe Practice  |
| CT      | Computed Tomography  |
| CTDI    | Computed Tomography Dose Index   |
| CME     | Continuing Medical Education   |
| CPD     | Continuing Professional Development  |
| FAASNMS | Fellow of the Australasian Association of Nuclear Medicine Specialists           |
| FDG     | Fluorine-18-2-fluoro-2-deoxy-D-glucose   |
| FRACP   | Fellow of the Royal Australasian College of Physicians                           |
| FRANZCR | Fellow of the Royal Australian and New Zealand College of Radiologists           |
| IAEA    | International Atomic Energy Agency   |
| IANZ    | International Accreditation New Zealand  |
| ISO     | International Organisation for Standardisation                                   |
| JSAC    | Joint Specialist Advisory Committee  |
| kV      | Kilovolts  |
| mA      | Milliamperes   |
| MIT     | Medical Imaging Technologist, includes Nuclear Medicine Technologist / Scientist |
| MRI     | Magnetic Resonance Imaging   |
| MRTB    | Medical Radiation Technologists Board  |
| NEMA    | National Electrical Manufacturers Association                                    |
| NZCRMP  | New Zealand Code of Radiology Management Practice                                |
| NZS     | Standards New Zealand  |
| ORS     | Office of Radiation Safety   |
| PCA     | Procedures and Conditions of Accreditation                                       |
| PET     | Positron Emission Tomography   |
| QC      | Quality Control  |
| RACP    | Royal Australasian College of Physicians   |
| MISPAC  | Medical Imaging Services Professional Advisory Committee                         |
| RANZCR  | Royal Australian and New Zealand College of Radiologists                         |
| SMPTE   | Society of Motion Picture and Television Engineers                               |
| SNR     | Signal-to-Noise Ratio  |
| SPECT   | Single Photon Emission Computed Tomography                                       |
| SUV     | Standardised Uptake Value  |
| TG-18   | (AAPM) Task Group 18   |

### 3 Scope of Accreditation

IANZ accreditation applies to specific imaging procedures or types of examination and does not constitute a blanket cover of all the diagnostic imaging activities of a medical imaging service. Accreditation is granted only for imaging modalities for which a medical imaging service is properly equipped and has demonstrated its capability.

Under the IANZ medical imaging accreditation programme, the range of examinations performed by a medical imaging service in a particular imaging modality is not described in great detail. A broad description of the imaging modalities in which a medical imaging service has demonstrated competence is provided in the terms of accreditation of the medical imaging service. Further detail of the imaging capability of an accredited medical imaging service is retained by IANZ but is not generally published.

*Note: Some medical imaging services might perform PET-CT examinations on veterinary animals or carry out examinations on human patients and other subjects for research purposes. These examinations are not covered by the IANZ medical imaging accreditation programme.*

### 4 Accommodation

General accommodation requirements are specified in the *New Zealand Code of Radiology Management Practice*.

Accommodation requirements for PET-CT facilities are more complex than those required for some other imaging modalities. In addition to the need to accommodate patients and medical imaging service staff members, the facility must ensure adequate accommodation shielding is in place to minimise occupational and non-occupational exposure. Details of location, type and thickness of shielding will need to be available for review along with personal dosimetry results for all relevant staff members.

The PET-CT facility needs to provide a reasonable standard of patient privacy and meet relevant ORS requirements. International standards and other industry specifications developed specifically by the AANMS, AAPM, ANZSNM, ACR and ORS pertaining to PET-CT facilities have been published and provide useful guidance for the design and construction of a PET-CT service.

All PET-CT services are expected to provide adequate accommodation for at least the following:

- (a) Appropriate emergency equipment and medications in the immediate vicinity to treat adverse reactions to administered medications and contrast media agents;
- (b) Areas for the storage of equipment accessories and consumables;
- (c) Controlled and uncontrolled areas with appropriate shielding and signage;
- (d) Dedicated patient toilet facilities;
- (e) Facilities for the performance of administrative duties;
- (f) Facilities for the supervised or secure storage of patient belongings;
- (g) Image viewing and reporting areas;
- (h) Imaging suite;
- (i) Patient change cubicles;
- (j) Patient injection/uptake areas and a chair and/or bed for each patient;
- (k) Patient interview and preparation areas;
- (l) Patient waiting areas;
- (m) Provision for the safe emergency egress from the site;
- (n) Remote monitoring and communication with radioactive patients;
- (o) Radiation protection optimisation through facility design, such as separate entrances and exits for patients use.



