

Jump to:

Physician's Section

Technologist's Section

Medical Physicist's Section

Physician's Section

Contents

I.	INTRODUCTION:	2
II.	RESPONSIBILITIES	3
A.	Supervising Physician	3
B.	All NM/PET Physicians	4
C.	Medical Physicist	4
	Baseline Measurements and Action Limits:	5
	Written Survey Reports and Follow-up Procedures:	5
	Purchase Specifications and Acceptance Testing:	6
D.	PET QC Technologist	6
III.	General	8
A.	Radiation Safety in Imaging	8
B.	Interpretive Quality Assurance	8
C.	Quality Management Team	8
IV.	Resources (links and proper citations forthcoming)	10

I. INTRODUCTION:

Consistent production of high-quality PET images is essential to patient care and a properly executed quality assurance (QA) program is necessary to ensure optimal image quality. Achieving the full potential of PET requires careful attention to both equipment performance as well as the execution of imaging studies. This manual was developed to help facilities establish and maintain an effective PET QA program, to assure the highest level of image quality and safety.

A key component to a continuous quality improvement program is a rigorous and adaptive QA program that includes an effective quality control (QC) program. The QC program should begin with acceptance testing, to ensure manufacturer specifications have been met and establish benchmark values for continued testing, followed by periodic testing to evaluate scanner performance and ensure compliance with regulatory requirements.

The Physician's Section, described herein, details the responsibilities of the modality supervising physician in an ongoing PET QC program. The supervising physician is responsible for ensuring that all QA requirements are met. The qualified medical physicist (QMP) is responsible for overseeing the equipment-related QC program. The QC technologist is specially trained and given responsibility to conduct QC activities appropriate to his or her role. Details of the tests to be performed by the QC technologist and the QMP can be found in their respective sections of this manual.

The ongoing QC program assesses relative changes in system performance as determined by the technologist, service engineer, QMP, or supervising physician. All facilities applying for accreditation or renewal must demonstrate compliance with ACR PET QC requirements by including a copy of the facility's most recent Annual PET Equipment Evaluation Summary Form and QC Review. The evaluation should be dated within one year (and must be dated within 14 months) of the date that the facility submitted its application for ACR PET accreditation. Facilities should refer to their state and local regulations to remain in compliance when these are more restrictive. The determination of additional QC testing to be performed to comply with state and local regulations should be determined by the QMP.

II. <https://www.acraccreditation.org/RESPONSIBILITIES>

A. Supervising Physician

The ACR requires the facility to designate both a Facility Supervising Physician, responsible for the entire site and overall quality standards of the facility, and a Modality Supervising Physician, responsible for the individual modality. These may or may not be the same individual, however, while the facility supervising physician may be any licensed physician, the modality supervising physician must meet the ACR qualifications for Supervising physician.

The modality supervising physician is responsible for site accreditation and therefore accountable for the quality of images at their site. The staff's commitment to high quality will often mirror that of the supervising physician. The individuals performing QC tests need to know that the supervising physician understands the program and is interested in the results. The physician needs to periodically review the test results and trends and provide direction when problems are detected. The modality supervising physician's specific responsibilities in PET QC are:

- Be responsible for the overall management and quality assurance standards of the modality. The modality supervising physician is ultimately responsible for the image quality produced under his or her direction and bears ultimate responsibility for both proper QC testing and QA procedures.
- Be responsible for developing and maintaining a program of quality control and continued quality improvement. The quality control program should be designed to minimize patient, personnel, and public radiation risks while maximizing the quality of the diagnostic information for therapeutic benefit.
- Be responsible for ensuring appropriate certification/licensing, training and CME requirements of personnel and must agree that no imaging procedures will be performed by personnel that do not meet these specified ACR requirements
- If required by the NRC or the state, the supervising physician must be a participating member or designate at least one physician member of the facility to be a participating member of the committee that deals with radiation safety.
- Maintain a hospital/institutional policy and procedure manual. This should include policies and procedures for dealing with pregnant or potentially pregnant patients. This manual should be reviewed and updated at least annually and must be reviewed and updated at least every three years.
- Develop, in collaboration with the QMP and QC technologist, a PET QA procedures manual that is available to all members of the staff. Proper documentation of procedures and test results is an integral part of maintaining a quality program and ensuring compliance with accrediting, and depending on facility certification, regulatory bodies. The QC testing described in this ACR QC Manual should be a central part of the site's QC procedures manual.

The site's QC procedures manual should include the following:

- Clearly assigned responsibilities for QC testing.

DRAFT

- Clearly developed procedures for QC testing, the required frequency of testing, and the acceptable levels of tolerance.
- Records of the QC tests performed by the QC technologist and QMP.
- Records of any corrective actions as a result of the QC testing.
- Records of routine and non-routine equipment service and maintenance.
- Records of quality management team (QMT) meetings.
- Procedures for proper use and maintenance of equipment
- A description of the orientation program for operators of imaging equipment, including its duration and content.

B. All NM/PET Physicians

Responsibilities of all NM/PET physicians in PET QC:

- Ensure established protocols are followed.
- Review with the technologist, image quality problems identified during interpretation of clinical images.
- Follow the facility procedures for corrective action when asked to interpret images of poor quality.
- Participate in the facility's practice improvement program.
- Provide documentation of current qualifications where he or she practices, in accordance with ACR accreditation and local rules.
- Be listed as an authorized user on the radioactive materials license of his or her institution.

C. Medical Physicist

The QMP is responsible for maintaining a quality assurance program for the routine assessment of PET camera performance to ensure proper operation of imaging equipment on a daily basis. QC testing procedures and their associated frequencies must be in accordance with the manufacturer's recommendations, the recommendations outlined in this procedure manual and any state or local regulatory requirements.

The QMP should evaluate the following characteristics on at least an annual basis as applicable to the design of the scanner:

- Image quality

Spatial resolution

CT scanner assessment

- SUV accuracy
- Image co-registration (if applicable)
- Count rate performance

DRAFT

- Sensitivity
- Image uniformity
- Acquisition workstation display monitor evaluation
- Safety evaluation
- Review of site's QC program

The QMP should evaluate the need for performance testing of the PET scanner after a major component of the equipment is either replaced or repaired.

The dose calibrator is integral in the operation of a clinical nuclear medicine department. Routine quality control as defined in the PET physicist section must be maintained. Annually the QMP should, at a minimum, review and document the constancy, linearity, and accuracy QC tests.

Typical radiation doses from radiopharmaceuticals should be available for all procedures. (At a minimum, the effective dose, and the critical organ and/or organ at risk absorbed dose should be available.) This information will require updating should any of the following occur: addition of new procedures and/or pharmaceuticals, changes in dosage schedules, change in route of administration and availability of more accurate dosimetry data.

Baseline Measurements and Action Limits:

The QMP is responsible for performing baseline QC measurements. The QMP establishes performance criteria for the QC program, specifically the determination of "action limits" or the tolerances of the specific parameters being evaluated, the frequency of each test, and who should perform each test based on the facility and machine usage.

The results of the QC program must be monitored at least annually by the QMP. If measured values of QC parameters fall outside the established tolerances, the QMP should recommend or, when appropriate, initiate investigative or corrective actions.

Written Survey Reports and Follow-up Procedures:

Written reports of the acceptance testing and annual performance evaluations of the imaging equipment must be provided to the professional in charge of obtaining or providing necessary service to the equipment and, if appropriate, to the supervising physician.

If required, the facility should be notified by the QMP of the necessary service. Communication is paramount; the QMP has the responsibility to provide clear communication regarding the need for the service request. The QMP should detail the specific tests that were performed and the observed/measured results along with the specifications not being met.

The facility has the responsibility to ensure corrective action is performed in a timely manner consistent with the importance of any adverse findings. The facility should retain service reports from service personnel as verification that the issues were appropriately resolved. Depending on the required service, the QMP may review the service report to

DRAFT

confirm that the equipment is performing in a safe and acceptable fashion or perform further testing of the equipment if required.

Should the continued use of the equipment pose a danger to life or health or potentially result in erroneous clinical findings, the QMP together with the interpreting physician and RSO must take immediate action to either limit the scope of use by indicating in writing what studies can be performed safely or prevent the use of the equipment until the equipment can be serviced and the machine safely used again.

Purchase Specifications and Acceptance Testing:

Many manufacturers sell PET systems with a variety of features. Assuring the appropriateness of new equipment to the particular practice and workflow needs of a facility is usually accomplished by the careful development and use of purchase specifications. Purchase specifications describe to the manufacturers the type of equipment that is desired by the purchaser. Purchase specifications are usually used by the manufacturers to prepare bids with detailed technical and performance specifications for the purchaser to use in the selection of equipment and as a set of quantitative performance specifications to be compared with measurements made during acceptance testing. Due to its complexity, a PET system's quality under all scan conditions may be difficult to discern, the help of the facility's QMP is essential in developing effective purchase specifications.

The purchase of new equipment should be contingent upon satisfactory performance during acceptance testing and completed before routine clinical use. Acceptance testing allows the facility an opportunity to evaluate the performance measurements cited by the manufacturer and establish baseline values that will serve as the basis for comparison during continued routine QC testing.

Acceptance testing is typically more rigorous than the routine QC testing detailed here and must be conducted by a QMP. The QA program should include documentation of acceptance testing.

D. PET QC Technologist

The PET technologist's general responsibilities center on patient care and image quality by verifying the day-to-day operation of instruments. The designated QC technologist is responsible for the QC procedures as designated by the manufacturer, QMP, or as defined in this QC manual. These recommendations should be strictly respected to ensure the functionality of the equipment and thus ensure optimal patient care through acquisition of accurate diagnostic information.

Before any radiopharmaceutical may be administered to a patient and to ensure no patient images are potentially compromised, routine QC procedures must be completed prior to the first scan of the day but should be completed prior to injecting the first patient of the day. The PET technologist section of this manual describes, in detail, the responsibilities of the PET QC technologist(s). An abbreviated summary of these tests is provided in table 1. In the case of dual modality systems, for which the associated modality is used only for attenuation correction, depending on local regulatory requirements the daily QC may fall to the PET technologist.

DRAFT

Equipment	Procedure	Frequency
Dose Calibrator	Constancy	Daily
PET	Basic system integrity inspection	Daily
	Routine PET QC	Daily
	Time clock synchronization	Daily
	Periodic PET QC (Per manufacturers recommendations)	Weekly/periodic
	SUV calibration	Semi-annually (quarterly preferred)
	Image Quality (ACR PET phantom)	Semi-Annual (quarterly preferred)
CT	Routine CT QC	Daily
MRI	Routine MRI QC	Daily, Weekly or as recommended by manufacturer

204

III. General

A. Radiation Safety in Imaging

It is the responsibility of radiologists, nuclear medicine physicians, medical physicists, registered radiologist assistants, radiologic technologists, and all supervising physicians to ensure workplace safety by keeping radiation exposures to staff and to society as a whole, “as low as reasonably achievable” (ALARA), and to ensure that individual patients receive radiation doses appropriate for their clinical procedure by considering the possible risk from the radiation exposure and the diagnostic image quality required to achieve the clinical objective. This requires all personnel working with ionizing radiation to understand the key principles of radiation protection and the principles of proper management of radiation dose to patients.

Facilities must have policies and procedures for the safe handling and administration of radiopharmaceuticals, and these must comply with all applicable radiation safety regulation and requirements of licensure imposed by the NRC and by the state and/or other regulatory agencies. Responsible staff must ensure adherence to these policies in accordance with ALARA. The quantity of radiopharmaceutical administered to the individual patient should be determined by prescription or protocol.

Nationally developed guidelines, such as the ACR’s Appropriateness Criteria, should be used to help choose the most appropriate imaging procedures to prevent unwarranted radiation exposure.

B. Interpretive Quality Assurance

The facility should be involved in an ongoing peer review/peer learning program. This may be accomplished with active participation in a peer review program such as the ACR’s RADPEER or have an alternative peer learning QA program (6). Procedures for interpretive QA are not specifically addressed in this manual.

C. Quality Management Team

An essential part of the QA program is a QMT. This group is tasked with overseeing the QA program. The QMT should convene on a frequency adequate to meet their responsibilities, with a minimum of meeting annually. It is the responsibility of the QMT to provide direction to the program, assess the effectiveness of the QA activities, assure that proper documentation is maintained, and determine any changes that should be made.

The QMT should consist of the following:

- One or more nuclear medicine physicians
- A QMP
- A supervisory, lead, or senior PET technologist
- The QC technologist (this may be the same individual as in item 3)

Additional department personnel who participate in the care for patients undergoing PET procedures may also be included.

