Nuclear Medicine/PET Accreditation Program Requirements

Overview

The Nuclear Medicine Accreditation Program involves the acquisition of clinical and phantom images and corresponding data for each unit. The acquisition of the phantom images involves the use of a designated SPECT phantom. Accreditation in nuclear medicine is unit based; all units used by a facility must pass the evaluation in order for a facility to be granted accreditation. Facilities will be able to choose from one or more of three modules for accreditation:

- **Module 1** – General Nuclear Medicine (planar imaging)
- **Module 2** – SPECT (single photon emission computed tomography)
- **Module 3** – Nuclear Cardiology Imaging
- **Module 4** – PET Imaging **(See page 12 for PET requirements)**

The facility must apply for all modules that are performed at the site. In addition, the site must apply for all isotopes used on each unit. Information will be collected on the quality control and quality assurance program in place, follow-up procedures, data collection, reporting, radiopharmaceutical procedures, and laboratory safety. Facilities are required to submit copies of their most recent state or Nuclear Regulatory Commission (NRC) audits. The written response to any violations must be included.

Mandatory Accreditation Time Requirements

Submission of all accreditation materials is subject to mandatory timelines. Detailed information about specific time requirements is located in the *Overview for the Diagnostic Modality Accreditation Program*. Please read and be familiar with these requirements.

Withdrawn, Added, or Replacement Units

The Nuclear Medicine Accreditation Program is unit based. Consequently, facilities ***must notify the ACR*** if they have permanently ***withdrawn*** (i.e., removed) a unit from service, if they have ***replaced*** that unit with a new one or have ***added*** another unit. The type of accreditation options available for a new unit will depend on the amount of ***time the facility has left on its current accreditation certificate:***

- ***Over 13 months*** – The facility needs to submit only unit information and additional testing materials. Once accreditation is approved, the new unit's expiration date will be the same as the previous expiration date.
- ***Less than 13 months*** - The facility must renew accreditation for all units at the facility including the new one. Once approved, all of the units at the facility will have an expiration date that is three years from the old expiration date.

Loaner unit

Accredited facilities may use a "loaner" unit to temporarily replace an accredited unit that is out of service for repairs, etc. for up to six months without submitting clinical and phantom images for evaluation. The accredited facility must immediately notify the ACR of the installation date, manufacturer and model of the loaner. Any loaner unit that is in use for more than one month will be

required to submit evidence of testing by a qualified medical physicist within 90 days of installation. If the loaner is in place for longer than six months, the facility must submit the unit for accreditation evaluation, including clinical and phantom image assessment and the corresponding fee.

Emergency Use of Units

Facilities may use units that are not accredited in specific modules for other types of nuclear medicine imaging in emergency cases without jeopardizing a facility's accreditation status. An emergency situation would be one in which less than 10 examinations are performed outside a unit's accreditation status in any 30 day period, or less than 50 examinations in any 12 month period. If the volume of examinations exceeds these limits, the facility must notify the ACR and submit testing for this module.

Personnel Qualifications

All interpreting physicians, medical physicists and technologists working in nuclear medicine (including part-time and locum tenens staff) *must meet and document* specific requirements in order for their facility to be accredited by the ACR.

The continuing education and continuing experience requirements are based on previous full calendar years. For example, if a site applies for accreditation in July 2009, the physicians at that site must have met the full requirement for continuing education from January 1, 2006 to December 31, 2008. Likewise, they must have met the full continuing experience requirements from January 1, 2007 to December 31, 2008. If they did not meet these requirements in the given timeframes, the ACR will accept continuing education credits or continuing experience obtained in 2009

Physician Qualifications

All physicians who supervise and/or interpret nuclear medicine examinations must be a licensed medical practitioner who meets the following minimum criteria:

<table>
<tr><th colspan="3">Requirements for all Physicians Supervising and/or Interpreting Nuclear Medicine Examinations</th></tr>
<tr><th>Qualifications</th><th>Interpreting Nuclear Medicine Physician</th><th>Non-Nuclear Medicine Physician/Radiologist Interpreting Cardiovascular Nuclear Medicine Only</th></tr>
<tr><td rowspan="3">Initial</td><td>• Board certified in radiology or diagnostic radiology, nuclear radiology, or nuclear medicine by:
o ABR,
o American Board of Nuclear Medicine,
o American Osteopathic Board of Radiology,
o American Osteopathic Board of Nuclear Medicine,
o Royal College of Physicians and Surgeons of Canada, or
o Le College des Medicins du Quebec.
OR
• Physicians trained prior to 1965 may be accepted as qualified if they interpreted at least an average of 50 scintigrams per month for the past 10 years.</td><td>• Board certified in cardiology by:
o American Board of Internal Medicine,
o American Osteopathic Board of Internal Medicine,
o Royal College of Physicians and Surgeons of Canada, or
o Le College des Medicins du Quebec, and
• Completion of the Level 2 Core Cardiology Training Symposium (COCATS) training program in nuclear cardiology (see Attachment I).
OR
• Cardiologists who trained prior to July 1995 must be board certified in cardiology and have the equivalent of Level 2 training.</td></tr>
<tr><td colspan="2">OR</td></tr>
<tr><td colspan="2">At a minimum, completion of a formal Accreditation Council of Graduate Medical Education (ACGME)-approved general nuclear medicine program which must include 200 hours in radiation physics and 500 hours of preparation in instrumentation, radiochemistry, radiopharmacology, radiation dosimetry, radiation biology, radiation safety and protection, and quality control. In addition, 1,000 hours of clinical training in general nuclear medicine is required which must cover technical performance, calculation of dosages, evaluation of images, correlation with other diagnostic modalities, and interpretation.</td></tr>
<tr><td>Continuing Experience</td><td colspan="2">Physicians reading nuclear medicine examinations must have read an average of 9 exams per month over the prior 24-month period.</td></tr>
<tr><td>Continuing Education</td><td colspan="2">Physicians must have earned at least 15 CME in nuclear medicine (half of which must be category 1) over the prior 36-month period. For non-nuclear medicine physicians interpreting cardiovascular nuclear medicine only, the 15 hours of CME should be in cardiovascular nuclear medicine.</td></tr>
</table>

In addition, all physicians supervising and/or interpreting nuclear medicine examinations must satisfy all applicable state and federal regulations that pertain to the *in vivo* use of radiopharmaceuticals and performance of imaging procedures.