In addition to the above accommodation requirements, a PET-CT facility is expected to adequately provide for at least the following specialist items relevant to the accommodation of the PET-CT scanner or radionuclides:

- (a) A workstation with the capability to display CT, PET and fused images with different percentages of CT and PET blending;
- (b) Acoustic and lighting control for optimal patient imaging and patient comfort;
- (c) Suitable temperature control in pre-scan patient areas and in the imaging area to minimise brown fat uptake;
- (d) Areas where PET radiopharmaceuticals are prepared, used or stored;
- (e) Optimal environment for storing computing equipment;
- (f) Patient and personnel decontamination facilities;
- (g) Radioactive waste storage and disposal facilities commensurate with the radionuclide half-lives used in the facility;
- (h) Remote communication with the patient being examined;
- (i) General temperature, humidity, ambient lighting control in addition to the special PET-CT requirements already noted;
- (j) Sedation and general anaesthesia facilities where appropriate;
- (k) Workflow efficiencies to reduce radiation dose to other patients, members of the public and staff members, and sensitive counting equipment to optimise use of radiopharmaceuticals.

## 5 Safety

General safety requirements are specified in the *New Zealand Code of Radiology Management Practice*.

PET-CT examinations involve the use of higher energy radiation when compared to diagnostic CT and most other Nuclear Medicine examinations, which can cause a radiation hazard to the patient and to staff members of the medical imaging service. A PET-CT facility has unique safety requirements, with the following to be documented and implemented:

- (a) The Licensee may delegate responsibility for non-clinical radiation safety to a suitably trained Radiation Safety Officer, who is supported by a qualified medical physicist;
- (b) A radiation safety plan that incorporates areas where patients may be held pre- and post-examination;
- (c) Procedures for decontamination and handling of radiation spills in the PET-CT facility;
- (d) Relevant ORS requirements, including improved radiation protection appropriate for a nuclear medicine facility<sup>1</sup>.

*Note: An assessment of the facility's compliance with the New Zealand Department of Labour health and safety requirements is not undertaken during IANZ on-site assessments.*

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<sup>1</sup> A CT diagnostic facility may not be suitable for PET-CT imaging unless additional considerations, such as shielding, occupancy and distance, are incorporated into facility redesign.

## 6 Staff

General requirements for medical imaging service staffing are specified in the *New Zealand Code of Radiology Management Practice*.

Combined PET and diagnostic quality CT devices provide functional information from PET and anatomic information from CT in a single examination. This necessitates staff members interpreting PET must be competent and maintain competence in the interpretation and reporting of PET, as well as CT. Cases may also require review and integration of imaging performed with other modalities (radiography, ultrasound, fluoroscopy, angio-intervention, other nuclear medicine studies etc), and therefore ability to interpret other modalities is expected. Examinations must be carried out frequently enough to ensure that competence is maintained.

All PET-CT facilities shall hold or have direct access to a comprehensive range of current specialist textbooks, scientific journals and other reference literature appropriate and relevant to the scope of activities performed.

In addition to the general requirements stated in the *NZCRMP*, each PET-CT facility is expected to demonstrate the following:

### Medical physicists

- (a) Must be on the ACPSEM's speciality register of nuclear medicine physicists,
- Or
- (b) Deemed eligible for ordinary membership by the ACPSEM, and
- (c) Has practiced as either a nuclear medicine physicist for at least the previous five years or as a PET-CT physicist for at least the previous two years.

### PET-CT Medical Imaging Technologists (MITs)

- (a) MIT staff members shall be registered by the MRTB in the scope of General Radiography (CT Scanning) and Nuclear Medicine (PET). Alternatively, at least one MIT must be registered in the scope of General Radiography (which includes CT Scanning) and one MIT in the scope of Nuclear Medicine (PET);
- (b) All MIT staff members shall actively participate in continuing medical education relevant and appropriate to PET-CT;
- (c) During image acquisition, at least one appropriately trained MIT must be located at the PET-CT system console where both the patient and the progress of the imaging study can be monitored.