DRAFT

Responsibilities of the QMT include:

- Must review the radiation safety manual with the radiation safety officer or QMP at least annually.
- Must review and update, if necessary, patient protocols with the QMP and lead technologist to ensure facility is imaging patients consistent with the most recent guidelines.
- Review CT acquisition parameters, as applicable to attenuation correction, with the QMP at least annually to optimize the relationship between minimal radiation dose and adequate image quality.
- Select an on-site technologist as the primary QC technologist responsible for conducting routine QC and to oversee tests that have been delegated to other individuals. It is not recommended to rotate this assignment among a group of technologists as doing so would introduce variability into the test results extraneous to the parameters being tested. However, it is essential to have properly trained backup QC technologists to ensure continuity when the primary QC technologist is unavailable.
- Select a QMP who will oversee the equipment-related QC program and perform the medical physicist's tests.
- Participate in the initial assessment of image quality at the implementation of the QC program and annually review quality control testing.
- Ensure the appropriate test equipment and materials are available to perform QC tests.
- Ensure adequate time is available to carry out the necessary tests and to record and interpret the results.
- Ensure NRC or applicable local or state license requirements are met.

IV. Resources (links and proper citations forthcoming)

ACR-AAPM Technical standard for medical physics performance monitoring of PET/CT imaging equipment and technical standard for use of radiopharmaceuticals

ACR-SNMMI Technical standard for Diagnostic procedures using radiopharmaceuticals

AAPM Task Group 126: PET/CT Acceptance Testing and Quality Assurance

ACR CT quality control manual 2017

ACR accreditation of nuclear medicine and PET imaging departments. JNM Technology, 2006

National Electrical Manufacturers Association. “NEMA Standards Publication NU 2-2018: Performance Measurements of Positron Emission Tomographs” Rosslyn, Virginia, USA, 2018.

Transitioning from peer review to peer learning: Report of the 2020 peer learning summit. (JACR) 2020: <https://doi.org/10.1016/j.jacr.2020.07.016>

Technologist's Section

Contents

I.....	INTRODUCTION	13
II.	IMPORTANT POINTS	14
A. Teamwork.....		14
B. Quality Control Testing		14
1. Quality Control Technologist(s).....		15
2. Quality Control Records		15
3. Alternative Procedures		16
4. Action Limits		16
II.	TECHNOLOGIST'S DAILY QUALITY CONTROL	17
A. Test Procedure Guidance		17
1. Assess the environmental conditions of the control and scanner room.....		17
Objectives		17
Frequency		17
Suggested Equipment		17
Test Procedure		17
Data Interpretation and Corrective Action:.....		17
2. Time Clock Synchronization.....		18
Objectives		18
Frequency		18
Required Equipment		18
Test procedure		18
Data Interpretation and Corrective Action.....		18
3. Routine PET QC		19
Objective.....		19
Frequency		19
Required Equipment		19
Test Procedure		19
Data Interpretation and Corrective Action.....		19
4. Dose Calibrator QC:.....		21
Objective.....		21
Frequency		21
Test Procedure		21
Performance Criteria and Corrective Actions		22

DRAFT

321	III.	TECHNOLOGIST’S PERIODIC QUALITY CONTROL	
322		23
323	A. Additional Unit-Specific Tests		23
324	Objectives		23
325	Frequency		23
326	Required Equipment		23
327	Test Procedure		23
328	Precautions and Caveats		23
329	IV.	TECHNOLOGIST’S QUARTERLY QUALITY CONTROL	
330		24
331	A. Test Procedure Guidance		24
332	1. Validation of scanner quantitative accuracy	Error! Bookmark not defined.	
333	Objective.....		24
334	Frequency		24
335	Required Equipment:		24
336	Test Procedure		24
337	Data interpretation and corrective action guidelines.....		24
338	V.	REFERENCES (proper links and citation style to come)	
339		25
340			
341			

I. INTRODUCTION

A well-designed, documented, and executed quality control (QC) program is essential to consistent production of high-quality PET images at reasonable administrated dose levels. The American College of Radiology (ACR) has developed this manual to assist radiologists, PET technologists, and qualified medical physicists (QMPs) in establishing and maintaining such QC programs. This is in accordance with the ACR's educational and patient service missions and is in response to growing requests from the diagnostic imaging community for guidance on PET QC.

Upon release of this document, all facilities applying for accreditation must maintain a documented QC program and must comply with the minimum frequencies of testing outlined in this manual. The ongoing QC program assesses relative changes in system performance as determined by the technologist, service engineer, QMP, or supervising physician. A QMP must be responsible for overseeing the equipment QC program and for monitoring performance upon installation and routinely thereafter. All facilities applying for accreditation or renewal must demonstrate compliance with the ACR QC requirements by including a copy of the summary form from the most recent [Annual PET System Performance Evaluation](#) of each unit at the facility which includes a review of the technologist QC program. The evaluation should be dated within one year (and must be dated within 14 months) of the date that the facility submitted its application for ACR PET accreditation. Facilities should refer to their state and local regulations to remain in compliance when these are more restrictive. The determination of additional QC testing to be performed to comply with state and local regulations should be determined by a QMP.

This section of the manual describes the PET technologist's duties in the QC program. They can be carried out with a reasonable investment in time and equipment. The technologist's responsibilities include regularly acquiring QC data, recording the data in QC records, and initiating appropriate corrective action as needed. The technologist should consult with the QMP regarding the QC results.

Each procedure description follows the same format:

- Objective
- Frequency
- Required Equipment
- Test Procedure
- Data Interpretation and Corrective Action

Table 1 under Important Points provides an overview of the technologist's QC program. It lists the required procedures, how often each must be performed, and approximately how long each task should take.

II. IMPORTANT POINTS

A. Teamwork

The PET technologist, QMP, and radiologist constitute a QC team. Each should be aware of the other's responsibilities, especially as they relate to their own, and should assist one another in achieving the overall objectives of the QC program.

With respect to the QMP, the technologist has three important QC functions:

- The technologist is responsible for ensuring the QC procedures defined by the QMP are completed correctly and at the required frequency.
- The technologist should work with the QMP to design the QC protocol technique to be used on each scanner. Sometimes this involves using a set of parameters specified by the manufacturer.
- The technologist should use the QMP as a resource to answer questions concerning image quality and patient dose to help identify and correct image quality problems or radiation dose issues.

With respect to the radiologist, the technologist has three important QC roles:

- The technologist participates with the radiologists in their review of image quality during the clinical image interpretation.
- When image quality or radiation dose issues arise, the radiologist decides whether patient studies can continue or must be postponed pending corrective action.
- The radiologist participates in the initial assessment of image quality at implementation of the QC program and regularly monitors QC results in the intervals between the annual QC data reviews. The physician should consult with the QMP regarding corrective actions related to QC and image quality.

B. Quality Control Testing

The technologist's QC testing procedure frequencies given in Table 1 and in the rest of this manual are the minimum recommended frequencies. These are the **minimum requirements; the QMP may use discretion as to whether more frequent testing is advisable or required for a particular unit or clinical environment.**

Table 1. Minimum Frequencies of Performing Technologist's QC tests

TEST	FREQUENCY
Basic system integrity inspection.	Daily
Time Clock Synchronization	Daily
Routine PET QC	Daily
Routine CT QC (if applicable)	Daily
Routine MRI QC (if applicable)	Daily, weekly or recommended interval
Dose calibrator QC	Daily
Tuning adjustment	Periodic*
SUV calibration	semi-annually (quarterly preferred)
ACR PET phantom	semi-annually (quarterly preferred)

*Optional QC according to manufacturer's requirement or recommendation

To ensure adequate scanner performance and best possible image quality provided by a PET system, minimum QC requirements as outlined in the table consisting of daily QC check and periodic QC performance should be adopted as applicable. The detailed requirements of PET routine QC may vary depending on the scanner model and should be performed following manufacturer's technical manual and recommendations as well as referring to the ACR PET QC manual guidelines.

Additionally, following repairs and relevant service events, appropriate QC tests should be performed prior to returning the system to clinical use. Consult with the QMP if questions arise as to what testing is needed.

1. Quality Control Technologist(s)

The technologist(s) performing QC should be charged with knowing the QC procedures for the particular PET scanner and its ancillary equipment. To ensure that the performance of QC tasks is not linked to a specific person's work schedule, all technologists should be trained to perform daily QC, and dedicated QC technologists should be trained to perform more specialized periodic QC.

2. Quality Control Records

QC records must be maintained, and the results of QC activities recorded at the time they are performed. Based on size, administrative organization, and QC team's preferences, facilities' QC record content will vary. Small facilities may have a single record encompassing all of their equipment; large facilities will often have separate records for equipment at different locations. In general, the QC records should include the following:

- A section describing the facility's QC policies and procedures for the equipment covered by the records.
- A section of data forms to use when recording QC procedure results for each piece of equipment covered by the records. This should include the person that performed the QC.
- A section for recording notes on QC problems and corrective actions.

DRAFT

The QC records must be kept in a location that is accessible and known to all members of the QC team and the service engineer, so that they may refer to it when questions arise. The section for recording QC problems and corrective actions can facilitate communication between the service engineer and QC team members who often have different work schedules. Records should be maintained in accordance with RAM license, state, or facility policy.

3. Alternative Procedures

Test procedures in this document are considered the minimum set of acceptable tests. All of these tests should be completed unless the recommended procedures are ineffective on a particular scanner. In that instance, alternative QC tests should be developed, or manufacturer's testing procedures should be used. The QC technologist should not conduct alternative testing procedures until those procedures are reviewed and approved by a QMP. The QMP must document the necessary procedures, analysis methods, and performance criteria for the alternative tests in the QC records. The QMP must provide appropriate training for the QC technologist concerning alternative QC procedures.

4. Action Limits

Performance criteria for the various QC measurements are specified in terms of action limits (also known as control limits, e.g., SUV values as noted in the NM/PET phantom criteria), which define the range of acceptable values. Outside those values, corrective action is required. In most cases, the stability of the equipment and the consistency of the technologist's measurements will result in measured values well within the action limits. In these cases, more restrictive action limits could increase sensitivity to potential developing problems. The QMP should review action limits annually and ensure that they are adequately sensitive to detect PET equipment problems. Action limits should be based on the performance of an individual scanner. In addition, action limits should be re-evaluated whenever there are hardware changes or major service activities. It is important for the facility, the QMP, and the service engineer to maintain a close working relationship.

V. TECHNOLOGIST'S DAILY QUALITY CONTROL

Technologist(s) must perform routine equipment QC on a daily basis and should confirm the QC pass prior to the first radiopharmaceutical patient administration of the day. This is to ensure the short-term stability of the PET (or PET/CT) scanner and the dose calibrator(s) as well as to avoid unnecessary radiation exposure to the patient. After daily QC images are acquired, the QC technologist must review the image quality to ensure that system performance is within the action limits.

The daily QC procedure consists of four parts:

1. Basic system integrity inspection.
2. Time Clock Synchronization.
3. Routine PET QC. (Including CT or MRI as applicable.)
4. Dose calibrator QC.

A. Test Procedure Guidance

1. Basic system integrity inspection.

Objective

To inspect any environmental condition changes such as room temperature, humidity and power or other apparent issues of the scanner and QC phantoms.

Frequency

Daily, prior to tracer administration to the first patient.

Required Equipment

Thermometer and hygrometer

Test Procedure

1. Check environment for temperature, humidity, power interference, water leaks, etc.
2. Check for any barriers to successful scanning.

Data Interpretation and Corrective Action

Contact a QMP or field service engineer (FSE) for troubleshooting issues that cannot be addressed by the technologist.

DRAFT

2. Time Clock Synchronization

Objective

To minimize time clock non-synchronization and improve PET quantification.

Frequency

Daily, prior to tracer administration to the first patient.

Required Equipment

Highly accurate clock.

Test procedure

3. Check the time clocks for the PET (or PET/CT or PET/MR) system console and the dose calibrator(s) and compare them to the real-world time clock used to record patient injection time
4. If needed (e.g., variance becomes more than 3 minutes), adjust and synchronize the time clock to the real-world time clock (I.e., cell phone, time server, or internet) according to manufacturer's recommendation.
5. Mobile PET/CT systems should be checked daily after the system changes locations.

Data Interpretation and Corrective Action

Contact a QMP, facility engineer or FSE for troubleshooting upon issues that cannot be addressed.

3. Routine PET QC

Objective

To analyze system performance and stability in a short-term manner and ensure that the PET (or PET/CT) unit is working properly and ready for clinical use.

Frequency

Daily, prior to tracer administration to the first patient.

Required Equipment

Vendor-specified PET QC phantom.