Facilities monitoring cardiac stress studies must have one individual that has current Advanced Cardiac Life Support (ACLS) certification present during the stress testing.

In addition to being in compliance with the interpreting physician qualifications stated above, the supervising physician also has the following responsibilities:

- Develop, implement and enforce policies and procedures related to radiation protection, the hazards of radiation exposure to both patients and radiological personnel, and appropriate monitoring requirements.
- Develop, implement and enforce policies and procedures to address safety issues, including sedation, and reduce exposure as much as reasonably possible for pediatric patients.
- Develop, implement and enforce policies and procedures to identify pregnant or potentially pregnant patients.
- Develop, implement and enforce policies and procedures consistent with ACR's Position Statement on Quality Control and Improvement, Safety, Infection Control, and Patient Concerns.
- Be responsible for reviewing (along with the radiation safety officer and medical physicist) the laboratory safety manual at least annually.
- Be responsible for assuring compliance with the recommendations of the medical physicist.
- Be responsible for the oversight and submission of all materials, including clinical and phantom images, as appropriate, quality control data and such other information as required by the Nuclear Medicine Accreditation Program.
- Be responsible for notifying the ACR within 15 days of any changes in imaging equipment (units) or changes in the use of equipment that could affect clinical or phantom images (i.e., in CT an adults-only approved scanner being used to scan pediatric patients).
- Ensure that all accreditation criteria are met and that the same standard of performance is maintained during the 3-year accreditation period.
- Provide immediate written notice to the ACR upon the termination of any accredited services provided by the Practice Site or a change in ownership of the operating location.
- Ensure that all physicians providing services at this facility are actively participating in a formal peer review program that meets the stated accreditation requirements.

Nuclear Medicine Technologist

All technologists performing nuclear medicine examinations ***must*** meet the minimum criteria in the table below. The ACR ***recommends*** that technologists be certified and actively registered in the modality they perform.

Qualifications	Nuclear Medicine Technologist
Initial	• ARRT(N) or NMTCB registered or equivalent state license for nuclear medicine technology OR • Completion of a training program in nuclear medicine that must include training in the basic and medical sciences as they apply to nuclear medicine technology and practical experience in performing nuclear medicine procedures.
Continuing Education	• Registered technologists - In compliance with the CE requirements of their certifying organization for the imaging modality in which they perform services - CE includes credits pertinent to the technologist's ACR accredited clinical practice • State licensed technologists - 24 hours of CE every 2 years - CE is relevant to imaging and the radiologic sciences, patient care - CE includes credits pertinent to the technologist's ACR accredited clinical practice • All others - 24 hours of CE every 2 years - CE is relevant to imaging and the radiologic sciences, patient care - CE includes credits pertinent to the technologist's ACR accredited clinical practice

In addition, ***nuclear medicine technologists*** must:

- Satisfy all applicable state and federal regulations that pertain to the *in vivo* use of radiopharmaceuticals and performance of imaging procedures.
- Have knowledge of radiation safety and protection, handling of radiopharmaceuticals, all aspects of performing examinations, operation of equipment, handling of medical and radioactive waste, patient safety, and applicable rules and regulations.

Nuclear Medicine Medical Physicist

The qualified medical physicist is responsible for the conduct of all surveys of the nuclear medicine equipment. The medical physicist may be assisted by properly trained individuals in obtaining data. These individuals must be approved by the medical physicist in the techniques of performing tests, the function and limitations of the imaging equipment and test instruments, the reasons for the tests, and the importance of the test results. The medical physicist must be present or in general supervision of properly trained assistants (and accessible by phone) during the surveys; review, interpret, and approve all data; and provide a report of the conclusions with his/her signature. Effective ***January 1, 2010***, all medical physicists providing these services must meet the following minimum criteria:

Qualifications	Medical Physicist
Initial	**Board Certified** Certified in Medical Nuclear Physics or Radiological Physics by the American Board of Radiology; in Nuclear Medicine Physics by the American Board of Medical Physics; in Nuclear Medicine Physics by the Canadian College of Physicists in Medicine; or in Nuclear Medicine Physics and Instrumentation by the American Board of Science in Nuclear Medicine **OR** **Not Board Certified in Required Subspecialty** • Graduate degree in medical physics, radiologic physics, physics, or other relevant physical science or engineering discipline from an accredited institution, ***and*** • Formal coursework in the biological sciences with at least - 1 course in biology or radiation biology, and - 1 course in anatomy, physiology, or similar topics related to the practice of medical physics • 3 years of documented experience in a clinical nuclear medicine environment **OR** **Grandfathered** Conducted surveys of at least 3 NM units between January 1, 2007 and January 1, 2010
Continuing Experience	2 NM camera surveys in prior 24 months
Continuing Education	15 CEU/CME (1/2 Cat 1) in prior 36 months (must include credits pertinent to the accredited modality)

Quality Control

Acceptance Tests and Performance Tests

Acceptance tests must be performed on systems when they are installed. At least annually thereafter, the performance tests listed below must be performed on all units. These tests do not need to be as rigorous as acceptance tests but must be a comprehensive suite of individual measurements that ensure adequate sensitivity for detecting detrimental changes in performance. A qualified practicing medical physicist may perform these tests. Alternatively, the tests may be performed by a qualified nuclear medicine technologist or medical physicist in training using National Electrical Manufacturers Association (NEMA) protocols and other testing protocols developed and approved by the qualified practicing medical physicist. The test results must be reviewed by the qualified medical physicist and documented in the annual survey report. As a part of this annual survey the qualified practicing medical physicist should meet with the supervising physician and the QC technologist to review the results of the survey and the effectiveness of the technologist QC program, and to recommend any corrective action or repairs that are needed. The supervising physician is responsible for assuring compliance with the recommendations of the medical physicist.

Nuclear Medicine Performance Tests – At Least Annually

1. **Intrinsic Uniformity** - Performed to ensure that the intrinsic detector integral and differential uniformity are sufficient to minimize the production of artifacts and ensure that patient abnormalities can be visualized without interference from the imaging system. These tests also monitor a scintillation unit for electronic problems and crystal deterioration (hydration).

