NCQDIS
National Coalition for Quality Diagnostic Imaging Services

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October 10, 2006

HAND DELIVERED

The Honorable Mark McClellan, M.D., Ph.D.
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1321-P

Dear Dr. McClellan:

The National Coalition for Quality Diagnostic Services ("NCQDIS") would like to thank you for the opportunity to comment on the Proposed Rule CMS-1321-P, "Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2007 and Other Changes to Payment under Part B" (the "Proposed Rule") published in the *Federal Register* on August 22, 2006.[1] Because we submitted detailed comments on CMS-1512-PN: "Five-Year Review of Work Relative Value Units under the Physician Fee Schedule and Proposed Changes to the Practice Expense (PE) Methodology" (the "Work/PE Proposed Notice"),[2] we will not repeat our recommendations for fine-tuning the proposed changes to the practice expense methodology. We would, however, like to incorporate those recommendations by reference. We hope our earlier suggestions coupled with the comments that follow will facilitate the development of a Physician Fee Schedule Final Rule that will ensure continued access to quality imaging services for the Medicare beneficiaries in 2007 and beyond. As requested, we have keyed our comments to the issue identifiers in the Proposed Rule.

In general, we are deeply concerned that the multiple proposed cuts in reimbursement will threaten access to, and the quality and safety of, imaging services provided to Medicare beneficiaries. IDTFs and other radiology physician offices simply cannot absorb all the proposed reductions in reimbursement. The imaging community is facing drastic reductions in reimbursement due to the cap imposed by Deficit Reduction Act of 2005 (the "DRA"), the multiple procedure reduction, the potential negative update factor, the practice expense methodology changes and the administrative burden of the proposed performance standards on IDTFs. Many IDTFs will find it financially impossible to continue to offer safe and quality imaging services to Medicare beneficiaries at these reduced payment rates. As a result, patients may be required to travel to hospital facilities for imaging service where they are likely to experience longer waiting times and significantly higher co-payments. It is also important to note that these cuts will also affect access to some hospital imaging services. This is especially

[1] 71 *Fed. Reg.* 48980 (Aug. 22, 2006).
[2] 71 *Fed. Reg.* 37168 (June 29, 2006).

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true because the above cuts seriously undermine many hospital-sponsored IDTFs, which have been developed in partnership with radiologists who are on staff at that hospital.

IDTF ISSUES

I. CMS SHOULD WITHDRAW ALL OF ITS PERFORMANCE STANDARDS AND, INSTEAD, WORK WITH THE PROVIDER COMMUNITY OVER THE NEXT YEAR TO DEVELOP MODALITY SPECIFIC STANDARDS FOR CY 2008 PROPOSED PHYSICIAN FEE SCHEDULE

A. CMS did not solicit or obtain any IDTF provider input before proposing the performance standards. Accordingly, the proposed standards are not modality specific and are not based on existing accreditation standards applicable to IDTFs which provide imaging services

We are disappointed that CMS did not solicit or obtain any input from the IDTF imaging provider community prior to the issuance of the proposed IDTF standards. Usually, CMS solicits stakeholder input before issuing regulations that will impose a significant burden on a provider community. In fact, when CMS was considering developing performance standards for DME suppliers, it consulted with DMEPOS suppliers, physicians and home care associations prior to releasing the proposed standards. The IDTF provider community should be provided a similar opportunity to work collaboratively with CMS on performance standards that will have such a substantial effect on their business practices.

Because CMS did not solicit provider input, CMS did not avail itself of the imaging provider community's knowledge and expertise regarding quality and safety measures discussed below. In particular, the proposed standards do not reflect the imaging community's rigorous modality specific standards that are a better measure of quality and safety than the CMS proposed IDTF standards and certainly more understandable both to the provider community and Medicare beneficiaries. Similar to the specific quality standards developed for DMEPOS suppliers[3], we believe that a modality specific approach will enhance the quality and safety of imaging services furnished to Medicare beneficiaries. Such a comprehensive approach will also guard against inappropriate utilization, which will offer CMS savings.