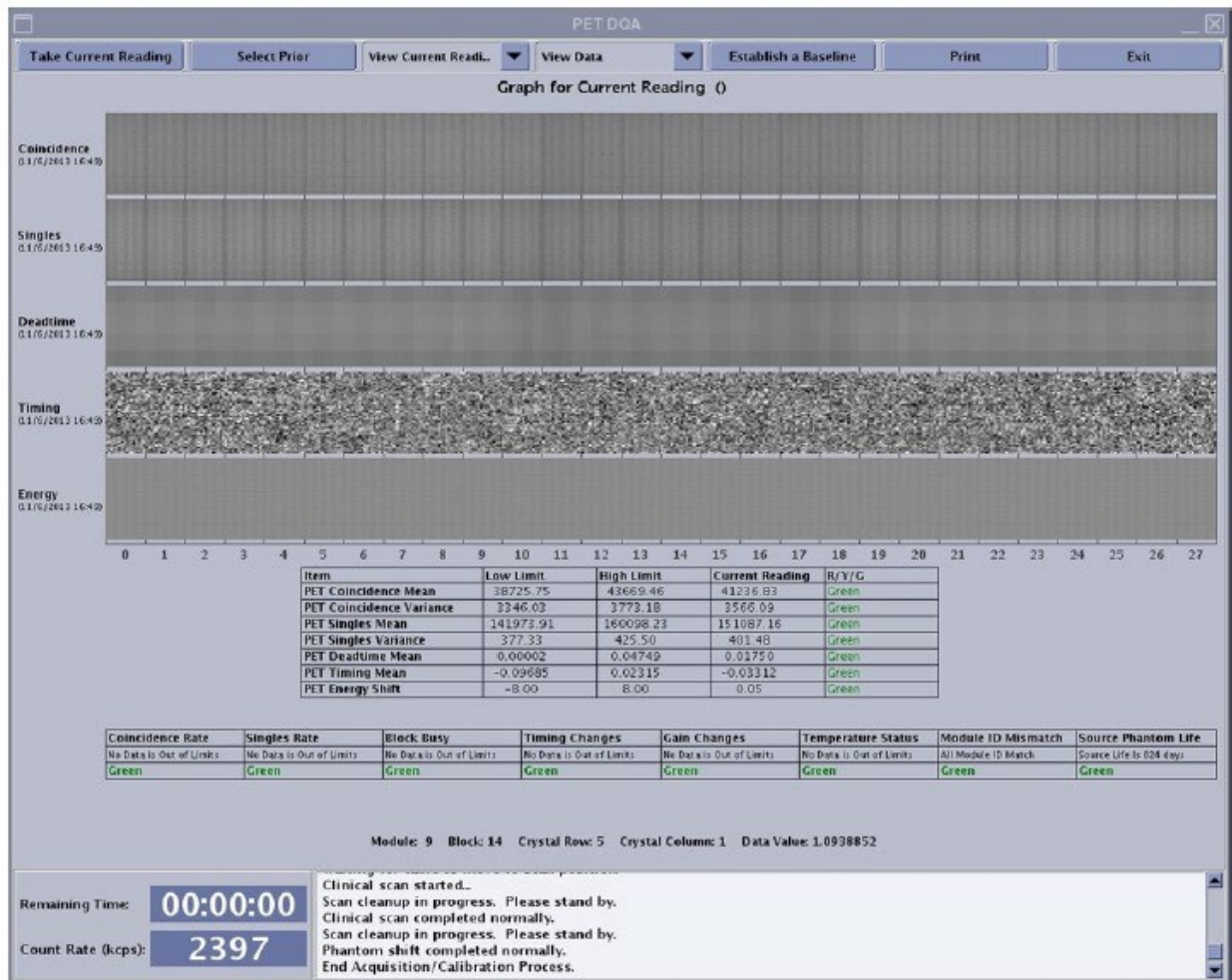
Test Procedure

1. Technologist(s) should follow the manufacturer's technical manual and recommendations for the daily PET QC.
2. QC of PET detectors for items such as coincidence detection, singles, dead time, PMT gain and energy resolution, TOF timing resolution, normalization variation and so on are routinely part of various QC acquisition depending on the manufacturer. The daily QC procedure is typically automatic or semi-automatic and can be performed according to manufacturers' recommendations and standardized protocols. Baseline collection is typically done after system calibrations by either the FSE or a QMP.
3. Daily CT or MRI QC should be performed for hybrid PET/CT or PET/MR scanners following manufacturer user manual and recommendations. CT scanner QC should include a water phantom scan for the evaluation of artifacts and CT number accuracy.
4. Precautions and Caveats: If the system has experienced a major power outage, either via storm or other disruption, it is generally advisable to perform daily QC to ensure system integrity. However, it is critical that the system is given enough time to stabilize and restore normal detector operating temperature prior to initiation.

Data Interpretation and Corrective Action

Typically, manufacturer's software will automatically perform the data analysis and compare it to the previous testing results or the baseline collection. Technologists should visually check the QC image (example in figure X_) for any potential artifacts such as those consistent with detector response variation (apparent hot or cold blocks or streaks). It is not recommended to rely solely on the automated QC processing and final pass/fail result. Contact a QMP or FSE for troubleshooting issues that cannot be addressed and corrected by the technologist.

DRAFT



548

549

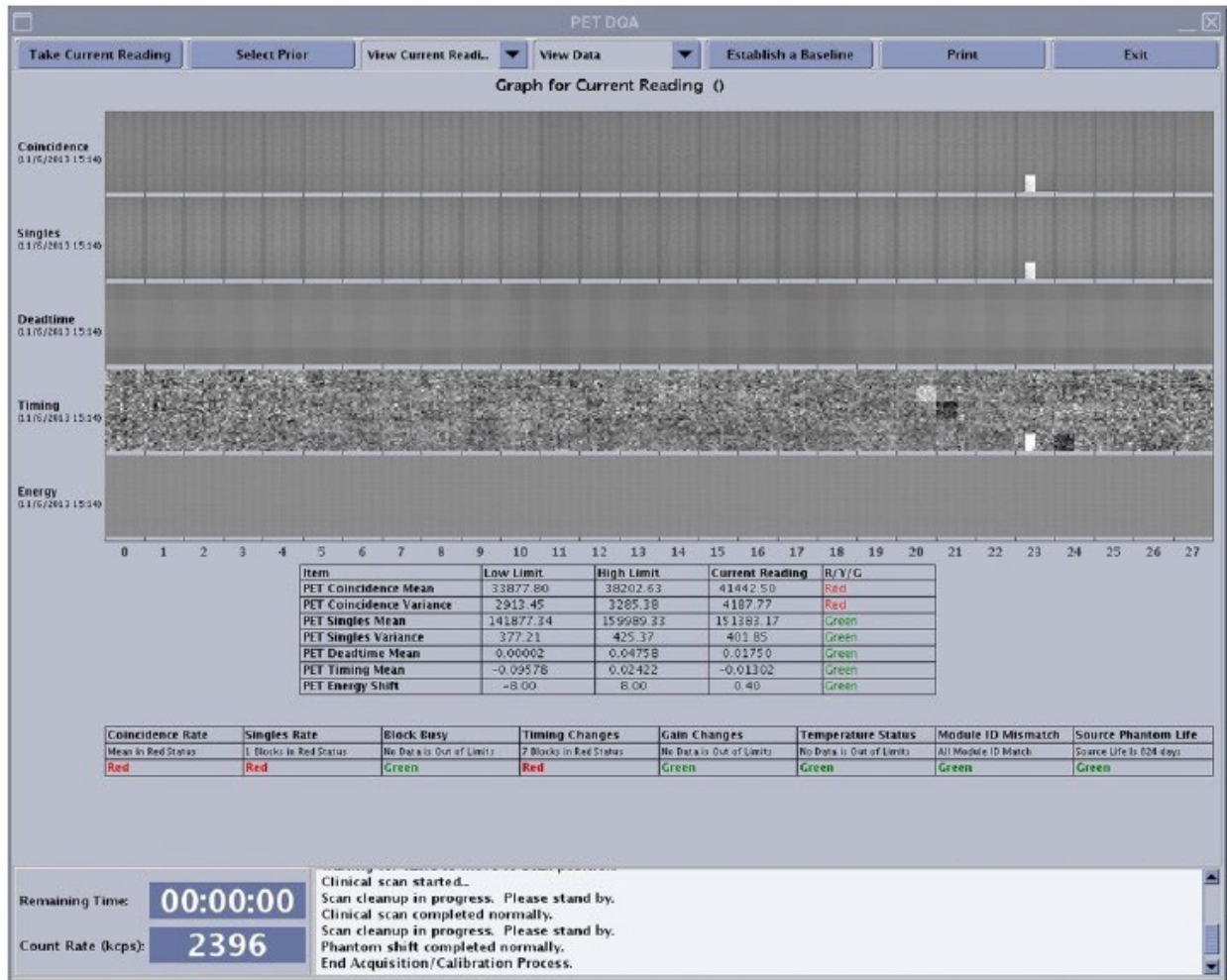


Figure X. Examples QC images: The top images shows a good images that passes all tests and shows no evidence of poor detector performance. The bottom image shows a QC image in which a block of detectors has failed.

4. Dose Calibrator QC:

Objective

To verify proper performance and consistent reading of the dose calibrator on multiple radionuclide settings.

Constancy is a QC test that is performed daily to verify that the calibrator is accurate and reliable for the assay of radiopharmaceuticals prior to administration to a patient.

Frequency

Daily, prior to injecting the first patient.

Test Procedure

1. Perform voltage check, battery check and background check.

DRAFT

2. Place the test source (a NIST traceable, long-lived standard such as Cs-137, Co-57 or Na-22) into the chamber of the dose calibrator and select the proper radionuclide channel on the dose calibrator.
3. Measure the source and record the reading.
4. Leave the source in the chamber and select the channels of commonly used radionuclides.
5. Record the readings.

Data Interpretation and Corrective Actions

The percent deviation of the measured reading must be within $\pm 10\%$ of the test reference values. The test reference values must be corrected for decay of the test source over time and should be updated at least annually and whenever the test source is replaced.

Service is needed if the deviation is beyond $\pm 10\%$.

VI. TECHNOLOGIST'S PERIODIC QUALITY CONTROL

A. Test Procedure Guidance

1. Additional Unit-Specific Tests

Objective

To optimize system performance and perform tuning adjustments for non-uniformities in detector gain and timing offsets between two detectors in coincidence.

Periodic QC is complimentary QC performed as an extension of Technologist's Daily PET QC.

Frequency

Periodic. Consult your user manual or applications support for manufacturer specific recommendations.

Required Equipment

Follow manufacturer recommendations (e.g., cylinder phantom, rod/pin/point source, etc.)

Test Procedure

Technologists should perform quality checks such as updating gains, timing, singles and so on periodically according to manufacturer recommendations and guidelines to ensure satisfactory completion.

Data Interpretation and Corrective Actions

Upon completion of the desired test(s), review any necessary data for system-specific QC compliance. Contact a QMP if needed.

Precautions and Caveats

If the system has experienced a major power outage it is advisable to perform periodic QC in addition to daily QC to ensure system integrity. However, it is critical that the system is given enough time to stabilize and restore normal detector operating temperature prior to initiation.

VII. TECHNOLOGIST'S QUARTERLY QUALITY CONTROL

A. Test Procedure Guidance

1. SUV Calibration

This test evaluates the overall quantitative accuracy of resultant PET images that might be affected by variability in dose calibrator, scanner calibration as well as data corrections and image reconstruction effects.

Objective

To validate the quantitative measurement (SUV) accuracy of PET images using the background measurement of the ACR PET phantom.

Frequency

Semi-annually (quarterly preferred)

Required Equipment

ACR PET phantom

Test Procedure

Phantom filling, set-up and image acquisition shall be performed as described in the Medical Physicist's Section, Image Quality test. Note that only the background SUV is being evaluated so filling the "hot" vials is not required.

Scan the phantom using your routine clinical protocol. The entire phantom shall be covered within the axial FOV, typically 1 or 2 bed positions are needed. Reconstruct the images using the standard clinical protocol parameters and then reformat the images such that the slice thickness is about 1 cm. Draw a 6 cm diameter region of interest on a slice covering the uniform section of the ACR phantom (choose a couple of central slices) and record the average SUV in the ROI.

Data interpretation and Corrective Action

To validate the scanner quantitative accuracy, the measured SUV in the phantom should be in the range 0.90 to 1.10 Bq/ml. If the measured value falls outside that range, please contact your QMP for further data interpretation and the implementation of the necessary corrective action.