2. **System Uniformity** - Performed to check all commonly used collimators for defects that might produce artifacts in planar and tomographic studies.

3. **Intrinsic or System Spatial Resolution** - Performed to ensure that the detector resolution is sufficient to provide satisfactory detection of lesions and delineate detail in clinical images.

4. **Sensitivity** - Performed to verify that count rate per unit activity is satisfactory to maintain image quality and preserve the integrity of quantitative studies.

5. **Energy Resolution** - Performed to verify that scatter rejection is sufficient to provide optimal contrast in clinical studies. *Note: On some systems, energy resolution is very difficult to measure precisely.*

6. **Count Rate Parameters** - Performed to ensure that the time to process an event is sufficient to maintain spatial resolution and uniformity in clinical images acquired at high count rates.

7. **Formatter/Video Display** - Performed to ensure that systems used to produce hard copy and monitors that are used for interpretation of clinical studies provide satisfactory image quality in terms of uniformity and spatial resolution.

8. **Overall System Performance for SPECT Systems** - Performed to quantitatively verify that SPECT systems provide satisfactory tomographic uniformity, contrast, and spatial resolution.

9. **System Interlocks** - Performed to verify that all system interlocks are operating as designed and that the system is safe and reliable for the nuclear medicine technologist to operate and for imaging patients.

10. **Dose Calibrators** - Performed annually to verify that readings from this instrument are accurate (accuracy test). All basic measurements of performance must be done at the time of installation and repeated after major repair. This test must be done according to protocols accepted by the appropriate state regulatory agencies or the NRC.

    - "Test" measurement of battery voltage (if applicable)
    - Zero adjustment (if applicable)
    - Background adjustment
    - Accuracy with NIST traceable standard
    - Linearity
    - Geometry
    - Constancy test

11. **Thyroid Uptake and Counting Systems** - Performed to verify energy calibration, energy linearity, energy resolution, sensitivity, and reliability (Chi-squared test) for the measurement of organ function and the assay of patient samples.

    - I-123 capsule or long-lived standard calibration check
    - Count of background
    - High voltage/gain checks
    - Energy resolution
    - Chi-square test

The nuclear medicine technologist is responsible for verifying day-to-day operation of instruments and performing a few additional tests on a quarterly basis. These requirements represent the standard of practice and are in compliance with requirements and recommendations of the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) and state and federal agencies.

Documentation of compliance with all quality control tests and corrective action is required as part of the application process.

Nuclear Medicine Technologist's Quality Control Tests

1. **Intrinsic or System Uniformity** (each day of use) - Performed to verify that components are properly functioning and provide a uniform image in response to a uniform flux of radiation.

2. **Intrinsic or System Spatial Resolution** (weekly) - Performed to quantitatively verify that detector spatial resolution is satisfactory for clinical imaging.

3. **Center-of-Rotation or Multiple Detector Registration Calibration/Test for SPECT Systems** (monthly) - Performed to maintain ability to resolve details in clinical SPECT studies.

4. **High-Count Floods For Uniformity Correction for SPECT Systems** (frequency as recommended by a qualified medical physicist) - Performed to correct for residual detector and collimator non-uniformity and to minimize the production of artifacts in clinical studies.

5. **Overall System Performance for SPECT Systems** (semiannually, quarterly recommended) - Performed to qualitatively verify that the system has maintained its capabilities with respect to tomographic uniformity, contrast, and spatial resolution that maximize the benefit in clinical studies. Technetium must be done at least semiannually; other radionuclides may be tested on alternate quarters.

6. **Dose Calibrators** (daily, quarterly, and semiannual)
   - Daily - Tests are performed to verify that the calibrator is accurate and reliable for the assay of doses administered to patients.
   - Quarterly - A linearity test must be performed to document that accurate readings are provided through the entire range of activities used clinically. Other qualified personnel may do these tests.
   - Semiannual - All non-exempt radionuclide sources must be tested to verify that radioactivity is not leaking from the sources. Other qualified personnel may also do these tests.

7. **Thyroid Uptake and Counting Systems** (each day of use) - Standards are measured to verify energy calibration and sensitivity for the measurement of organ function and the assay of patient samples.

SPECT Phantom

Planar and SPECT (if appropriate) images must be obtained and submitted for review using the phantom that has been approved by the ACR Committee on Nuclear Medicine Accreditation. ***NOTE: Some unit manufacturers provide this phantom with the purchase of nuclear medicine units. If you currently have a phantom that meets the specifications outlined below (with or without flange), we recommend that you contact the manufacturer to make sure all joints, O-rings, and seals are still intact. If the phantom has not been drained and allowed to dry before storage it may have deteriorated.***

The ACR-approved SPECT phantom is commonly used for quality control in nuclear medicine. For cameras that are used to perform **planar and SPECT imaging** studies, an ACR-approved phantom must be used for evaluating planar and tomographic image quality. The **ACR approved phantom** is a cylinder with an internal radius of 10.8 cm. The lower portion of the cylinder contains 6 sets of acrylic

rods arranged in a pie shaped pattern with the following diameters: 4.8, 6.4, 7.9, 9.5, 11.1, and 12.7 mm. The upper section contains six solid spheres with the following diameters: 9.5, 12.7, 15.9, 19.1, 25.4, and 31.8 mm. The spheres must be placed in order of increasing size and the rod and sphere diameters must be listed in the appropriate place on the worksheets. The reviewers will use this information to properly score the images.

Note: Effective July 1, 2010, the Standard inserts will no longer be accepted.

Data must be collected and processed according to the instructions provided in the testing package. The procedures may differ from those normally used by the applicant but were designed to minimize the variability in the images submitted by different facilities. Despite the use of a specific protocol, it is understood that there may still be some differences even if the data were collected on the same type and model scintillation unit.

The following are available directly from Data Spectrum of Chapel Hill, NC:

1. The Jaszczak Deluxe Flangeless ECT phantom and the PET faceplate (can be used for both SPECT and PET acquisitions) for $2536.
2. The Jaszczak Deluxe Flangeless ECT phantom (for SPECT only) for $1521.
3. Flangeless PET phantom (for PET only) for $2028.
4. The PET faceplate made to fit an existing flangeless or flanged Jaszczak Deluxe ECT phantom for $1071.