We ask that CMS withdraw its proposed-but-non-specific performance standards and work with the provider community over the next year to create modality specific standards. The imaging standards that are developed should be based on existing accreditation standards and therefore their development will not require an exhaustive effort. The imaging accreditation standards are already acknowledged through peer reviewed literature to be best practice. Moreover, they have become a community standard because of their adoption within the commercial payer community. IDTFs are expected to comply with national modality accreditation standards developed by the American College of Radiology ("ACR"), the American Institute of Ultrasound in Medicine, and/or the American Association of Physicists in Medicine ("AAPM"). Attached

[3] CMS developed product specific standards. For example, there are specific standards for respiratory equipment, manual wheelchairs and power mobility equipment. CMS DMEPOS supplier quality standards are available at http://www.cms.hhs.gov/CompetitiveAcqforDMEPOS/04_New_Quality_Standards.asp#TopOfPage.

as Appendix I is a summary of ACR's extensive accreditation criteria for certain modalities. We believe that other accrediting bodies will be willing to make their criteria available for CMS to use. Additionally, some IDTFs which provide imaging services also comply with Joint Commission on Accreditation of Healthcare Organizations ("JCAHO") standards. Accreditation standards help ensure that the equipment meets stringent technological, diagnostic and maintenance criteria, technologists have passed a national modality specific exam, measures are implemented to provide for radiation safety, and appropriate supervision and interpretation requirements are satisfied. Furthermore, basing the standards on existing accreditation standards will create one set of consistent standards. This will reduce the administrative burden on IDTF providers, reduce the number of inconsistent and conflicting standards, minimize any confusion about the standards, and improve compliance.

We share CMS's concern about the delivery of quality imaging services to Medicare beneficiaries. We recommend that CMS make the effort to properly allow for the development of IDTF standards tailored to the IDTF imaging community and allow providers to make the necessary operational changes. To that end, NCQDIS is committed to working with CMS to assist in identifying already-existing standards which will better assure consistency of care for Medicare beneficiaries. We would welcome the opportunity to work collaboratively with CMS to develop modality specific standards designed to improve the quality and safety of imaging services provided to Medicare beneficiaries. Again, because so many community standards have already been researched and developed in the private sector and through medical and trade associations, this request is not a major undertaking for CMS.

B. The nature of the erroneous payments identified in the OIG Report (A-03-03-00002) do not appear to support the development of the CMS proposed IDTF standards

The development of the proposed IDTF standards in response to the OIG Report Review of Claims Billed by Independent Diagnostic Testing Facilities for Services Provided to Medicare Beneficiaries During Calendar Year 2001 (A-03-03-00002) (the "OIG Report")[4] is misguided and, therefore, has also become misleading to policymakers and others committed to quality services for Medicare beneficiaries. While the OIG Report reports that Medicare overpaid IDTFs by $164,839 in 2001,[5] it does not identify widespread abuse across the country that would warrant the development of industry wide standards. Rather, the report identifies erroneous payments linked to a small number of beneficiaries and a small number of IDTFs located in California and Florida. The total dollar amount of the overpayment is small—less than $200,000 and average payments were in the range of $100/procedure. None of this suggests that there is widespread abuse in the IDTF provider community, especially among imaging IDTFS. It is

[4] OIG Report No. A-03-03-00002 *Review of Claims Billed by Independent Diagnostic Testing Facilities for Services Provided to Medicare Beneficiaries During Calendar Year 2001* (June 30, 2006) available at http://oig.hhs.gov/oas/reports/region3/30300002.htm.

[5] We object to the estimated overpayment amount of $71.5 million. The report identified alleged abuse that involved a small number of facilities and services. It is unlikely that the same level of fraud exists in the entire universe of IDTF providers and especially with respect to imaging services.

unfair to impose burdensome standards on the entire provider community to correct a very localized incidence of fraud.

Furthermore, it is unknown how many IDTFs providing imaging services were involved. Nor does it appear that the erroneous payments were for imaging services—there is only one reference to "3 ultrasounds" performed on a single Medicare beneficiary. IDTFs that solely provide imaging services are unduly punished by these proposed standards as it does not appear that the overpayments were for imaging services.