DRAFT

VIII. REFERENCES (proper links and citation style to come)

1. ACR CT Quality Control Manual
2. Zanzonico P. Routine quality control of clinical nuclear medicine instrumentation: a brief review. J Nucl Med. Jul 2008;49(7):1114-1131.
3. MacFarlane CR. ACR accreditation of nuclear medicine and PET imaging departments. J Nucl Med Technol. 2006;34(1):18-24.
4. 2017 EANM Technologists Guide: Quality Control of Nuclear Medicine Instrumentation and Protocol Standardization
5. AAPM TG Report 126

Medical Physicist's Section

Contents

I.	INTRODUCTION	31
II.	Qualified Medical Physicist (QMP) Responsibilities	33
A.	Baseline Measurements and Action Limits	33
B.	Acceptance Testing	33
C.	Quality Control Testing	33
	QC Tests and Applicability	34
III.	Test Procedures	36
1.	Image Quality	36
	Purpose	36
	Applicability	36
	Frequency	36
	Required Equipment	36
	Test Procedure	37
	Data Analysis and Interpretation	37
	Action Limits and Remediation	37
	Alternatives	37
2.	Spatial Resolution	38
	Purpose	38
	Applicability	38
	Frequency	38
	Required Equipment	38
	Test Procedure	38
	Data Analysis and Interpretation	38
	Action Limits and Remediation	39
	Alternatives	39
3.	CT Dose Assessment, Image Quality, and CT Number Accuracy	Error! Bookmark not defined.
	Purpose	Error! Bookmark not defined.
	Frequency	40
	Testing Procedure	40
	Alternatives	40
	CT Number Accuracy Test Procedure	Error! Bookmark not defined.
	Data Analysis and Interpretation	Error! Bookmark not defined.
	Action Limits and Remediation	Error! Bookmark not defined.
4.	Standard Uptake Value (SUV) Accuracy	40
	Purpose	40

DRAFT

696	Frequency	40
697	Required Equipment	40
698	Applicability	Error! Bookmark not defined.
699	Test Procedure	40
700	Data Analysis and Interpretation	40
701	Action Limits and Remediation	42
702	Alternatives.....	43
703	5. Image Co-registration.....	44
704	Purpose	44
705	Applicability	44
706	Frequency	44
707	Required Equipment	44
708	Test Procedure	44
709	Data Analysis and Interpretation	44
710	Action Limits and Remediation.....	45
711	Alternatives.....	45
712	6. Count Rate Performance	46
713	Purpose	46
714	Applicability	46
715	Frequency	46
716	Required Equipment	46
717	Test Procedure	46
718	Data Analysis and Interpretation	47
719	Action Limits and Remediation.....	47
720	Alternatives.....	47
721	7. Sensitivity.....	48
722	Purpose	48
723	Applicability	48
724	Frequency	48
725	Required Equipment	48
726	Test Procedure	48
727	Data Analysis and Interpretation	49
728	Action Limits and Remediation.....	50
729	Alternatives.....	50
730	8. Image Uniformity.....	51
731	Purpose	51
732	Applicability	51
733	Frequency	51
734	Required Equipment	51

DRAFT

735	Test procedure	51
736	Data Analysis and Interpretation	51
737	9. Action Limits and Remediation	52
738	Alternatives.....	53
739	10. Acquisition/Processing Workstation Display Monitor Calibration	57
740	Purpose	57
741	Applicability	57
742	Frequency	57
743	Required Equipment	57
744	Test Procedure	57
745	Data Analysis and Interpretation	58
746	Action Limits and Remediation.....	58
747	Alternatives.....	59
748	11. Safety Evaluation	60
749	Purpose	60
750	Applicability	60
751	Frequency	60
752	Required Equipment	60
753	Test Procedure	60
754	Data Analysis and Interpretation	60
755	Action Limits and Remediation.....	61
756	Alternatives.....	61
757	IV. Resources.....	62
758	V. Appendix A: Preparing the PET ACR Phantom for Enhanced Accuracy	63
759	VI. Appendix B: Non-imaging (Ancillary) Devices	65
760	A. Dose Calibrators	65
761	1. Accuracy	65
762	Purpose	65
763	Frequency	65
764	Required Equipment	65
765	Test Procedure	65
766	Evaluation.....	65
767	Action Limits and Remediation.....	66
768	2. Linearity.....	66
769	Purpose	66
770	Frequency	66
771	Required Equipment	66
772	Test Procedure	66
773	Evaluation.....	67

DRAFT

774	Action Limits, Remediation.....	67
775	3. Constancy.....	67
776	Purpose	67
777	Frequency	67
778	Required Equipment	67
779	Testing Procedure	68
780	Evaluation.....	68
781	Action Limits and Remediation.....	68
782	4. Geometry.....	68
783	Purpose	68
784	Frequency	68
785	Required Equipment	68
786	Testing Procedure	68
787	Evaluation.....	69
788	Action Limits, Remediation.....	69
789		
790		

791 **Working group:**
792 **Matthew Palmer**
793 **Frank DiFilippo**
794 **Osama Mawlawi**
795 **Jun Zhang**
796
797

IX. INTRODUCTION

The following describes the responsibilities of the qualified medical physicist (QMP). The tests described here are intended to ensure that the scanner is functioning as designed in all respects and to help ensure that the scanner is being utilized optimally.

Although equipment service engineers ensure the system is performing to within manufacturer's specifications and technologists perform specified calibrations and quality control (QC), the QMP is uniquely qualified to perform certain tests and then analyze the data to determine which sets of specifications are relevant to a particular imaging problem. The QMP is able to bridge the gap between the technical aspects and clinical image quality of the system. The QMP testing allows the QMP to recognize equipment failures before they unacceptably degrade clinical images. The QMP can also perform tests to determine if imaging irregularities can be attributed to procedural or equipment errors.

All facilities applying for accreditation or renewal must maintain a documented quality control (QC) program and must comply with the minimum frequencies of testing outlined in this manual. The ongoing QC program assesses relative changes in system performance as determined by the technologist, service engineer, QMP, or supervising physician. A QMP must be responsible for overseeing the equipment QC program and for monitoring performance upon installation and routinely thereafter. All facilities applying for accreditation or renewal must demonstrate compliance with the ACR QC requirements by including a copy of the Annual System Performance Evaluation Summary Form from the most recent annual PET system performance evaluation for each unit at the facility. The evaluation must be dated within one year (12-14 months) of the date that the facility submitted its application for ACR PET accreditation. Facilities should refer to their state and local regulations to remain in compliance when these are more restrictive. The determination of additional QC testing to be performed to comply with state and local regulations should be determined by a QMP.

It is the responsibility of the QMP conducting these tests to accurately convey test results in a written report, to make recommendations for corrective action according to the test results, and to review the results with the radiologists and technologists working on each scanner, when appropriate. Communicating test results and recommending corrective action are areas that should be given focused attention, as this is a vital interface between the technical assessment and the clinical practice. Corrective action should not be limited to repair of PET equipment by a qualified service engineer. It should also include recommendations concerning use of the PET scanner, protocol optimization, image processing, viewing conditions, and the QC program. The QMP should periodically review the results of the routine QC tests conducted by the technologist and make recommendations regarding these tests, if appropriate. Furthermore, the QMP should participate in periodic reviews of the PET QC program as a whole in order to ensure that the program is meeting its objectives.

Many of the tests described below provide suggested acceptable action limits. These are provided as guidelines in the case no other acceptable action limits exist; if the manufacturer has specified both testing conditions as well as acceptable action limits, the QMP may elect to use both those testing conditions and action limits as part of the QC program. In some cases, the manufacturer's testing conditions (phantom, protocol) and

DRAFT

specifications may take into account specific capabilities and functions of the scanner and therefore may be preferred.

Each QMP test procedure description follows the same format:

- Purpose
- Applicability
- Frequency
- Required Equipment
- Test Procedure
- Data Analysis and Interpretation
- Action Limits and Remediation
- Alternatives

X. Qualified Medical Physicist (QMP) Responsibilities

A. Baseline Measurements and Action Limits

The QMP is responsible for performing baseline QC measurements. The QMP establishes performance criteria for the technologists' QC program. This applies specifically to the determination of "action limits," which are the thresholds of QC results that, if exceeded, require corrective action. Corrective action includes, but is not limited to, contacting appropriate service personnel to address equipment-related causes of QC failures.

During the annual review, the QMP also examines the records of the routine QC tests performed by the QC technologist(s). Following this review and the completion of the physics tests, recommendations may be made regarding improvements in equipment performance or improvements in the QC process.

B. Acceptance Testing

The purpose of acceptance testing is primarily to determine if the PET equipment performs according to the manufacturer's specifications as stated in the documentation received from the manufacturer. Acceptance testing should be conducted by an experienced QMP. The manufacturer specified phantoms and test procedures must be used when comparing measured performance values to those specified by the manufacturer. The description of acceptance testing procedures and limits is outside the scope of this document; however, testing performed during acceptance testing provides an opportunity to establish baseline values that will serve as the basis for comparison for ongoing QC testing.

The QC program described in this manual is intended to document consistency of performance after the unit has been accepted and put into service. Therefore, the QMP should consider using the tests described below as part of the set of QC tests for the ongoing QC program. The QMP may also consider performing additional tests that can serve as baseline measurements to be used in comparison with daily, weekly, quarterly, or annual tests described in this manual.

C. Quality Control Testing

Instructions for each test (and acceptable action limits where appropriate) have been provided with specific guidance for the standard phantoms described here. The QMP may also perform testing with the manufacturer's phantom (and acceptable action limits). However, in certain instances where the QMP determines that a specific test is necessary, and for which neither the ACR PET phantom nor the manufacturer's phantom is appropriate, the QMP may use an alternative phantom appropriate for that test.

It should be noted that there is great diversity in scanner technology, phantoms, testing procedures, and tolerances. The primary intent of the ACR PET QC manual is to help facilities establish and maintain an effective QC program, and a secondary goal is to provide a reasonably uniform approach to testing. However, there may be instances in which the QC manual's described tests may not be appropriate on a

DRAFT

specific scanner in which case the use of the manufacturer's phantom, testing procedure and specifications, especially in these situations, is appropriate and encouraged.

In instances where a scanner does not pass a specification recommended by the ACR in their QC manual or a specification that the medical physicist designed, the following steps should be followed before issuing a call to the service engineer. First, the test should be repeated to confirm the result. Next, the manufacturer's technical manual should be consulted. If the same type of test is provided in the manufacturer's technical manual, then that test should be performed as specified by the manufacturer using their criteria. If the manufacturer's specification passes and the images do not have a clinically significant image quality issue, corrective action is likely not needed. If the manufacturer-provided test result is outside the manufacturer's specification, or there is believed to be a clinically significant degradation of image quality, corrective action should be recommended.

Communication is key in these instances. The QMP should not just perform a test and inform the site that a service call is required; the QMP has a responsibility to provide clear communication regarding the following:

- The specific metric/issue under discussion
- The specific tests that have been performed, including test objects
- The observed/measured results
- The specifications (e.g., manufacturer's specifications) not being met

The site has the responsibility to ensure that effective and timely corrective action is performed and documented and that any comments or recommendations for quality improvement are addressed.

If the manufacturer does not provide specifications for a particular test, then the ACR or medical physicist's test result should be benchmarked and monitored over time. Please note that additional testing outside of the manufacturer specifications may not be supported by the manufacturer.

QC Tests and Applicability

The QMP must include the evaluations listed in Table 1 below in the annual quality control program. The recommended test procedures are designed to minimize the number of acquisitions and eliminate special apparatus. If the QMP follows the recommended test protocol, the entire annual physics testing can be accomplished with, at most, four distinct acquisitions and two additional tests that don't require a phantom.

DRAFT

933

Table 1. QMP annual evaluations

Test	Acquisition	Applicability	Notes
Image Quality	ACR PET Phantom	PET, PET/CT, PET/MR	The annual acquisition forms the basis for further analysis. In addition, the ACR PET phantom acquisition is part of the Technologists' QC Program.
Spatial Resolution		PET, PET/CT, PET/MR	
SUV Accuracy		PET, PET/CT, PET/MR	On PET/MR systems, phantom-specific mu-maps may be required for accurate SUV measurements
Image Co-Registration		PET/CT, PET/MR	
Count Rate Performance	ACR PET Phantom with boost activity	PET, PET/CT, PET/MR	Recommended for all systems. Required for systems acquiring high count-rate studies (see details)
Sensitivity	Syringe	PET, PET/CT, PET/MR	Required for systems that do not provide independent sensitivity tracking QC data.
Image Uniformity	Uniform Cylinder	PET, PET/CT, PET/MR	
CT Scanner Assessment	CT Phantoms	PET/CT	Required unless the CT scanner is tested independently.
Acquisition Workstation Display Monitor Evaluation	(do not require PET acquisitions of phantoms)	PET, PET/CT, PET/MR	
Safety Evaluation		PET, PET/CT, PET/MR	
Review of Site's QC Program		PET, PET/CT, PET/MR	

XI. Test Procedures

1. Image Quality

Purpose

The image quality test utilizes a standardized phantom to assess overall imaging performance under a realistic clinical imaging situation. The ACR PET phantom includes several features that indicate scanner performance:

- Uniform background region: assessment of scanner uniformity, noise level, and artifacts, as well as quantitative accuracy (SUV analysis)
- “Cold” rods: evaluation of low-contrast resolution (“cold” rod visibility)
- “Hot” vials: evaluation of high-contrast resolution (“hot” vial visibility and SUV analysis) and by qualitative analysis of recovery
- “Cold” vials: evaluation of quantitative accuracy (SUV analysis) in different materials (simulating bone, water, and air)

The ACR PET phantom is very convenient in that visual inspection of the phantom features in images provides a rapid assessment of overall scanner performance. The phantom provides information regarding certain characteristics (e.g., resolution, image uniformity, and PET/CT co-registration). Thus, for annual performance testing, it is a practical and acceptable alternative to specialized phantoms and fixtures for the specific performance tests.