The above are available following the submission of the initial application to the ACR. **You may contact Data Spectrum at (919) 732-6800. You may also consider contacting your unit manufacturer or other vendor to see if it will provide the ACR-approved phantom.**

Quality Assurance

Policies and procedures related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control and Patient Education Concerns. The site will have a quality assurance program that incorporates the following two elements:

Physician Peer-Review Requirements

Examinations should be systematically reviewed and evaluated as part of the overall quality improvement program at the facility. Monitoring should include evaluation of the accuracy of interpretation as well as the appropriateness of the examination. Complications and adverse events or activities that may have the potential for sentinel events must be monitored, analyzed and reported as required, and periodically reviewed in order to identify opportunities to improve patient care. These data should be collected in a manner that complies with statutory and regulatory peer-review procedures in order to ensure the confidentiality of the peer-review process.[1]

All sites initially applying for ACR accreditation and all sites renewing their accreditation must actively participate in a physician peer review program that performs the following functions:

[1] 2005 ACR Guidelines and Technical Standards. ACR Position Statement on Quality Control and Improvement, Safety, Infection Control, and Patient Education Concerns. Page IV.

- Includes a double reading (2 MDs interpreting the same study) assessment.
- Allows for random selection of studies to be reviewed on a regularly scheduled basis.
- Exams and procedures representative of the actual clinical practice of each physician.
- Reviewer assessment of the agreement of the original report with subsequent review (or with surgical or pathological findings).
- A classification of peer review findings with regard to level of quality concerns (One example is a 4-point scoring scale).
- Policies and procedures for action to be taken on significant discrepant peer review findings for the purpose of achieving quality outcomes improvement.
- Summary statistics and comparisons generated for each physician by imaging modality.
- Summary data for each facility/practice by modality.

There are several options available to meet this requirement. Sites may develop their own peer review program, use a vendor product or RADPEER, a peer review process developed by the ACR. For information about RADPEER or eRADPEER please visit the ACR web site at: http://www.acr.org/SecondaryMainMenuCategories/quality_safety/radpeer.aspx.

Appropriateness/Outcome Analysis

The results of an appropriateness/outcomes analysis and the actions taken to correct any deficiencies should be maintained as quality assurance records at the facility. Policy and procedures should be in place to look at the diagnostic accuracy and outcome of nuclear medicine examinations. Documentation may be requested as part of an on-site survey.

Accreditation Testing

If appropriate, planar and/or SPECT phantom images must be obtained and submitted for review using the phantom that has been approved by the ACR Committee on Nuclear Medicine Accreditation. Please see the section on quality control above for further information.

Clinical Images

Clinical images are evaluated for each unit within each module. The facility must submit two different examination types for each module/sub module (see table below).

Required Nuclear Medicine Exams for Module 1, Module 2, and Module 3		
Module 1 - Planar	**Module 2 – SPECT**	**Module 3 - Nuclear Cardiology**
• Whole body or spot bone (required). If unit does not perform bone scans, two exams must be selected from the list below. **(*If MUGA performed on unit and site not applying for Nuclear Cardiology module, you MUST select MUGA as one of the exams.)*** **Plus one of the following:** • Whole body bone • Spot bone • Hepatobiliary • Perfusion lung • MUGA • Thyroid • I131 Whole Body • I131 Spot • Gallium Whole Body • Gallium Spot • Octreotide Whole Body • Octreotide Spot	• Bone SPECT (required) If unit does not perform bone scans, two exams must be selected from the list below. *Only one myocardial perfusion scan may be selected, and if selected, site must also apply for the Nuclear Cardiology module. **Plus one of the following:** • Bone SPECT • Brain SPECT • Hepatic blood pool • Liver SPECT • Myocardial perfusion • Gallium SPECT • Octreotide SPECT	• Myocardial perfusion (required) **Plus one of the following:** • Myocardial Perfusion • MUGA

The examinations submitted should be consistent with the ACR Guidelines and Technical Standards. A corresponding, dated physician report that clearly states the type of exam performed and the clinical history must accompany all exams. The parameters that will be scored on the clinical images include: radiopharmaceutical biodistribution, image acquisition, processing, and display, as well as film and report identification. ***Sites may not submit images performed on models or volunteers.*** Patient films will be returned with the final report.

As with all of the ACR accreditation programs, the primary assumption of the clinical image reviewers is that the images chosen by the facility represent examples of their best work. It is strongly recommended that the images submitted be normal studies.

Exam Identification and Labeling

All films are an important part of the medical record. The following should be permanently recorded on each image of the study: patient name, patient age (or date of birth), patient identification number,

date of exam, and institution name. The technologist's name, initials, or other means of identifying the technologist who performed the study should also be indicated.

The Nuclear Medicine Accreditation Committee has determined that ALL images for ALL submitted studies must be labeled for laterality and orientation. This requirement is necessary to reduce the number of serious treatment errors resulting from the lack of appropriate labeling and to address quality patient care issues raised by the recent focus on patient safety in medicine. *THIS IS A PASS/FAIL CRITERION.*

Clinical Protocols

The typical scanning protocols for the submitted clinical images will be required for accreditation; the images should reflect use of those protocols. The facility should submit its protocols in the format that it normally uses on site, but they need to be readily understandable by a reviewer charged with correlating those protocols with the submitted images.

Nuclear Medicine Accreditation Fees

Checks should be made payable to the American College of Radiology (include modality accreditation ID#, if available). American Express, MasterCard, and Visa are accepted.

Accreditation Fees	
Cycle	**Fees**
Accreditation (Initial cycle and renewal)	$1200 facility fee Plus per unit (module 1, 2, or 3): One module $600 Two modules $1200 Three modules $1800
Repeat	$600 per module, if repeating clinical exams $600 if repeating phantoms
Reinstate/Corrective Action Plan	$600 for each module
Add Units (mid cycle)	Per unit (module 1, 2, or 3): One module $600 Two modules $1200 Three modules $1800
Add New Modules (mid cycle)	$600 per module
Replacement Certificate	$50 per certificate
Phantom	$2536 ECT phantom and the PET faceplate (can be used for both SPECT and PET acquisitions) $1521 ECT phantom (for SPECT only) $ 2028 PET phantom (for PET only) $ 1017 PET faceplate made to fit an existing flangeless or flanged ECT phantom

Note: Fees subject to change without notice.