### PET-CT specialists

- (a) The Principal Licensee/s in charge of the PET-CT facility shall be clearly identified;
- (b) All specialists practicing PET-CT shall actively participate in a recognised continuing medical education programme relevant and appropriate to PET-CT;
- (c) All specialists practicing PET-CT must have specific training in and knowledge of clinical indications, alternative imaging methods<sup>2</sup>, contrast agents, radiopharmaceuticals and other medications, and examination protocols, to assure the quality of images and interpretations and assure patient safety;
- (d) All specialists practicing PET-CT shall meet relevant ORS licensing requirements and hold a current license to use ionising radiation<sup>3</sup>;
- (e) All specialists who report PET-CT images shall hold current (not greater than three years old) optometrists reports and shall wear any prescribed optical aids while reporting.

All specialists who practice PET-CT shall hold vocational registration in medical imaging or nuclear medicine and must have undergone recognised specific training in PET-CT interpretation and reporting. For those

<sup>2</sup> Including but not limited to the use of angiography, CT, general radiography, MRI, ultrasound and alternative nuclear medicine studies.

<sup>3</sup> Please refer to the ORS Core of Knowledge for a Licence to use Radioactive Material for Medical Diagnostic Purposes publication.

PET-CT specialists vocationally registered as a radiologist or nuclear medicine physician in New Zealand, this could be through the JSAC of the RACP and RANZCR. Alternatively, this could be through cumulative PET-CT experience of cases with feedback, for which a log or certification has been kept and can be made available for review. This may become subject to additional standards recommended by the RANZCR New Zealand Branch.

Specialists practicing PET-CT must maintain ongoing competence in PET-CT procedures by the following:

- (f) Participate in CME relevant and appropriate to PET as well as CT (as outlined in RANZCR CPD guidelines), which could include attendance at clinical meetings during which PET-CT studies are reviewed.

Or

- (g) Meet the ongoing PET competency requirements of the Joint Specialist Advisory Committee (JSAC) of the RACP as well as participate in CME for CT (as outlined in RANZCR CPD guidelines).

While voluntary, it is recommended that those reporting PET-CT accumulate a total of 15 PET-CT specific RANZCR CPD points (or equivalent) each triennium. This can include CPD activities in closely related topics which include PET-CT as an indispensable part of the topic (e.g. applications of MRI with PET-CT correlation). Incorporating audit and quality assurance CPD activities, such as peer review and active presentation of cases with feedback is strongly recommended.

There may be circumstances where the requirements for PET credentialing and ongoing competence are met through a conjoint approach e.g. by a radiologist and a nuclear medicine physician who jointly satisfy the criteria. The requirements for these two separate specialists are detailed in the relevant modality specific IANZ Supplementary Criteria for Accreditation documents.

## 7 Patient Management

General requirements for the management of patients undergoing an examination are specified in the *New Zealand Code Radiology Management Practice*.

In addition to these general requirements, there are a number of patient issues specific to a PET-CT service which needs to be carefully managed to ensure the quality of PET-CT images and the comfort and well-being of the patient. The following additional issues need to be incorporated into documented policy and procedures where appropriate:

- (a) Completion of a blood-glucose analysis immediately prior to FDG administration;
- (b) Counselling of patients with regard to claustrophobia and the examination procedure;
- (c) Fasting and dietary instructions;
- (d) Instructions for patients and other persons exposed to radiation as to the risks associated and precautions to take to minimise their radiation dose;
- (e) Minimisation of time that staff members spend with radioactive patients and materials;
- (f) Obtaining information from the patient in relation to any medical condition such as diabetes, surgery, occupation / other exposure history, recent exercise, dates of diagnosis and treatments, recent trauma or infections, or other history, such as medications, which may complicate the examination or influence post examination management of the patient;
- (g) Obtaining informed patient consent where appropriate;
- (h) Preparing patients in a warm environment prior to injection and then in a quiet and dimly lit room post injection for those procedures using glucose-sensitive radiopharmaceutical if appropriate;
- (i) Provision for a medical doctor to be available during each examination;
- (j) Provision for the post-examination care and discharge of patients, where necessary;
- (k) Provision of useful information to the patient in relation to the examination procedure;
- (l) Recognition and management of reactions to medications, radiopharmaceuticals and contrast media agents;
- (m) Special procedures and precautions for paediatric, pregnant or breast-feeding patients;

- (n) Special procedures for patients with allergies or renal impairment;
- (o) Voiding of bladder after uptake and prior to imaging.