Applicability

All clinical PET scanners, including dedicated PET, PET/CT, and PET/MR, with a bore diameter greater than 25 cm and capable of scanning an axial range of at least 20 cm (via bed motion for example).

For PET/MR scanners, quantitative accuracy may be limited by the lack of an MR-derived attenuation map of the phantom. The plastic components (outer cylinder wall, cold rods) are not visible in Dixon MR images used to generate the attenuation map. Use of an inaccurate MR-derived attenuation map can cause significant quantitative error in SUV measurements. Use of a phantom template or CT-derived attenuation map is necessary to produce accurate PET images. The PET/MR vendor may offer this option for performing PET phantom studies.

Frequency

This test must be performed as part of the annual evaluation. Additionally, it must be completed at the initiation of the QC program and following major repairs that could affect image quality. It should also be performed following reconstruction software upgrades and significant protocol changes.

Required Equipment

- ACR PET phantom.

DRAFT

Test Procedure

Note that it is imperative that the scanner and activity assay clocks be synchronized. A few minutes discrepancy will propagate to significant errors in quantification (SUV Accuracy).

Preparation of the ACR PET phantom is described in Appendix A. The procedure is compatible with an ACR accreditation submission but includes a few refinements designed to improve accuracy. The phantom is scanned using the site's standard clinical FDG body protocol, starting 60 minutes after the activity assay time.

Data Analysis and Interpretation

For the Image Quality test, reconstructed images of the phantom are assessed visually. Subsequent tests examining spatial resolution, contrast and quantitative accuracy are described in later test procedures of this manual.

Display attenuation corrected axial slices of the phantom. Use the original, not resampled or summed, image set.

Adjust the display window width and level to minimum 0 SUV and maximum 3.0 SUV or to minimum 0% and maximum 100% (if SUV is not available).

Examine each slice to check for artifacts, such as those related to:

- Detector normalization: Improper normalization of one or more detector blocks may produce streaks, excessive noise or other nonuniformities.
- Protocol settings: For example, improper image reconstruction settings may cause artifacts related to non-convergence (e.g., insufficient iterations in iterative algorithms) or image noise (e.g., excessive iterations).
- Attenuation correction and/or scatter correction: Slices should have uniform intensity background, and vials not filled with radioactivity should appear "cold".

Action Limits and Remediation

Image quality will vary according to the PET scanner capability, acquisition duration and the reconstruction filter settings applied by the clinical protocol. The physicist should evaluate baseline images in consultation with the clinical staff and then images can be evaluated with respect to this expected performance.

The cause of any serious artifacts such as streaking or excessive noise should be investigated. If reconstruction protocol settings are suspected of causing artifacts, then the site's clinical protocols should be revised as needed.

Alternatives

None.

2. Spatial Resolution

Purpose

To ensure stability of the PET spatial resolution.

Applicability

All clinical PET, PET/CT and PET/MRI scanners.

Frequency

This test must be performed as part of the annual evaluation. Additionally, it must be completed at the initiation of the QC program and following major repairs that could affect spatial resolution. It should also be performed following reconstruction software upgrades and significant protocol changes.

Required Equipment

- ACR PET Phantom – This test makes use of images acquired for Image Quality evaluation.

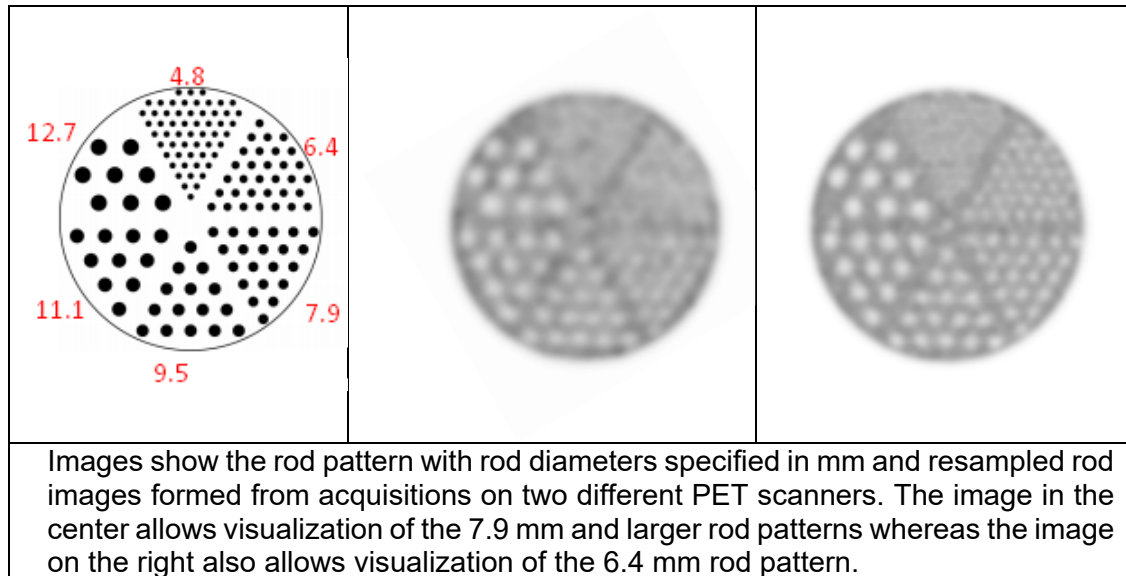
Test Procedure

1. Load the axial images onto the image review workstation.
2. Resample the axial images to form a set of contiguous non-overlapping axial slices with 1 cm thickness spaced at 1 cm intervals.
3. Display the 1 cm thick axial slices and adjust the display window width and level to minimum 0 SUV and maximum 3.0 SUV or to minimum 0% and maximum 100% (if SUV is not available).
4. Visually assess the appearance of the cold rod section of the phantom.

Data Analysis and Interpretation

Record the size of the smallest rods that can be visualized with high contrast. Since this is somewhat subjective or observer dependent, a copy of the image should be maintained for serial comparison.

DRAFT



Action Limits and Remediation

In general PET scanner performance should result in the 11.1 mm and 12.7 mm rods being clearly visible. However, results will vary according to the PET scanner capability and the reconstruction filter settings applied by the clinical protocol. The physicist should establish a limiting spatial resolution based on initial evaluation and consultation with the clinical staff and then subsequent resolution images can be evaluated with respect to this expected performance.

Alternatives

None.

3. Standard Uptake Value (SUV) Accuracy

Purpose

To ensure the accuracy of the standardized uptake value for accurate and robust PET quantification.

Applicability

All clinical PET, PET/CT and PET/MRI scanners.

Frequency

This test must be performed as part of the annual evaluation. Additionally, it must be performed at the initiation of the QC program and after major repairs that could affect PET quantification.

Required Equipment

ACR PET Phantom – This test makes use of images acquired for Image Quality evaluation.

Test Procedure

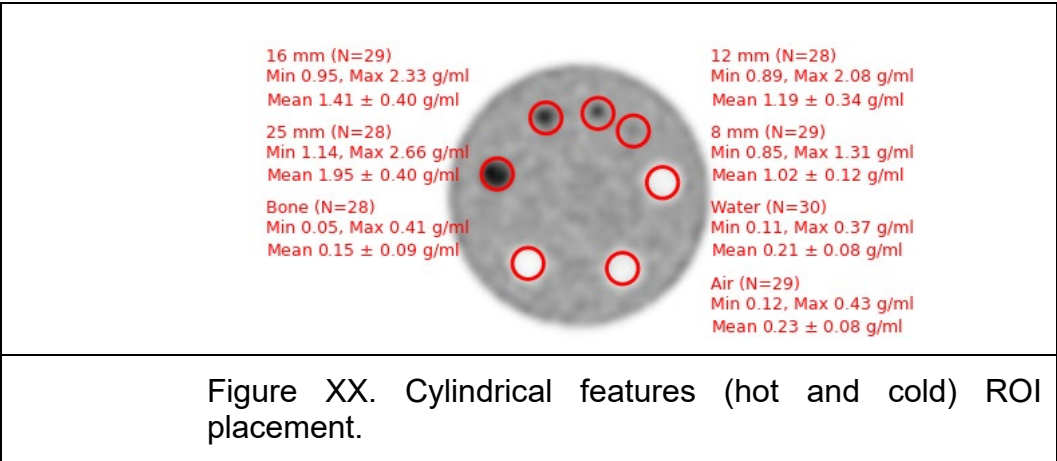
Load the reconstructed PET images acquired for image quality evaluation.

- Resample the axial images to form a set of contiguous non-overlapping axial slices with 1 cm thickness spaced at 1 cm intervals.
- Display the 1 cm thick axial slices and adjust the display window width and level to minimum 0 SUV and maximum 3.0 SUV or to minimum 0% and maximum 100% (if SUV is not available).
- Place 25 mm diameter ROIs centered over the “hot” and “cold” vials on a slice midway through the section of the ACR phantom containing those vials (see figure XX).
- Place 180 mm diameter background ROIs on three uniform slices in the uniform section midway between the slices containing the “hot” and “cold” vials and those containing the “cold” rods insert (see figure XY)
- Record the SUV_{max}, SUV_{mean}, and SUV_{min} of the ROIs.

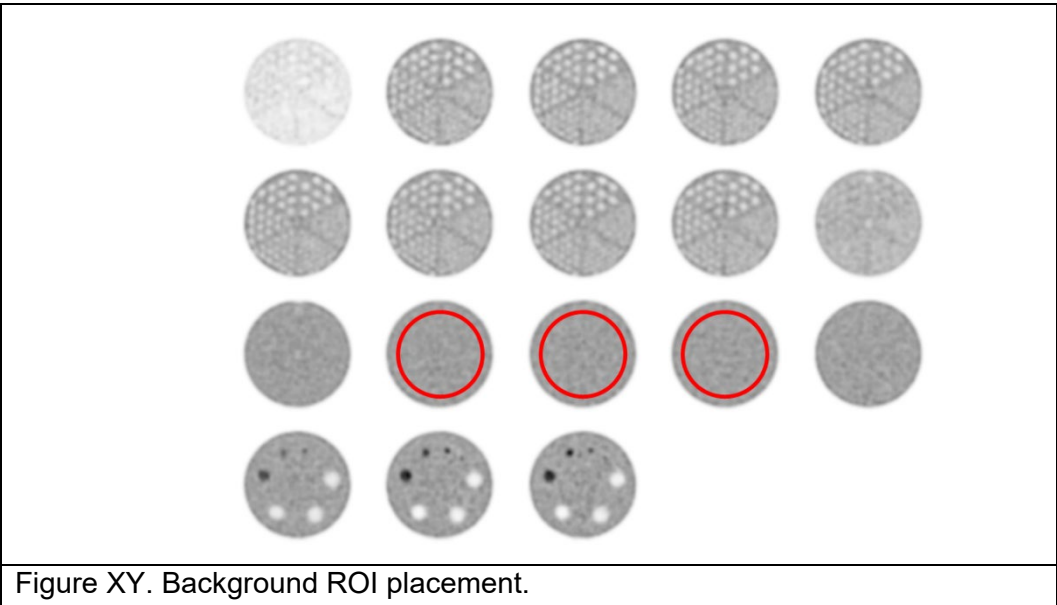
Data Analysis and Interpretation

Record the ROI values of the “hot” and “cold” vials and calculate their ratios as shown in the following Table 2.

1076



1077



1078

DRAFT

Table 2. Example of record of ROI values and ratio calculations using the data from ROIs shown in Figure XX and XY.

A) Contrast - Table 1				
	"Hot" Vial			
	8 mm	12 mm	16 mm	25 mm
Max SUV	1.31	2.08	2.33	2.66
B) Scatter/Attenuation - Table 2				
	Background	Bone	Air	Water
Mean SUV	1.00	0.15	0.23	0.23
Min SUV		0.05	0.12	0.11
C) Ratio Calculations (using data from Tables 1 & 2 Above)				
	8mm/bkgd	12mm/bkgd	16mm/bkgd	25mm/bkgd
	1.31	2.08	2.33	2.66
		8mm/25mm	12mm/25mm	16mm/25mm
		0.49	0.78	0.88

Compare ROI values and ratios from the current phantom to those obtained in the last annual test.

Action Limits and Remediation

The most important quantitative evaluation is of background SUV_{mean} which should ideally be 1.00. SUV_{max} of the cylindrical hot features should increase with increasing diameter. SUV_{mean} and SUV_{min} of cold features should approach 0. The SUV_{max} of the 25 mm diameter "hot" vial SUV_{max} to background SUV_{mean} should be in the range of 1.9 to 2.9. An SUV ratio falling outside this range may be due to an error in preparing the phantom or system calibration.

For the purpose of accreditation, the ACR defines the acceptable background SUV_{mean} range but, for the purpose of annual testing, background SUV_{mean} should be between 0.95 and 1.05 (i.e. +/- 5%). If SUV_{mean} falls outside the range of 0.9 and 1.0, the cause should be investigated and corrected. Possible causes include human error in preparing the phantom or acquisition setup (e.g., correct activity, weight, and time), scanner calibration accuracy, or dose calibrator accuracy.