For Additional Information

For further information log on to the ACR Web site at www.acr.org, click on "Accreditation" and click on "Nuclear Medicine and PET". A link to "Frequently Asked Questions" is available in the Nuclear Medicine and PET menu, along with other useful information about accreditation and many of the program's forms. To contact the ACR Nuclear Medicine Accreditation Program office by phone, dial (800) 770-0145.

ACR Practice Guidelines and Technical Standards

The following ACR Practice Guidelines and Technical Standards are pertinent to achieving and maintaining Nuclear Medicine Accreditation. These guidelines and standards form the basis of the accreditation program.

ACR Practice Guideline for Imaging Pregnant or Potentially Pregnant Adolescents and Women with Ionizing Radiation

ACR Practice Guideline for the Performance of Single Photon Emission CT (SPECT) Brain Perfusion and Brain Death Studies

ACR Practice Guideline for the Performance of Adult and Pediatric Skeletal Scintigraphy (Bone Scan)

ACR Practice Guideline for the Performance of Cardiac Scintigraphy

ACR Practice Guideline for the Performance of Pulmonary Scintigraphy

ACR Practice Guideline for the Performance of Adult and Pediatric Hepatobiliary Scintigraphy

ACR Practice Guideline for the Performance of Liver/Spleen Scintigraphy

ACR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals

ACR Technical Standard for Medical Nuclear Physics Performance Monitoring of Nuclear Medicine Imaging Equipment

ACR Technical Standard for Medical Physics Performance Monitoring of SPECT CT Imaging Equipment

ACR Practice Guideline for Communication of Diagnostic Imaging Findings

PET Module
Program Requirements

Overview

The ACR Positron Emission Tomography (PET) Accreditation program was developed and is directed by the Committee on Nuclear Medicine Accreditation of the Commission on Quality and Safety. The PET Accreditation Program involves the acquisition of clinical and phantom images and corresponding data for each unit. The acquisition of the phantom images involves the use of a designated PET phantom. Accreditation in PET is unit based; all units used by a facility must pass the evaluation in order for a facility to be granted accreditation. Facilities will be able to choose from one or more of three modules for accreditation:

- **Module 1** - Oncology
- **Module 2** - Brain
- **Module 3** - Cardiac

The facility must apply for all modules that are performed at the site. Information will be collected on the quality control and quality assurance program in place, follow-up procedures, data collection, reporting, radiopharmaceutical procedures, and laboratory safety. Facilities are required to submit copies of their most recent state or Nuclear Regulatory Commission (NRC) audits. The written response to any violations must be included.

Mandatory Accreditation Time Requirements

Submission of all accreditation materials is subject to mandatory timelines. Detailed information about specific time requirements is located in the *Overview for the Diagnostic Modality Accreditation Program*. Please read and be familiar with these requirements.

Withdrawn, Added, or Replacement Units

The PET Accreditation Program is unit based. Consequently, facilities ***must notify the ACR*** if they have permanently ***withdrawn*** (i.e., removed) a unit from service, if they have ***replaced*** that unit with a new one or have ***added*** another unit. The type of accreditation options available for a new unit will depend on the amount of ***time the facility has left on its current accreditation certificate:***

- ***Over 13 months*** – The facility needs to submit only unit information and additional testing materials. Once accreditation is approved, the new unit's expiration date will be the same as the previous expiration date.
- ***Less than 13 months*** - The facility must renew accreditation for all units at the facility including the new one. Once approved, all of the units at the facility will have an expiration date that is three years from the old expiration date.

Personnel Qualifications

All interpreting physicians, medical physicists and technologists working in PET (including part-time and locum tenens staff) *must meet and document* specific requirements in order for their facility to be accredited by the ACR.

The continuing education and continuing experience requirements are based on previous full calendar years. For example, if a site applies for accreditation in July 2009, the physicians at that site must have met the full requirement for continuing education from January 1, 2006 to December 31, 2008. Likewise, they must have met the full continuing experience requirements from January 1, 2007 to December 31, 2008. If they did not meet these requirements in the given timeframes, the ACR will accept continuing education credits or continuing experience obtained in 2009.

Physician Qualifications

All physicians who supervise and/or interpret PET examinations must be a licensed medical practitioner who meets the following minimum criteria:

<table>
<tr><th colspan="3">Requirements for all Physicians Supervising and/or Interpreting PET Examinations</th></tr>
<tr><th>Qualifications</th><th>PET Physician</th><th>Non-Nuclear Medicine Physician/Radiologist Interpreting Cardiovascular PET Only</th></tr>
<tr><td rowspan="5">Initial</td><td>• Board certified in radiology or diagnostic radiology, nuclear radiology, or nuclear medicine by:
o ABR,
o American Board of Nuclear Medicine,
o American Osteopathic Board of Radiology,
o American Osteopathic Board of Nuclear Medicine,
o Royal College of Physicians and Surgeons of Canada, or
o Le College des Medicins du Quebec.
OR
• Physicians trained prior to 1965 may be accepted as qualified if they interpreted at least an average of 50 scintigrams per month for the past 10 years.</td><td>• Board certified in cardiology by:
o American Board of Internal Medicine,
o Royal College of Physicians and Surgeons of Canada, or
o Le College des Medicins du Quebec, and
• Completion of the Level 2 Core Cardiology Training Symposium (COCATS) training program in nuclear cardiology (see Attachment I).
OR
• Cardiologists who trained prior to July 1995 must be board certified in cardiology and have the equivalent of Level 2 training.</td></tr>
<tr><td colspan="2">OR</td></tr>
<tr><td colspan="2">At a minimum, completion of a formal Accreditation Council of Graduate Medical Education (ACGME)-approved general nuclear medicine program which must include 200 hours in radiation physics and 500 hours of preparation in instrumentation, radiochemistry, radiopharmacology, radiation dosimetry, radiation biology, radiation safety and protection, and quality control. In addition, 1,000 hours of clinical training in general nuclear medicine is required which must cover technical performance, calculation of dosages, evaluation of images, correlation with other diagnostic modalities, and interpretation.</td></tr>
<tr><td colspan="2">AND</td></tr>
<tr><td>• Twenty hours of CME in PET.
• In the past three years the following numbers must be met. If interpreting:
1. Cardiac PET exams, at least 20 studies must be interpreted or multi-read.
2. Brain PET exams, at least 30 studies must be interpreted or multi-read.
3. Oncologic PET exams, at least 80 studies must be interpreted or multi-read.
• If interpreting brain and oncologic PET exams, interpretation must include direct image correlation with CT or MRI. Teaching cases are acceptable with documented interpretation.</td><td>• Twenty hours of CME in PET.
• In the past three years, at least 20 cardiac PET exams must be interpreted or multi-read.</td></tr>
<tr><td>Continuing Experience</td><td colspan="2">Physicians reading PET examinations must have read an average of 9 exams per month over the prior 24-month period.</td></tr>
<tr><td>Continuing Education</td><td colspan="2">Physicians must have earned at least 15 CME in PET (half of which must be category 1) over the prior 36-month period.</td></tr>
</table>