Patient management procedures shall be subject to regular review (at least annually is recommended), by the medical imaging service director or designee), and where necessary, revised. Records of such reviews shall be maintained.

## 8 Imaging Procedures

General imaging procedure requirements are specified in the *New Zealand Code of Radiology Management Practice*.

To an extent, the amount of instructional detail documented in imaging procedures for PET-CT will depend on the experience and ability of staff members in addition to the user-friendliness of the PET-CT scanner and its control console. Sufficient instructional detail shall be documented to ensure the consistent operation of the equipment by all staff members who may at any time be asked to participate in the examination of patients.

Documented examination procedures shall include at a minimum the following:

- (a) Study identification;
- (b) Summary of clinical indications and justification;
- (c) Summary of patient conditions that may impact the procedure or interpretation of images;
- (d) Patient preparation required;
- (e) Specific administered activity of radiopharmaceutical for each adult and paediatric procedure to be measured immediately prior to examination and any precautions or restrictions that may apply;
- (f) Details of medications and other materials that may be utilised during the procedure, and any precautions or restrictions that may apply;
- (g) Route of administration;
- (h) Time interval between radiopharmaceutical administration and imaging;
- (i) Routine patient positioning;
- (j) Equipment set-up;
- (k) Required regions and any special region that may be regularly required;
- (l) Acquisition parameters for PET-CT;
- (m) Reconstruction process parameters;
- (n) Technical and acquisition factors;
- (o) Image display and processing requirements, including details of any quantitative analysis, such as SUV measurements and reported SUV values;
- (p) Reference to any special QC checks required that are specific to the procedure;
- (q) Where appropriate, reference to medical literature for additional information.

All imaging procedures shall be reviewed regularly (at least annually is recommended) by the medical imaging service director or designee and, where necessary, revised to ensure that they remain appropriate and relevant to the activities of the PET-CT facility. The review process should take into consideration the results of research relevant to PET-CT and industry trends specific to PET-CT. Review and revision must be completed by the medical imaging service director or designee, who must approve any changes. Records of such reviews shall be maintained. Where imaging parameters differ from that of the manufacturer's official written or published recommendations, the investigation and decisions that led to the adoption of new imaging parameters must be documented.

In addition to the general requirements documented in the *NZCRMP*, there are a number of additional activities specific to a PET-CT facility for which formally documented procedures are necessary and where appropriate, include the following:

- (a) Additional measures to reduce radiation dose to patients and facility staff members;
- (b) Administration of local or general anaesthetic and subsequent discharge of patient ;
- (c) Administration of radiopharmaceuticals;
- (d) Administration of sedatives and subsequent discharge of patient;
- (e) Calculation and measurement of radioactive material activity to be dispensed for administration, including documentation of the methods of compensation for patient weight or BMI;
- (f) Emergency evacuation of the facility;
- (g) Operation and maintenance of automatic injector, patient monitoring and resuscitation equipment;
- (h) Screening of patients for clinical and medical information pertinent to the examination.

## 9 Examination Reports

General reporting requirements are specified in the *New Zealand Code of Radiology Management Practice*.

The medical imaging service shall issue a formal report pertaining to each patient examination, which in addition to the requirements stated in the *NZCRMP* shall include at least the following:

- (a) Address and contact details of the PET-CT facility where the examination took place;
- (b) Details of any medications given prior to or during the scan which may affect metabolic behaviour of the radiopharmaceutical;
- (c) Details of contrast media and radiopharmaceutical dose/activity, type and route of administration
- (d) Blood-glucose level for FDG-PET studies;
- (e) A description of the location, extent, and intensity of abnormal positron-emitting radiopharmaceutical uptake in relation to normal comparable tissues;
- (f) An estimate of the intensity of uptake, and where relevant measurement of SUV;
- (g) Description of relevant morphologic findings related to PET abnormalities on the CT images;
- (h) Correlation of PET and CT findings;
- (i) Comparison with prior studies, including prior SUV values, where relevant;
- (j) Clinically important findings on the CT scan, where appropriate;
- (k) Any deviation from the standardised examination protocol as documented in the procedure manual;
- (l) Name and designation of the reporting specialist. If a trainee has reported under supervision, the name and designation of the trainee and supervising PET-CT specialist is to be included.