If the ratio of 25 mm diameter "hot" vial SUV_{max} to background SUV_{mean} falls outside the recommended range, it may be due to the reconstruction protocol. A retrospective reconstruction with resolution recovery switched off may resolve the problem (see for example, Tsutsui et al). Alternatively, reducing the number of

DRAFT

iterative reconstruction updates (subsets and iterations) or adjusting filter settings may resolve the issue. The purpose of this criteria is for quality control of the phantom itself. If the underlying contrast ratio of solutions in the phantom is in doubt, then the phantom acquisition should be repeated. If reconstruction parameters are found to significantly affect quantitative accuracy, changes to the clinical protocols should be considered. If year over year changes are significant, as defined by the QMP, and cannot be traced to protocol changes, the cause must be investigated.

Alternatives

SUV accuracy can be assessed with other water-filled phantoms that use chambers permitting mixtures with more than one concentration.

4. Image Co-registration

Purpose

To ensure registration of coordinate systems for PET and CT (or MR) image sets that comprise an image volume.

Applicability

All clinical PET/CT and PET/MR scanners.

Frequency

This test must be performed annually. Additionally, it must be completed at the initiation of the QC program and following major repairs that involve separation of the PET and CT or PET and MR gantries.

Required Equipment

- ACR PET Phantom – This test makes use of images acquired for Image Quality evaluation.
- 3D imaging workstation capable of either fused or simultaneous multimodality display with linked cursors. In addition, software must be capable of display in coronal or sagittal planes as well as conventional axial slice display. If the latter is not met, then multiplanar reformats will need to be generated on the scanner.

Test Procedure

Load PET/CT or PET/MR data into the display workspace

Select an axial slice near the middle of the phantom.

Confirm that corresponding images from the two modalities are registered horizontally (x-axis) and vertically (y-axis) using linked cursors or measurement tools. If an offset is visible, measure the extent.

- Either switch views to display data in coronal or sagittal views or load the coronal or sagittal multiplanar reformats produced by the scanner.
- Confirm that corresponding images from the two modalities are registered vertically (z-axis) in the coronal or sagittal views using linked cursors or measurement tools. If an offset is visible, measure the extent.
- Record the registration error along each axis.

Data Analysis and Interpretation

Misregistration between PET and CT or MR coordinates is assessed as the displacement seen along the three principal axes. Note that this is not a full quantitative assessment of misregistration but rather a visual check of gross alignment.

DRAFT

Action Limits and Remediation

Misregistration between PET and CT or MR data should not be perceptible and should be less than the spatial resolution (NEMA FWHM (FBP) specification) of the PET scanner along each of the principal axes. Misregistration greater than this is likely to affect clinical interpretation; therefore, corrective action to repair the registration should be recommended.

Alternatives

The manufacturer's proprietary phantoms or software can be used for this test. In which case, manufacturer's specifications may be employed. In addition, the registration assessment described in TG 126 can be used.

5. Count Rate Performance

Purpose

Depending on PET detector and scanner design, detectors more or less operate with significant count loss from detector dead time. This is particularly the case for detectors with BGO crystals, flat-panel detector designs, and fully 3D (septa-less) scanners. Dead time corrections are included during PET image reconstruction for quantitative accuracy. However, the accuracy of dead time corrections is limited, especially at high count rates. The goal of this count rate performance test is to evaluate quantitative accuracy for clinical imaging studies.

Accurate quantification relies on accurate dead-time correction throughout the clinical dynamic range of count rates experienced during clinical studies. Typically, a PET scanner is calibrated under baseline operating conditions, for which dead-time loss is relatively small. However, a confirmation of dead-time correction accuracy is not part of routine scanner calibration. Thus, in addition to the SUV accuracy test with the standardized ACR PET phantom, an evaluation of SUV accuracy at higher counting rates is beneficial.

Applicability

Although it is recommended to evaluate higher count rate performance for all PET scanners, it is required for scanners (PET, PET/CT, PET/MRI) performing high count rate clinical studies. The QMP must evaluate the clinical usage and the PET detector design to determine the need to include this test in the annual physics survey.

Examples of clinical scans with higher count rates include:

- Dynamic myocardial perfusion studies (with ^{82}Rb -chloride or ^{13}N -ammonia)
- PET studies starting immediately after injection of the activity (such as ^{18}F -fluciclovine)
- Studies (e.g., with short-lived tracers ^{11}C , ^{13}N) for which high activities are injected.

Frequency

This test must be performed annually. Additionally, it must be completed at the initiation of the QC program in order to establish baseline performance.

Required Equipment

ACR PET Phantom.

Test Procedure

The standard test involving the ACR PET phantom evaluates SUV accuracy and so a convenient method of evaluating count rate performance is to rescan the ACR PET phantom with higher activity concentration and to compare results.

DRAFT

When preparing the activities for the ACR PET phantom, prepare an additional ^{18}F activity with twice the activity as the background activity (“Dose B”). Record the activity and assay time of this “boost syringe”.

- Immediately after scanning the ACR PET phantom, place the phantom upright on a flat surface. Open the bubble trap port, inject and flush the boost syringe in the phantom background chamber. (Take appropriate measures to avoid spills.) Close the port and ensure the phantom does not leak. Mix well to ensure that the activity is uniformly distributed throughout the phantom prior to imaging. Record the residual activity in the syringe and the assay time. If the residual is not negligible decay correct it back to the original boost-dose assay time and subtract it from the boost dose.
- Setup the acquisition on the scanner by entering the patient weight and the sum of the original activity plus boosted activity (minus residuals, possibly decay-corrected).
- Place an ROI on the same area of the background as was used in background SUV evaluation of the ACR phantom and record SUVmean.

Data Analysis and Interpretation

Calculate the ratio of boosted SUVmean to SUVmean obtained in the SUV Accuracy test.

Action Limits and Remediation

The ratio of boosted SUVmean to SUVmean obtained in the SUV Accuracy test, should be between 0.9 and 1.1

Alternatives

Count rate performance test can be performed with other phantoms or test procedures that simulate the clinical dynamic range of count rates such as AAPM TG126 and NEMA NU2.

6. Sensitivity

Purpose

This test measures PET system sensitivity to a specific distribution of radioactivity in order to ensure stability of the PET system sensitivity over time.

Applicability

All clinical PET, PET/CT and PET/MRI scanners. Required for systems that do not provide tracking of sensitivity calibration data (e.g., daily QC with Ge-68 or Na-22 source – see Alternatives).

Frequency

This test must be performed annually. Additionally, it must be completed at the initiation of the QC program to establish baseline measurements and following major repairs that could affect system sensitivity.

Required Equipment

- 3 ml or smaller syringe
- Low density support block (expanded polystyrene block or an empty cardboard box)

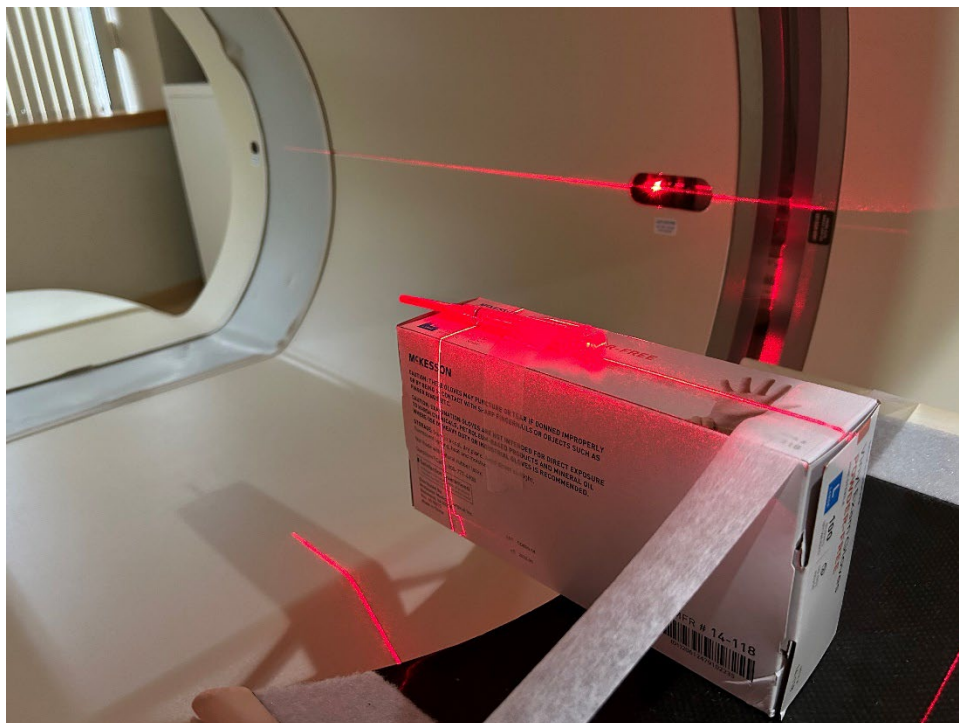
Test Procedure

Draw approximately 0.1 mCi of ^{18}F into the syringe. Replace the needle with a fresh needle or syringe cap. The volume of the solution should be as small as possible (less than 0.1 ml).

- Place the syringe in the dose calibrator and record the activity and time.
- Support the syringe on the low-density block, align it with the z-axis and center it in the field of view (Figure YY). If possible, cantilever the low-density support block so that the patient bed is kept outside the field of view. (Note that attenuation by the bed or support block will affect quantitative accuracy. Setup should be kept consistent between time points.) Note also that point-based sensitivity is highly position-dependent so consistency in source positioning is imperative.
- Use lasers or scan planning tools (CT localizer) to ensure that the activity is located in the geometric center of the PET bore – both in-plane and along the axial extent of the scanner.
- Use the acquisition mode used most commonly in the clinic for whole-body imaging to acquire an emission scan of 60 seconds duration with stationary bed.
- From the PET acquisition headers and interfiles, obtain an estimate of the total net counts (Trues) recorded during the 60 second scan or obtain the total counts (Prompts) and an estimate of the total random counts

DRAFT

(Randoms). The manner in which the estimates of Trues or Prompts and Randoms counts are obtained varies by vendor. Consult the vendor's user manual for steps to obtain the trues or the prompts and randoms data. Alternatively, the AAPM TG126 describes the procedures for some models of PET scanners in Appendix A of AAPM Report 126.



Sensitivity measurement using a syringe supported by an empty glove box, cantilevered over the end of the patient bed.

Data Analysis and Interpretation

Calculate the sensitivity of the PET scanner as:

$$\frac{(\text{Trues}) / 60}{(A \times 0.97)} \times 100\%$$

$$(A \times 0.97)$$

, or as:

$$\frac{(\text{Prompts} - \text{Randoms}) / 60}{(A \times 0.97)} \times 100\%$$

$$(A \times 0.97)$$

DRAFT

1277

1278

1279

1280

1281

1282

1283

1284

1285

1286

Where A is the activity in Bq, measured by the dose calibrator, decayed to the start of acquisition. Note that $1 \text{ Bq} = 1 \text{ mCi} \times 3.7^{+7}$ Bq/mCi. The constant 0.97 is the relative number of positrons emitted per decay for ^{18}F . Change the constant as appropriate if another radioisotope is used for the test. The constant 60 accounts for the 60 second duration of the acquisition and converts counts to counts per second. Sensitivity is the percentage of positrons emitted during the scan that were recorded as coincident photons by the scanner.

1287

Action Limits and Remediation

1288

1289

A change in sensitivity between subsequent annual tests should be less than 10%. The cause of significant sensitivity loss should be investigated.

1290

Alternatives

1291

1292

1293

1294

1295

1296

There are alternative methods to assess the system sensitivity. In particular, AAPM TG126 details tests using the NEMA NU2 PET sensitivity phantom to evaluate sensitivity, and alternatively details tracking certain calibration factors as surrogates for sensitivity. Sensitivity, however, should not be confused with SUV accuracy. The latter includes a cross-calibration factor for system sensitivity with respect to ^{18}F activity.

1297

7. Image Uniformity

Purpose

This test is used to assess the uniformity of the activity concentration within a slice as well as across slices of a uniform phantom.

Applicability

All clinical PET, PET/CT and PET/MRI scanners.

Frequency

This test should be done annually or after major repairs of the scanner.

Required Equipment

Uniform water filled phantom or prefilled uniform Ge-68 phantom.

Test procedure

If using a uniform water filled phantom, add ^{18}F to the phantom such that the activity concentration is about 0.1-0.15 uCi/cc at the time of imaging. Make sure the activity is uniformly distributed in the phantom before imaging. Place the phantom centrally in the field of view of the scanner and image it using the standard clinical protocol for static imaging with FDG. Make sure the phantom is imaged using the whole axial extent of the scanner. This may require moving the phantom and acquiring additional scans.