In addition, all physicians supervising and/or interpreting nuclear medicine examinations must satisfy all applicable state and federal regulations that pertain to the *in vivo* use of radiopharmaceuticals and performance of imaging procedures.

Facilities monitoring cardiac stress studies must have one individual that has current Advanced Cardiac Life Support (ACLS) certification present during the stress testing.

In addition to being in compliance with the interpreting physician qualifications stated above, the supervising physician also has the following responsibilities:

- If performing PET/CT, develop, implement and enforce policies and procedures related to radiation protection, the hazards of radiation exposure to both patients and radiological personnel, and appropriate monitoring requirements.
- Develop, implement and enforce policies and procedures to address safety issues, including sedation, and reduce exposure as much as reasonably possible for pediatric patients.
- Develop, implement and enforce policies and procedures to identify pregnant or potentially pregnant patients.
- Develop, implement and enforce policies and procedures consistent with ACR's Position Statement on Quality Control and Improvement, Safety, Infection Control, and Patient Concerns.
- Be responsible for reviewing (along with the radiation safety officer and medical physicist) the laboratory safety manual at least annually.
- Be responsible for assuring compliance with the recommendations of the medical physicist.
- Be responsible for the oversight and submission of all materials, including clinical and phantom images, as appropriate, quality control data and such other information as required by the PET Accreditation Program.
- Be responsible for notifying the ACR within 15 days of any changes in imaging equipment (units) or changes in the use of equipment that could affect clinical or phantom images (i.e., in CT an adults-only approved scanner being used to scan pediatric patients).
- Ensure that all accreditation criteria are met and that the same standard of performance is maintained during the 3-year accreditation period.
- Provide immediate written notice to the ACR upon the termination of any accredited services provided by the Practice Site or a change in ownership of the operating location.
- Ensure that all physicians providing services at this facility are actively participating in a formal peer review program that meets the stated accreditation requirements.

PET Technologist

All technologists performing PET examinations ***must*** meet the minimum criteria in the table below. The ACR ***recommends*** that technologists be certified and actively registered in the modality they perform.

Qualifications	PET Technologist
Initial	• ARRT(N) or NMTCB registered or equivalent state license for nuclear medicine technology OR • Completion of a training program in nuclear medicine that must include training in the basic and medical sciences as they apply to nuclear medicine technology and practical experience in performing nuclear medicine procedures.
Continuing Education	• Registered technologists - In compliance with the CE requirements of their certifying organization for the imaging modality in which they perform services - CE includes credits pertinent to the technologist's ACR accredited clinical practice • State licensed technologists - 24 hours of CE every 2 years - CE is relevant to imaging and the radiologic sciences, patient care - CE includes credits pertinent to the technologist's ACR accredited clinical practice • All others - 24 hours of CE every 2 years - CE is relevant to imaging and the radiologic sciences, patient care - CE includes credits pertinent to the technologist's ACR accredited clinical practice

In addition, PET technologists must:

- Satisfy all applicable state and federal regulations that pertain to the *in vivo* use of radiopharmaceuticals and performance of imaging procedures.
- Have knowledge of radiation safety and protection, handling of radiopharmaceuticals, all aspects of performing examinations, operation of equipment, handling of medical and radioactive waste, patient safety, and applicable rules and regulations.

PET Medical Physicist

The qualified medical physicist is responsible for the conduct of all surveys of the PET equipment. The medical physicist may be assisted by properly trained individuals in obtaining data. These individuals must be approved by the medical physicist in the techniques of performing tests, the function and limitations of the imaging equipment and test instruments, the reasons for the tests, and the importance of the test results. The medical physicist must be present or in general supervision of properly trained assistants (and accessible by phone) during the surveys; review, interpret, and approve all data; and provide a report of the conclusions with his/her signature. Effective ***January 1, 2010***, all medical physicists providing these services must meet the following minimum criteria:

Qualifications	PET Medical Physicist
Initial	**Board Certified** Certified in Medical Nuclear Physics or Radiological Physics by the American Board of Radiology; in Nuclear Medicine Physics by the American Board of Medical Physics; in Nuclear Medicine Physics by the Canadian College of Physicists in Medicine; or in Nuclear Medicine Physics and Instrumentation by the American Board of Science in Nuclear Medicine **OR** **Not Board Certified in Required Subspecialty** • Graduate degree in medical physics, radiologic physics, physics, or other relevant physical science or engineering discipline from an accredited institution, ***and*** • Formal coursework in the biological sciences with at least - 1 course in biology or radiation biology, and - 1 course in anatomy, physiology, or similar topics related to the practice of medical physics • 3 years of documented experience in a clinical PET environment **OR** **Grandfathered** Conducted surveys of at least 3 PET units between January 1, 2007 and January 1, 2010
Continuing Experience	2 PET camera surveys in prior 24 months
Continuing Education	15 CEU/CME (1/2 Cat 1) in prior 36 months (must include credits pertinent to the accredited modality)

Quality Control

PET Performance Tests

It is recommended that the quality control testing be performed in accordance with the ACR Technical Standard for Medical Nuclear Physics Performance Monitoring of PET Imaging Equipment, as applicable. Data will continue to be collected regarding the quality control tests performed by the facility. Based on this data, the ACR Committee on Nuclear Medicine Accreditation may establish QC requirements at the time of renewal. At this time, the ACR strongly recommends quarterly testing of each PET system with an appropriate phantom such as described below in addition to other tests recommended by the vendor. At a minimum, testing with the appropriate phantom must be performed semi-annually.