There are a number of related issues for which the medical imaging service will need to develop and document policy and procedures. These issues include the following:

- (a) Confidentiality of results and other patient records;
- (b) Mechanism and authority for the release of urgent results;
- (c) Provision of advice in relation to follow-up studies or additional examinations;
- (d) Release of images and/or results to patients, referrers or third parties;
- (e) Release of results by telephone, fax or other electronic means;
- (f) Routine double reading of PET-CT examinations during specialist training until the competencies in Section 6 of this Supplementary Criteria have been met;
- (g) Seeking second opinions for difficult to interpret, ambiguous images or for images arising from highly specialised examination procedures.

## 10 Records

General record requirements are specified in the *New Zealand Code of Radiology Management Practice*.

This Supplementary Criteria section defines additional record requirements for those records arising from PET-CT examination of patients which may not normally be included in the examination report ultimately despatched to the referring clinician.

Formal records shall be maintained for at least the following items relevant to the examination of a patient:

- (a) Advice given to the patient in relation to the risks associated with the examination, radiation of radiopharmaceuticals and, where necessary, obtaining the patient's consent to proceed with the examination. Documentation could include evidence of provision of an information sheet as part of or together with the appointment document;
- (b) Any QC checks completed as part of the procedure;
- (c) Daily patient log;
- (d) Medications or radiopharmaceuticals administered, including details of the volume and strength of medications or type and dose of radiopharmaceutical used, the time and means of administration in addition to injection site, and the identity of the person or persons responsible for the administration;
- (e) Patient records to include examination type and purpose, in addition to unique patient identification, sex, date-of-birth, pregnancy status, name of referrer, date of request, patient history screening prior to administration of radiopharmaceuticals and other medications, radiopharmaceutical identity and activity, identity of any medications administered, route of administration, contrast media or radiopharmaceuticals administered, any subsequent adverse reaction to medications, any deviation from documented examination procedures and the name of the PET-CT technologist who performed the procedure;
- (f) Radiopharmaceutical receipt, preparation and ultimate fate or decay in storage;
- (g) Supplier and source of the radiopharmaceutical.

Where patients and/or patient records are kept in a relatively public area of the medical imaging service, provision for the privacy of the patient and the confidentiality of patient information will be assessed as part of the on-site review.

## 11 Equipment Management

General requirements for the management and calibration of radiographic equipment are specified in the *New Zealand Code of Radiology Management Practice*.

A dedicated PET scanner is required that can operate in 3D acquisition mode and has a diagnostic quality CT scanner. The correct management and calibration of PET-CT scanners and associated image processing equipment is essential to the provision of a quality imaging service and shall include a formal preventive maintenance and service programme.

Development and implementation of a formal schedule of routine checks, tests and calibrations of the PET-CT scanner and image processing equipment are necessary. While some of the more basic checks and tests may be competently completed by staff members of the PET-CT service, others of a more complex nature or requiring sophisticated reference equipment will need to be completed, at a minimum annually, by a qualified medical physicist.

The results of all acceptance and compliance testing must be approved by a medical physicist, with baseline image quality performance for the system established. Annual review of the quality assurance programme by the medical physicist will define the frequency at which each of the calibrations and checks are required to be completed.

Where performance parameters measured are required to fall within pre-determined maximum and minimum specifications, these maximum and minimum control limits shall be clearly identified. Medical imaging services should meet current ACR phantom imaging quality criteria guidelines and shall comply with ANZSNM minimum performance parameters for PET-CT scanners.



In the event the pre-determined control limits are exceeded, there shall be a detailed record kept of all actions and corrective measures taken to address any non-compliance. In circumstances of major non-compliance with performance specifications, one such action may be the cessation of all patient imaging activity until such time as the non-compliance is corrected.

Under no circumstances shall the completion of necessary equipment servicing or calibration be delayed or cancelled in order to accommodate further patient examinations.