If using a ^{68}Ge phantom, change the isotope setting to ^{68}Ge -68 instead of ^{18}F , to avoid decay correction errors when moving the bed during acquisition.

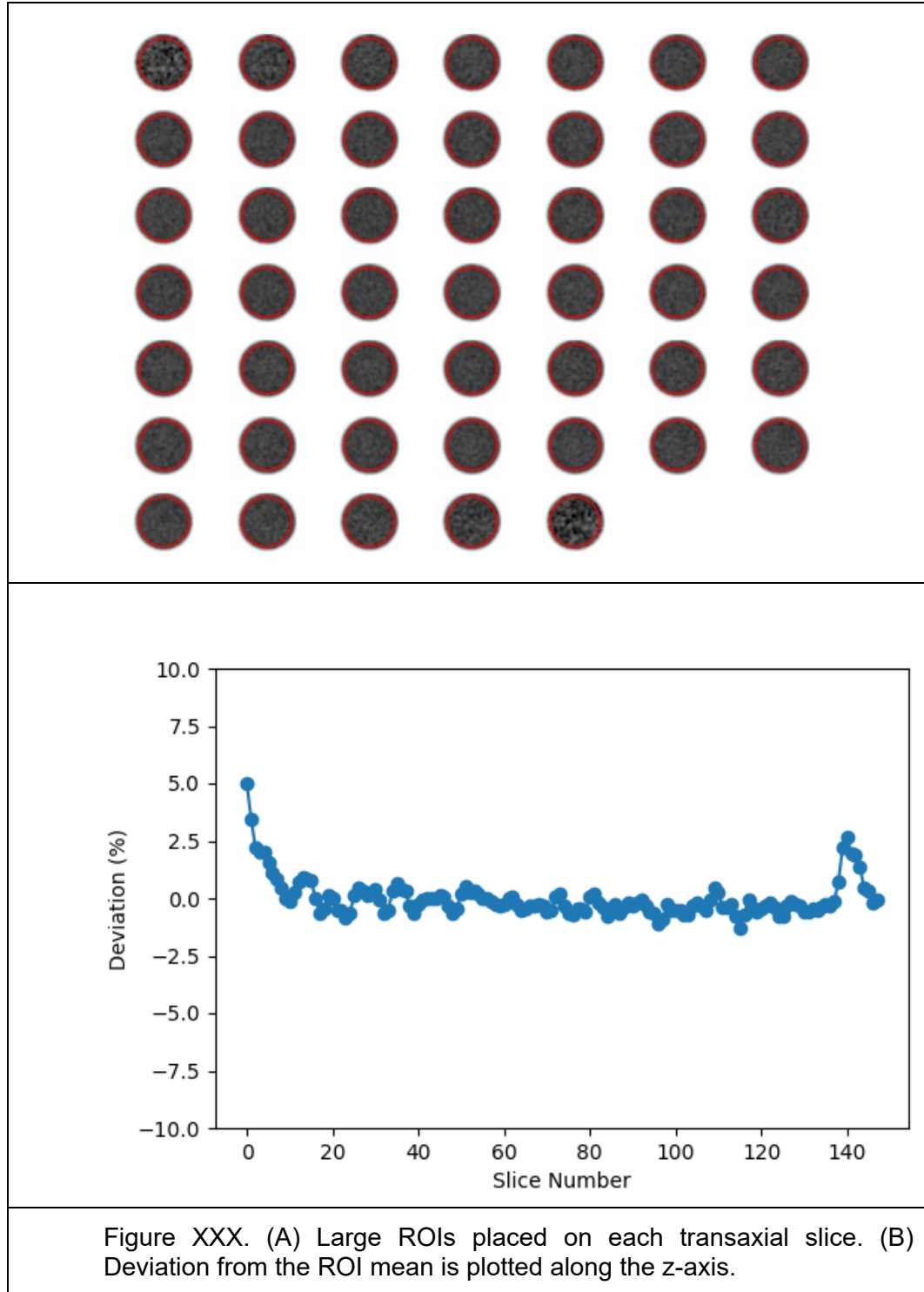
Reconstruct images using the standard clinical protocol for static imaging with FDG.

If the site does not perform clinical FDG studies, the QMP can select an alternative clinical protocol for this test.

Data Analysis and Interpretation

1. Place a large circular ROI (diameter approximately 90% of cylinder diameter) on each axial slice excluding the noisiest slices at either end. Ideally, slices corresponding to 85% or more of the axial extent of the scanner should be included in the ROI analysis.
2. For each ROI record the mean activity concentration (ROI_{mean}). Units can be either Bq/ml or SUV (g/ml).
6. Calculate the deviation of each ROI measurement from the mean of all the ROIs:

$$\text{Deviation} = (\text{ROI}_{\text{mean}} / \text{mean}(\text{ROI}_{\text{mean}}) - 1) \times 100\%$$



8. Action Limits and Remediation

If deviation is greater than an absolute value of 5% the cause should be investigated. It is possible that excessive noise may cause the measured uniformity to exceed this threshold. This might be resolved by increasing acquisition time or adjusting reconstruction protocol settings. If deviation exceeds 10% for any slice (except for

DRAFT

1338 the slices at each end outside of the central 85% of the axial extent of the scanner)
1339 the test fails, and corrective action should be recommended.

1340 ***Alternatives***

1341 If this analysis procedure cannot be automated either by use of the copy, paste and
1342 export features of the workstation or image analysis software then a subset of ROIs
1343 can be used. A minimum of 10 slices spanning the axial extent of the bore should
1344 be analyzed.

1345

9. CT Scanner Assessment

Purpose

Since performance requirements and image quality in a PET/CT system depends also on the performance of the CT component, it is therefore recommended that for best practice, the QMP verifies and ensures appropriate CT operation for the purposes of PET/CT imaging.

Emphasis should be placed on possible CT artifacts as well as the accuracy of the CT numbers, as this could affect the accuracy of CT based attenuation correction of the PET images. Image quality attributes that should be checked include CT number accuracy, CT noise and resolution, and image homogeneity (uniformity).

Applicability

Clinical PET/CT scanners.

Frequency

At Acceptance Testing: Verify that the measurements meet the manufacturer's specifications and published reports. The results will be used to create baseline measurements and action limits for subsequent annual surveys.

At Annual Physics Survey: Verify that the measurements meet the manufacturer's specifications and published reports, and that there is no significant deviation when compared with previous annual testing or with those obtained at acceptance testing.

Required Equipment

The ACR CT quality control manual (ACR CT QC Manual) guidelines should be followed for appropriate CT testing equipment.

Testing Procedure

If the CT is used for diagnostic CT imaging, then the ACR CT QC Manual should be followed for appropriate complete CT testing. If the CT component is used only for CT based attenuation correction of PET images and anatomical localization through image fusion of PET and CT, then, the following subset of tests from the ACR CT QC Manual are recommended as part of the annual testing of the PET/CT:

- Low-Contrast Performance

CT Number Accuracy

Artifact Evaluation

CT Number Uniformity

Dosimetry

These tests should be performed for the most commonly used clinical PET/CT protocols to include, for example and if applicable, one for head and one for body

DRAFT

imaging. If the PET/CT system is used for both adults and pediatric patients, then it should be appropriately tested in both the adult and pediatric protocols.

The methodologies of how these CT tests should be performed are described elsewhere (please see ACR CT QC Manual).

Data Analysis and Interpretation

The ACR CT QC Manual should be followed for appropriate CT testing data analysis and interpretation criteria.

However, due to the variety of CT models in PET/CT systems and the frequent use of low-dose imaging protocols, the threshold for CNR as measured in the Low-Contrast Performance test should be reduced. The determination of that relaxed threshold will be made by the QMP in consultation with the facility radiologists.

Alternatives

None.

DRAFT

1397

10. Acquisition/Processing Workstation Display Monitor Calibration

Purpose

To ensure that images display the entire range of gray shades produced by the PET scanner.

Applicability

All clinical PET, PET/CT and PET/MRI scanners.

Frequency

This test must be performed annually. Additionally, it must be completed at the initiation of the QC program and whenever a significant change is made to the display monitors. If this test was performed as part of the CT or MR annual test, it can be documented as such and does not need to be repeated.

Required Equipment

- SMPTE or TG18-QC test pattern (AAPM TG270). These should be compatible with the monitor bit depth and software display capability (e.g. DICOM Part 10 or TIFF). Do not use a lossy-compressed format such as JPEG or PNG. In many cases, the scanner manufacturer provides a scheme to load test patterns on the monitors – if so, use that method.
- Calibrated photometer with adequate precision, accuracy, and calibration to effectively measure luminance in the range 0.1 to 500 cd/m².

Test Procedure

1. The monitor should be positioned so that there is no glare from room lighting.
2. Display the test pattern on the monitor. Set the display window width/level to the manufacturer-specified values for the pattern. Do not set the window width/level by eye; doing so invalidates this procedure.
3. Examine the pattern to confirm that the gray level display on the imaging console is subjectively correct.
 - a. Review the line pair patterns in the center and at each of the corners.
 - b. Review each black-white transition for sharpness.
 - c. Examine areas of smooth gradations for evidence of “scalloping” (loss of bit depth) or geometric distortion.
 - d. Examine the image for signs of spectral distortion (coloration) – the test patterns are pure grayscale images and no colors should be rendered.
 - e. Confirm that the 5% and 95% gray level transitions are visible.
4. Adjust the window width/level to achieve pure black and use the photometer to measure the minimum monitor brightness.

DRAFT

5. Adjust the window width/level to achieve pure white and use the photometer to measure the maximum monitor brightness at the center and near all four corners of the display.

Data Analysis and Interpretation

Visual Analysis

The visual impression should be an even progression of gray levels around the ring of gray level patches. All gray level steps in the ring of gray levels must be visibly distinct from adjacent steps.

7. The 5% patch must be visible in the 0/5% patch; the 95% patch must be visible in the 95/100% patch.
8. If these conditions are not met, do not adjust the display window width/level in an effort to correct the problem. Corrective action for the monitor is needed.
9. Ensure that the finest line pair pattern can be visualized in the center and at each of the four corners.
10. There must not be visible bleed-through in either direction of all black-white transitions. All high-contrast borders must be straight, not jagged.
11. There must not be scalloping of the gray scale. There must not be geometric distortion in the image.

Photometric Analysis

The maximum brightness should be greater than or equal to 100 cd/m², and minimum luminance ratio (L_{\max} / L_{\min}) should be greater than 1.0

Calculate the nonuniformity of the display brightness using the equation% difference = $200 \times (L_{\max} - L_{\min}) / (L_{\max} + L_{\min})$, where L_{\max} and L_{\min} are the maximum and minimum measured luminance values of the five measurements made in step 5 above, respectively. The nonuniformity should not exceed 30% for CRTs and should be within $\pm 15\%$ for flat panel displays.

Action Limits and Remediation

In many instances, problems are caused by incorrect adjustment of the monitor's brightness and contrast. Excessive ambient lighting can aggravate this problem. Problems can also be caused by poor connections, which are easily remediated.

Perform the manufacturer's recommended procedure for monitor contrast and brightness adjustment. If there is any doubt about the correct procedure or if the brightness and contrast controls are not accessible, have the service engineer make the adjustments.

If after corrective action is attempted and the monitor does not meet these specifications, additional action should be determined by the lead interpreting physician in consultation with a QMP. If the monitor is used exclusively for cursory QC checks and never used for image interpretation or analysis of any kind (for

DRAFT

1472 example manipulations such as reformatting or reprocessing) then it may be
1473 deemed acceptable for use within this limited scope.

1474 ***Alternatives***

1475 Display monitor manufacturer's test procedure or specifications may be used
1476 instead of those described here.

1477

DRAFT

11. Safety Evaluation

Purpose

To ensure the safety of persons and equipment and prevent instrumentation related safety issues from happening.

Applicability

All clinical PET, PET/CT and PET/MRI scanners.

Frequency

This test must be performed annually at a minimum.

Required Equipment

None

Test Procedure

Operator control panels testing:

Usually there are two operator control panels for a PET/CT (PET, PET/MRI) scanner, one on the gantry face and another in the control room next to the console. Test each of the buttons on the panels for its function and monitor the display screen on both panels.

Laser light testing:

There are usually three positioning laser lights available for a PET/CT (PET, PET/MRI) scanner: lateral (for table height positioning), axial (for inner and outer positioning in axial direction) and sagittal (for left and right positioning). Unless being tested with CT surveys already, check all the laser lights by positioning a PET phantom to make sure it's functioning and accurate.

Communication system testing:

The communication system of a PET/CT (PET, PET/MRI) scanner, also called intercom system, usually consists of microphone and loudspeaker, and allows users to communicate with the patient. Test the intercom by switching it on during scanning, and make sure the operator and patient can hear each other well.

Table and detector cover:

Ensure there is no damage to the table and PET detector cover and make sure there are no attenuating materials present that may interfere with image acquisition.

Data Analysis and Interpretation

For operator panel testing, laser lights testing and intercom testing, if any malfunction is identified, perform troubleshooting and then recommend corrections as appropriate.