Acceptance Tests

Initial performance testing of imaging equipment must be performed upon installation and should be completed before clinical use. This testing should be more comprehensive than periodic performance testing and shall be consistent with current acceptance testing practice.

Annual Physics Survey

A physics survey must be performed on each PET unit at least annually. A qualified practicing medical physicist may perform the testing. Alternatively, testing may be performed by a qualified PET technologist or medical physicist in training approved by the qualified practicing medical physicist. The test results must be reviewed by the qualified medical physicist and documented in the annual medical physicist survey report. As a part of the annual survey, the qualified practicing medical

physicist should meet with the supervising physician and the QC technologist to review the results of the survey and the effectiveness of the technologist QC program, and to recommend any corrective action or repairs that are needed. The supervising physician is responsible for assuring compliance with the recommendations of the medical physicist.

This evaluation must include the following:

- **ACR-approved Phantom** - Testing of each PET system with an appropriate phantom as described below
- **Dose Calibrators** - Performed annually to verify that readings from this instrument are accurate (accuracy test). All basic measurements of performance must be done at the time of installation and repeated after major repair. This test must be done according to protocols accepted by the appropriate state regulatory agencies or the NRC.

    - Linearity
    - Accuracy with NIST traceable standard

PET Phantom

PET images must be obtained and submitted for review using the PET phantom that has been approved by the ACR Committee on Nuclear Medicine Accreditation. ***NOTE: The PET phantom uses the base of the Jaszczak Deluxe Flangeless ECT phantom with the spheres removed (as described below) and a PET faceplate.*** The ACR- approved phantom is a cylinder with an internal radius of 10.8 cm. The faceplate has fillable thin-walled cylinders (8, 12, 16, and 25 mm in diameter), two additional 25-mm cylinders, one for air and one for "cold" water, and a Teflon cylinder. The lower portion of the cylinder contains six sets of acrylic rods arranged in a pie-shaped pattern with the following diameters: 4.8, 6.4, 7.9, 9.5, 11.1, and 12.7 mm. In addition, for the SPECT/PET version of the phantom, the upper section contains six solid spheres with the following diameters: 9.5, 12.7, 15.9, 19.1, 25.4, and 31.8 mm. ***The spheres must be removed for PET studies.***

PET data must be collected and processed according to the instructions provided in the testing package. The acquisition and processing must be essentially the same as those used for clinical whole body scans. Despite the use of a specific protocol, it is understood that there may still be some differences even if the data are collected on the same type and model PET unit.

The following are available directly from Data Spectrum of Chapel Hill, NC:

1. The Jaszczak Deluxe Flangeless ECT phantom and the PET faceplate (can be used for both SPECT and PET acquisitions) for $2536.
2. The Jaszczak Deluxe Flangeless ECT phantom (for SPECT only) for $1521.
3. Flangeless PET phantom (for PET only) for $2028.
4. The PET faceplate made to fit an existing flangeless or flanged Jaszczak Deluxe ECT phantom for $1071.

The above are available following the submission of the initial application to the ACR. **You may contact the company at (919) 732-6800. You may also consider contacting your unit manufacturer or other vendor to see if it will provide the ACR-approved phantom.**

PET Technologists Responsibilities

The PET technologist is responsible for verifying day-to-day operation of instruments and performing a few additional tests on a quarterly basis. These requirements represent the standard of practice and are in compliance with requirements and recommendations of the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) and state and federal agencies. Documentation of compliance with all quality control tests and corrective action is required as part of the application process.

Physician Peer-Review Requirements

Examinations should be systematically reviewed and evaluated as part of the overall quality improvement program at the facility. Monitoring should include evaluation of the accuracy of interpretation as well as the appropriateness of the examination. Complications and adverse events or activities that may have the potential for sentinel events must be monitored, analyzed and reported as required, and periodically reviewed in order to identify opportunities to improve patient care. These data should be collected in a manner that complies with statutory and regulatory peer-review procedures in order to ensure the confidentiality of the peer-review process.[2]

All sites initially applying for ACR accreditation and all sites renewing their accreditation must actively participate in a physician peer review program that performs the following functions:

- Includes a double reading (2 MDs interpreting the same study) assessment.
- Allows for random selection of studies to be reviewed on a regularly scheduled basis.
- Exams and procedures representative of the actual clinical practice of each physician.
- Reviewer assessment of the agreement of the original report with subsequent review (or with surgical or pathological findings).
- A classification of peer review findings with regard to level of quality concerns (One example is a 4-point scoring scale).
- Policies and procedures for action to be taken on significant discrepant peer review findings for the purpose of achieving quality outcomes improvement.
- Summary statistics and comparisons generated for each physician by imaging modality.
- Summary data for each facility/practice by modality.

There are several options available to meet this requirement. Sites may develop their own peer review program, use a vendor product or RADPEER, a peer review process developed by the ACR.

For information about RADPEER or eRADPEER please visit the ACR web site at: http://www.acr.org/SecondaryMainMenuCategories/quality_safety/radpeer.aspx.

Accreditation Testing

Phantom images must be obtained and submitted for review using the phantom that has been approved by the ACR Committee on Nuclear Medicine Accreditation. Please see the section on quality control above for further information.

[2] 2005 ACR Guidelines and Technical Standards. ACR Position Statement on Quality Control and Improvement, Safety, Infection Control, and Patient Education Concerns. Page IV.

Clinical Images

Clinical images are evaluated for each unit within each module. The facility must submit two examinations for each module (see table below).

Module 1 - **Oncology** – The site must submit two exams, one of which must be abnormal. The exams can be any combination of the following: a whole body, with and without measured attenuation correction and/or chest and abdomen, with and without measured attenuation correction, if routinely used.

Module 2 - **Brain** – The site must submit two exams, one of which must be abnormal, with attenuation correction.

Module 3 - **Cardiac** – The site must submit two exams, one of which must be abnormal, with and without measured attenuation correction, if available.