Following calibration or a major service, MIT personnel will need to complete quality control checks to ensure equipment continues to perform as expected. The qualified medical physicist may provide guidance as to the most appropriate checks to complete following a major service or calibration.

Staff members of the medical imaging service shall be responsible for the collection, collation, review and retention of all records pertaining to the management of the PET-CT scanner and radionuclides, irrespective of the persons responsible for carrying out the service or calibration work.

## Acceptance Testing

Acceptance testing of newly installed PET-CT scanners, or partial acceptance testing of damaged/relocated PET-CT scanners, must be completed prior to clinical use by a qualified medical physicist or a qualified medical physicist directly overseeing testing by a supplier engineer. Both CT and PET systems are to undergo acceptance testing, with the PET tests completed to establish and confirm equipment compliance with published National Electrical Manufacturers Association (NEMA) NU-2 2007 performance criteria for PET systems, in addition to ANZSNM minimum performance parameters for PET scanners.

Each system should be tested individually and together to examine co-registration. The PET-CT service is also expected to complete any additional requirements established by the ORS. Detailed records shall be kept of all service work, calibrations, QC checks and other tests carried out to confirm on-going compliance of the PET-CT scanner and radionuclides with performance specifications.

## Calibrations

Quality control and calibration checks are to be completed to ensure the quantitative accuracy of PET-CT scanners are maintained. The manufacturer's calibration programme needs to be documented and detail the following:

- (a) The calibrations to be performed and by who;
- (b) The frequency or activation criteria for calibrations.

## Routine Equipment Quality Control

In general, the frequency of checks must assure the PET-CT service of the on-going satisfactory performance of the PET-CT scanner and image processing equipment, which may be influenced by:

- (a) Equipment manufacturer's recommendations;
- (b) Established performance history;
- (c) Minimum performance criteria set by the ANZSNM and phantom image quality criteria set by the ACR;
- (d) Regulatory or legislative requirements including ORS CSP3 and CSP5;
- (e) The make, model, age, and workload of the equipment.

Those items in need of annual checking or calibration include at least the following:

- (a) Alignment between the CT and PET scanners;
- (b) Dose calibrators;
- (c) Evaluation of organ dose and/or a review of the administered activity schedule for all procedures that involve administration of radiopharmaceuticals;
- (d) Evaluation of patient radiation absorbed dose for representative CT examinations;
- (e) Image display using the AAPM TG-18 QC image, or similar, and hardcopy testing where relevant;
- (f) Image quality, accuracy of attenuation and scatter corrections;

- (g) Sensitivity, if a sensitivity phantom is available and appropriate;
- (h) Uptake calibration check at high and low count rates, or a count rate performance check – parameters of count loss correction, total/random/scatter/net true coincidences and noise equivalent count rate;
- (i) System interlocks.

As part of the annual survey, the medical physicist shall review the effectiveness of quality control checks performed by MIT personnel and provide feedback and annual endorsement of the quality assurance programme.

Those items in need of regular checking by MITs include at least the following:

| Test  | Suggested frequency |
|---|---------------------|
| <ul style="list-style-type: none"> <li>• CT daily calibrations</li> <li>• Check of dose calibrator background, zero, high voltage and constancy using a long half-life source</li> <li>• Liver parenchyma SUV check on the first patient of the day, assuming it is normal, to confirm data is within the expected range</li> <li>• PET-CT scanner QC utilising a built-in source, gel phantom or uniform volume phantom.</li> <li>• Radionuclide contamination checks</li> <li>• Synchronisation checks between the dose calibrator and the PET-CT scanner console time (or alternative time-keeping methods to record the time the radioactivity and residual were measured)</li> <li>• Visual inspection of key equipment</li> </ul> | Daily               |
| <ul style="list-style-type: none"> <li>• CT checks, including image quality, as per the IANZ Supplementary Criteria for Accreditation: CT Scanning publication</li> <li>• PET-CT scanner checks as recommended by the manufacturer</li> <li>• Radiotherapy planning laser lights alignment, where appropriate</li> </ul>  | Weekly              |
| <ul style="list-style-type: none"> <li>• Calibration programme and quality control checks as recommended by the manufacturer</li> <li>• Constancy checks of the radiation survey meters utilising a long half-life source</li> <li>• Image display testing using the AAPM TG-18 QC test pattern or equivalent</li> <li>• CT checks as per the IANZ Supplementary Criteria for Accreditation: CT Scanning publication</li> </ul>   | Monthly             |
| <ul style="list-style-type: none"> <li>• High count reconstructed uniformity check utilising a uniform volume phantom</li> <li>• SUV/uptake calibration check utilising a uniform volume phantom and clinical acquisition parameters<sup>4</sup></li> </ul>   | Quarterly           |

<sup>4</sup> This test can be combined with the high count uniformity check if the clinical acquisition and processing parameters are used (but with higher than clinical counts).