DRAFT

1512 If any attenuating materials (dirt contamination. etc.) is noted on the detector cover,
1513 troubleshoot the extent of the issue and recommend corrective actions, such as
1514 cleaning or repairs. If any damage is found to the table that may cause patient safety
1515 issues, or any damage to gantry detector screens, repair should be recommended.

1516 ***Action Limits and Remediation***

1517 The QMP should define the action limits and should recommend service as
1518 appropriate.

1519 ***Alternatives***

1520 None.

1521

XII. Resources

- AAPM. PET/CT acceptance testing and quality assurance. The Report of the American Association of Physicists in Medicine Task Group 126. Virginia; 2019.
- National Electrical Manufacturers Association. “NEMA Standards Publication NU 2-2012: Performance Measurements of Positron Emission Tomographs,” Rosslyn, Virginia, USA, 2013.
 - National Electrical Manufacturers Association. “NEMA Standards Publication NU 2-2018:
 - International Atomic Energy Agency. “IAEA Health Human Series No. 1: Quality Assurance for PET and PET/CT Systems,” Vienna, Austria, 2009.
 - American College of Radiology. “Computed Tomography Quality Control Manual.” Reston, Virginia: 2017.
 - American College of Radiology. “PET Accreditation Program Testing Instructions.” Reston, Virginia: 2018
 - Tsutsui Y, Awamoto S, Himuro K, Umezue Y, Baba S, Sasaki M. Edge Artifacts in Point Spread Function-based PET Reconstruction in Relation to Object Size and Reconstruction Parameters. Asia Ocean J Nucl Med Biol. 2017 5(2):134-143.
 - Carey, J. E., P. Byrne, L. DeWerd, R. Lieta, and N. Petry. AAPM Report No. 181. The Selection, Use, Calibration, and Quality Assurance of Radionuclide Calibrators Used in Nuclear Medicine. AAPM, 2012.
 - AAPM. Display quality assurance. The Report of the American Association of Physicists in Medicine Task Group 270. Virginia; 2019.
 - Bevins, N., et al. (2019). “Practical application of AAPM Report 270 in display quality assurance: A report of Task Group 270.” Med. Phys. 47(9)e920-8.
 - Samei, E., et al. (2015). “Assessment of Display Performance for Medical Imaging Systems: Executive Summary of AAPM TG18 report.” Med. Phys. 32(4)1205–25.

XIII. Appendix A: Preparing the PET ACR Phantom for Enhanced Accuracy

The following preparation scheme includes refinements to the standard published ACR procedure for preparing the PET ACR Phantom that will improve the accuracy and consistency of SUV assessment.

Activity Assays

Choose DoseA (“hot” vials) and DoseB (background) target activities by scaling DoseC, where DoseC is the activity used clinically for imaging a 70 kg patient with FDG. The scaling is performed using the equations:

$$\text{DoseA} = 0.0350 \times \text{DoseC}$$

$$\text{DoseB} = 0.0824 \times \text{DoseC}$$

For example, a clinic that administers 10 mCi ¹⁸F-FDG for a 70 kg patient, the target activities DoseA and DoseB are 0.35 mCi and 0.82 mCi respectively.

DoseA will be diluted into a 1000 ml solution of water or saline to form the stock solution to fill the cylindrical “hot” vial features. DoseB will be diluted into the phantom background. For each of these dilution steps, with the target activity in mind, draw the activity, inject it into the solution and measure the residual. Record the initial activity, residual activity and the assay times, then calculate and record the net activity.

When drawing the activities for DoseA and DoseB, precision is important. Errors herein either activity measurements or assay times will propagate and affect the measured SUVs. Since we are aiming to measure background SUV within a range of +/- 5%, the accuracy of DoseB must be considerably better than that.

Scanner Setup

For reference, the ACR PET phantom background volume is 5640 ml. When setting up the scan prior to acquiring images, enter the DoseB net activity and enter the patient weight as 5.64 kg (the approximate weight of the water in the phantom). If the scanner doesn’t allow fractional weights as is the case with some older models, multiply both the net DoseB by a factor of 10 and enter the patient weight as 56 kg.

In this scheme, the net activity and the approximate weight of the water in the phantom background are used during setup of the PET scan. The advantage of this scheme compared to the ACR submission scheme, which use a nominal patient activity and weight, is that it will eliminate the error in SUV measurements associated with deviation of the net activity from the target activity.

Hot Feature to Background Ratio

Again, the ACR PET phantom background volume is 5640 ml. The ratio of activity concentration in “hot” vials features to the background, FBR, is therefore:

$$\text{FBR} = \text{DoseA}/\text{DoseB} \times 5.64$$

If your net DoseA and DoseB activities are exactly as prescribed above, then FBR = 2.39.

DRAFT

DoseA is less critical than DoseB for quantitative evaluations of PET performance (SUV accuracy test) or for visual assessments of the image quality (image quality tests). Changes in visibility of the “hot” vials may not be discernable if the FBR deviates by less than 15% (~2.05 to 2.75). Therefore, the greater effort should be placed on attaining the target net activity for DoseB.

Expert Notes

In practice, it's difficult to sequentially draw two activities of ^{18}F (or other radionuclide with a short half-life) and maintain a target ratio of activity concentrations. However, it is possible to obtain both DoseA and DoseB from a single activity assay by using a two-step dilution process.

To facilitate this, use two 50 ml syringes or test tubes.

Draw up a single activity, DoseU, that has a target of 2% higher than the DoseB target for your clinic (i.e. $1.02 \times 0.0824 \times \text{DoseC}$).

- Record the activity and assay time.
- Disperse that into a syringe or tube and top up to obtain a final volume of 48 ml.
- Measure the residual and calculate the net activity of DoseU.
- Mix thoroughly then transfer 1 ml of that first dilution to a second 50 ml syringe or tube and fill to a final volume of 50 ml.
- The first dilution is now DoseB and is added to the phantom background. After thorough mixing, draw 50 ml back into the syringe or tube to create Dose2.
- The second dilution is Dose1, the stock solution for filling the “hot” vials.

With this dilution scheme, errors due to decay of the radionuclide are eliminated and the ratio of activity concentrations is closer to the target ratio:

$$\text{Dose1/Dose2} = 5640 / 47 / 50 = 2.40$$

The activity entered into the scanner is:

$$\text{DoseB} = \text{net activity of DoseU} \times 47 / 48 = 0.979 \times \text{net activity of DoseU}$$

XIV. Appendix B: Non-imaging (Ancillary) Devices

It is the responsibility of the QMP to ensure that non-imaging measurement devices such as the dose calibrator and the uptake probe are operating properly and within specifications, and therefore the applicable quality control testing should be appropriately performed. While some of the tests should be performed by the QMP, there are tests that are typically performed by the Technologist as part of routine quality control; these tests should be verified by the QMP as part of the comprehensive evaluation of the performance of the instrument.

A. Dose Calibrators

1. Accuracy

Purpose

To verify proper performance and accurate reading of the dose calibrator

Frequency

Testing is to be performed at installation, annually and repeated after major repair.

Required Equipment

One or more NIST traceable, long-lived standard such as Cs-137, Co-57, Ba-133 or Na-22 to be used as the test source.

Test Procedure

Perform a “Test” measurement of the battery voltage (if applicable)

- Perform a zero adjustment (if applicable)
- Perform a background check/correction.
- Place the test source into the chamber of the dose calibrator and select the proper isotope on the dose calibrator.
- Measure the source and record the reading.
- If additional test sources are available, steps 2 and 3 should be repeated for each source.

Evaluation

The actual activity in the test source(s) must be calculated by correcting for decay of the source(s).

- The measured source reading is then compared to the decay corrected actual reading.
- The percent deviation of the measured activity from the decay corrected activity must be within $\pm 10\%$.

DRAFT

Action Limits and Remediation

If the deviation is greater than $\pm 10\%$, the instrument should be taken out of use and the unit must be serviced.

2. Linearity

Purpose

To verify the dose calibrator has a linear response from the highest activity level used clinically to less than 30 uCi.

Frequency

Testing is to be performed at installation, annually (recommended quarterly) and after major repair. Please check with local state or NRC applicable regulations regarding the frequency of this test.

Required Equipment

Equipment could include the use of commercially available linearity tubes consisting of different thicknesses of lead. These are used as attenuators to mimic the decay of a radioactive source.

Test Procedure

Testing can be performed by two different methods that are described below:

Decay Method

A source of radioisotope activity should be assayed in the dose calibrator. The source activity should be at least as large as the maximum activity assayed for administration. Ideally this test should be performed with ^{18}F , but $^{99\text{m}}\text{Tc}$ may also be used as an alternative if ^{18}F is not available.

- Record the activity, time and date. This will be considered time 0.
- Re-assay the source over multiple time points throughout the day in intervals corresponding to approximately one-half of the half-life of the radioisotope, such as every one hour for ^{18}F (or every three to four hours for $^{99\text{m}}\text{Tc}$). Record the activity, time and date of each assay.
- Continue taking measurements until the source has decayed below 30 uCi. Depending on the source activity this may take several hours or several days.
- Using the activity at time 0 and the half-life of the radioisotope, calculate the expected activity at each time point.
- Compare the expected activity to the measured readings.
- All measured readings should be within $\pm 10\%$ of the expected activity.

Attenuator Sleeves/Tubes Method

DRAFT

Remove the “dipper” from the chamber and place the first set of tubes in the chamber. The radioisotope used should be in accordance with the manufacturer’s instructions, and the source activity should be greater than the highest activity administered to patients.

- Measure the source and record the reading and time.
- Tubes should be added/removed in accordance with the manufacturer’s instructions.
- Continue until the source measures below 30 uCi.
- Once completed, the measured readings are multiplied by attenuation factors of the tubes in accordance with the manufacturer’s instructions.
- If necessary, use the activity at time 0 and the half-life of the radioisotope, calculate the expected activity at each time point.
- Compare the expected activity to the measured readings.
- All measured readings corrected by the attenuation factors should fall within the range of $\pm 10\%$ of the expected activity value.

Evaluation

The measured source reading is then compared to previous results.

The percent deviation of the measured activity to the previous results must be within $\pm 10\%$.

Action Limits, Remediation

If the deviation is greater than $\pm 10\%$, mathematically corrected dosage reading can be applied, or the unit may be serviced.

3. Constancy

Purpose

To verify proper performance and consistent reading of the dose calibrator on multiple isotope settings.

Frequency

This is a Technologist’s test performed each day of use (see Technologist QC section). The reference values for comparing the technologist’s measured reading and the action limits should be defined by the QMP. The following testing procedure is included for reference.

Required Equipment

A NIST traceable, long-lived standard such as Cs-137, Co-57 or Na-22 to be used as the test source.

DRAFT

Testing Procedure

The baseline measurements for the test are performed at installation of the dose calibrator and at each replacement of the source. The reference values for the daily test are calculated by correcting the baseline measurement for the decay of the source over time.

Perform background check.

- Place the test source into the chamber of the dose calibrator and select the proper isotope channel on the dose calibrator.
- Measure the source and record the reading.
- Leave the source in the chamber and select the channels of commonly used isotopes.
- Record the readings.

Evaluation

The measured source reading is compared to a reference value for that channel.

- The percent deviation of the measured activity to the reference value must be within $\pm 10\%$.

Action Limits and Remediation

If the deviation is greater than $\pm 10\%$, the instrument should be taken out of use and the unit must be serviced.

4. Geometry

Purpose

To verify proper performance and consistent reading of the dose calibrator with different source sizes such as vials and syringes.

Frequency

Testing is to be performed at installation and after major repair.

Required Equipment

Glass vials and syringes in all sizes that are clinically used. Vial of saline.

Testing Procedure

Testing can be performed by two different methods that are described below:

Vial Method

Perform background check.

- Add 2-5 mCi of ^{18}F in one mL to a 10-cc glass vial. Record the reading.
- Add 1 mL of normal saline to the vial. Record the reading.

DRAFT

- Continue to add 1 mL of normal saline and take the reading until 8 mL have been added (8 readings).

Syringe Method – 3 mL syringe

Perform background check.

- Add 1-2 mCi of ^{18}F in 0.5 mL to a 3 mL syringe. Record the reading.
- Add 0.5 mL of normal saline to the syringe. Record the reading.
- Continue to add 0.5 mL of normal saline and take the reading until 3 mL have been added.
- This should be performed in all syringe sizes used routinely in the clinic. Please note, for 1 mL syringes, saline should be added in 0.2 mL increments up to 1 mL. For larger size syringes, saline should be added in 1 mL increments.

Evaluation

Choose one reading as the reference volume activity.

- Calculate the difference in the readings for each volume compared to the reference activity.
- The percent deviation of the measured activity to the reference volume activity must be within $\pm 10\%$.

Action Limits, Remediation

If the deviation is greater than $\pm 10\%$, mathematically corrected dosage reading can be applied, or the unit may be serviced.