Required PET Exams for Sub Modules		
Oncology	**Brain**	**Cardiac**
• Two exams required ,one of which must be abnormal	• Two exams required, one of which must be abnormal	• Two exams required, one of which must be abnormal

The examinations submitted should be consistent with the ACR Guidelines and Technical Standards. A corresponding, dated physician report that clearly states the type of exam performed and the clinical history must accompany all exams. The parameters that will be scored on the clinical images include: radiopharmaceutical biodistribution, image acquisition, processing, and display, as well as film and report identification. ***Sites may not submit images performed on models or volunteers.*** Patient films or CDs will be returned with the final report.

As with all of the ACR accreditation programs, the primary assumption of the clinical image reviewers is that the images chosen by the facility represent examples of their best work.

Exam Identification and Labeling

All films are an important part of the medical record. The following should be permanently recorded on each image of the study: patient name, patient age (or date of birth), patient identification number, date of exam, and institution name. The technologist's name, initials, or other means of identifying the technologist who performed the study should also be indicated.

The Nuclear Medicine Accreditation Committee has determined that ALL images for ALL submitted studies must be labeled for laterality and orientation. **This requirement is necessary to reduce the number of serious treatment errors resulting from the lack of appropriate labeling and to address quality patient care issues raised by the recent focus on patient safety in medicine.** *THIS IS NOW A PASS/FAIL CRITERION.*

Clinical Protocols

The typical scanning protocols for the submitted clinical images will be required for accreditation; the images should reflect use of those protocols. The facility should submit its protocols in the format that it normally uses on site, but they need to be readily understandable by a reviewer charged with correlating those protocols with the submitted images.

PET Module Accreditation Fees

Checks should be made payable to the American College of Radiology (include modality accreditation ID#, if available). American Express, MasterCard, and Visa are accepted.

Accreditation Fees	
Cycle	**Fees**
Accreditation (Initial cycle and renewal)	$1200 facility fee Plus per unit (module 1, 2, or 3): One module $600 Two modules $1200 Three modules $1800
Repeat	$600 per module, if repeating clinical exams $600 if repeating phantom
Reinstate/Corrective Action Plan	$600 for each module or sub module
Add Units (mid cycle)	Per unit (module 1, 2, or 3): One module $600 Two modules $1200 Three modules $1800
Add New Modules (mid cycle)	$600 per module
Replacement Certificate	$50 per certificate
Phantom	$2536 ECT phantom and the PET faceplate (can be used for both SPECT and PET acquisitions) $1521 ECT phantom (for SPECT only) $2028 PET phantom (for PET only) $1017 PET faceplate made to fit an existing flangeless or flanged ECT phantom

Note: Fees subject to change without notice.

For Additional Information

For further information log on to the ACR Web site at www.acr.org, click on "Accreditation" and click on "Nuclear Medicine and PET". A link to "Frequently Asked Questions" is available in the Nuclear Medicine and PET menu, along with other useful information about accreditation and many of the program's forms. To contact the ACR PET Accreditation Program office by phone, dial (800) 770-0145.

ACR Practice Guidelines and Technical Standards

The following ACR Practice Guidelines and Technical Standards are pertinent to achieving and maintaining PET Accreditation. These guidelines and standards form the basis of the accreditation program.

ACR Practice Guideline for Imaging Pregnant or Potentially Pregnant Adolescents and Women with Ionizing Radiation

ACR Practice Guideline for Performing FDG-PET/CT in Oncology

ACR Technical Standard for Medical Nuclear Physics Performance Monitoring of PET Imaging Equipment

ACR Technical Standard for Medical Nuclear Physics Performance Monitoring of PET-CT Imaging Equipment

ACR Practice Guideline for Communication of Diagnostic Imaging Findings

Attachment I

Level 2 Core Cardiology Training Symposium (COCATS) Training Program

Specialized Training - Level 2 (4 to 6 Months)

Fellows who wish to practice the specialty of clinical nuclear cardiology should be required to have at least 4 to 6 months of total training. In training institutions with a high volume of nuclear cardiology procedures, clinical experience may be acquired in a period of time as short as 4 months. In institutions with a lower volume of procedures, a total of 6 months of clinical experience will be necessary for level 2 competency. This additional training should be dedicated to enhancing clinical skills and qualifying for Nuclear Regulatory Commission (NRC) licensure.

Didactic program

Appropriate radiation safety training (currently 200 hours) should be provided to satisfy NRC licensure requirements. The training should provide fellows with a series of lectures and laboratories dealing with basic radiation physics, radiation protection, radiopharmaceutical chemistry, radiation biology and instrumentation according to NRC requirements. This program might be scheduled over a 12 to 24 month period concurrent with other fellowship assignments.

Clinical experience

The fellow should participate in interpretation of all nuclear cardiology imaging data for the 4 to 6 month training period. During the course of the 4 to 6 month training period, it is imperative that the fellow have experience in correlating catheterization/angiographic data with radionuclide-derived data in a minimum of 30 patients. A teaching conference in which the fellow presents the clinical material and scintigraphic results is an appropriate forum for such an experience. Another appropriate source of interpretative experience can consist of an established teaching file. For level 2 training, a total of 300 cases should be interpreted under supervision, either from direct patient studies or from the teaching file, consisting of diverse types of procedures. Minutes or a written logbook should be kept; cases and diagnoses should also be listed to provide documentation.

Hands-on experience

Fellows acquiring level 2 training should have additional hands-on experience with patient studies. Additional intensive experience should be acquired in a minimum of 50 patients; optimally 25 patients for myocardial (perfusion) imaging and 25 patients for radionuclide angiography (total 50 patients). Such supervised experience should include pretest patient evaluation, radiopharmaceutical preparation (including experience with relevant radionuclide generators), performance of the study (rest, exercise dipyridamole or adenosine or other pharmacologic stress), administration of the dosage, calibration and setup of the gamma camera, setup of the imaging computer and processing the data for display after acquisition.

Additional experience

In addition, the training program must provide experience in computer methods for analysis of perfusion imaging studies, including single-photon emission computed tomography (SPECT), and ejection fraction and regional wall motion measurements from radionuclide angiographic studies.

Evaluation

Both the person responsible for the nuclear cardiology training program and the program director should also be responsible for evaluating the competence of the trainee in nuclear cardiology at the completion of the program. This can be accomplished by observing the performance of the fellow during the daily reading sessions or by a formal testing procedure, or both.