Those items in need of regular checking by qualified medical physicists include at least the following:

| Test  | Suggested frequency |
|---|---------------------|
| <ul style="list-style-type: none"> <li>• Count-rate performance check</li> <li>• Dose calibrator checks<sup>5</sup>, including automatic radionuclide injections with a built-in dose calibrator, of calibration, constancy, geometry correction factors, linearity and reproducibility</li> <li>• PET-CT image quality phantom (ACR) check of contrast, resolution, uniformity and SUV calibration for the clinical acquisition protocol utilising the ACR PET-CT phantom with the Esser faceplate, or equivalent measurement method; high count check of the scanner performance utilising the same phantom</li> <li>• PET-CT registration check</li> <li>• Wipe testing sealed sources, as per any ORS guidelines</li> <li>• Calibration and alignment of laser lights or other aids to patient location for correlation between imaging and external radiation therapy</li> </ul> | Annual              |

Specific checks for diagnostic CT scanner performance are included in the IANZ *Supplementary Criteria for Accreditation: CT Scanning* publication.

Additionally, the following checks also need to be completed:

- (a) Ambient light level in the image review room;
- (b) Automatic injectors and any anaesthetic equipment;
- (c) Emergency stop and other safety systems;
- (d) Light output of film viewing boxes and display monitors.

## 12 Quality Control

General requirements for quality control are specified in the New Zealand Code of Radiology Management Practice.

In addition to these general requirements, a PET-CT service shall place particular emphasis on the following aspects:

- (a) Checks, calibrations and tests in accordance with the requirements defined in Section 11 of this Supplementary Criteria;
- (b) Participation in a phantom image review programme, if available;
- (c) Regular correlation of medical imaging interpretations and diagnoses with surgical and other patient outcomes, where possible.

Detailed records shall be kept of all quality control activities and these records shall be closely monitored to ensure that the PET-CT scanner, imaging and reporting procedures continue to conform to pre-determined performance standards. Where anomalies in performance are detected, these shall be an effectively investigated and resolved through the corrective and preventive action procedures of the medical imaging service.

<sup>5</sup> Dose calibrator traceability of PET radionuclide calibration to an international standard may be accomplished by checks against a traceable source, such as Ge/Ga-68 syringe source, or participation in the ANZSNM dose calibrator proficiency testing programme for PET radionuclides (when it becomes available).

## 13 Bibliography

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6. ACR: *Practice Guideline for Performing FDG-PET/CT in Oncology*
7. ACR: *Technical Standard for Medical Nuclear Physics Performance Monitoring of PET/CT Imaging Equipment*
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9. ACRIN: *Imaging Core Laboratory Standard Operating Procedure – Patient Preparation and FDG Administration Procedure for ACRIN FDG-PET Scans*
10. ACRIN: *Imaging Core Laboratory Standard Operating Procedure – PET Scanner Qualification Image Review and Quality Control*
11. ACRIN: *Imaging Core Laboratory Standard Operating Procedure – PET Scanner Qualification Image Review and Quality Control Analysis*
12. ANZHSN: *National Horizon Scanning Unit Horizon Scanning Report*
13. ANZSNM: *Technical Standards Committee Requirements for PET Accreditation (Instrumentation & Radiation Safety) 2nd Edition (2012)*
14. ARSAC: *Notes for Guidance on the Clinical Administration of the Radiopharmaceuticals and use of Sealed Radioactive Sources*
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19. ORS: *Code of Safe Practice for the use of Unsealed Radioactive Materials in Medical Diagnosis, Therapy and Research CSP3*
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24. RANZCR: *Standards for Diagnostic and Interventional Radiology*