Finally, it is unclear how many of the proposed IDTF standards will address the fraud identified in the OIG Report. The OIG Report did not identify that the overpayments were caused by the absence of IDTF standards. Rather, it was noncompliance with existing requirements that led to the overpayments.

C. Imaging IDTFs are already subject to more stringent requirements and are undertaking educational efforts on appropriateness criteria intended to minimize utilization

Higher quality standards already exist for IDTFs. Carriers have developed, and continue to develop, stringent enrollment and quality standards for IDTFs.[6] Compliance is required by both free-standing and mobile IDTFs. NCQDIS questions if CMS considered the practicality of imposing its proposed requirements on mobile imaging centers, many of which provide accessible, convenient services to smaller communities and their hospitals. Even though IDTFs bear more administrative costs because of these requirements, the reimbursement is the same for IDTFs as for physician offices which offer imaging services to their patients through self-referral. IDTFs which provide imaging services must identify the supervising physician on the CMS Form 855B, document the supervising physician's proficiency according to the local carrier policies, and maintain documentation of physician supervision. All IDTF technologists must be duly qualified to perform the diagnostic tests. IDTFs can only perform tests pursuant to written orders from the patient's treating physician and the order must specify a diagnosis. On the other hand, physician offices are not subject to many of these requirements. The following chart provides a comparison of requirements imposed on IDTFs, physician offices and hospitals:

[6] While the carrier policies vary slightly on minor requirements, the policies are consistent in how they approach criteria designed to minimize fraud and abuse.

COMPARISON OF MEDICARE REQUIREMENTS FOR IMAGING PROVIDERS

Medicare Criteria	IDTF	Physician	Hospital
Physician Supervision	REQUIRED	REQUIRED	NOT REQUIRED
Supervising Physician Qualifications Determined by Carrier **(Radiologist, and for many Carriers, Board-Certified)**	REQUIRED	NOT REQUIRED	NOT REQUIRED
Non-Physician Personnel (Technologist) Qualifications	REQUIRED	NOT REQUIRED	NOT REQUIRED
Written Orders	REQUIRED	NOT CLARIFIED	NOT CLARIFIED

In addition, NCQDIS is committed to continuing its education efforts with physicians who refer their patients for imaging to independent IDTF and radiology offices to minimize utilization of imaging services in these settings. Many of NCQDIS' members have volunteered to provide information about their education efforts and appropriateness criteria efforts. Attached as Appendix II is a summary of the educational efforts of one three-radiologist practice in Central Minnesota, serving a primarily rural population. NCQDIS prepared this summary to respond to CMS staff's request for information regarding current educational efforts undertaken by the IDTF community. NCQDIS fervently believes that appropriate utilization is possible – with significant savings to the Medicare program – but only if the treating physicians (whether self-referring or not) are prompted to provide written orders, which include consistent appropriateness criteria, and are required to maintain written reports of the imaging test outcome. Generally speaking, this is common practice within the imaging IDTF community. NCQDIS supports applying this standard to all imaging providers, not just IDTFs.

To summarize, there are a number of compelling reasons why CMS should withdraw its proposed performance standards:

- Many of the proposed standards are not supported by, nor related to, the OIG findings. It is unclear how the proposed standards will address the abuse identified in the OIG Report. This suggests that CMS is rushing to propose performance standards in an attempt to respond to a negative report issued just prior to the publication of the Proposed Rule.

- The proposed standards are not modality specific nor are they based on current modality specific accreditation standards developed to ensure that safe and quality imaging services are provided to patients.

- The proposed standards assume that the IDTFs are fixed facility (non-mobile) providers.

- Many of the proposed standards duplicate current carrier requirements. Carriers have developed extensive policies on physician supervision and already require IDTF providers to update their enrollment information.

- Many of the proposed performance standards are needlessly burdensome, are unlikely to minimize fraud and abuse, will have minimal benefit to the Medicare program and may actually be a detriment to Medicare program.

II. IF CMS CHOOSES TO FINALIZE THE PROPOSED PERFORMANCE STANDARDS FOR 2007, CMS SHOULD REVISE THE FOLLOWING PROPOSED STANDARDS: THE 30 DAYS NOTICE, THE NON-SOLICITATION, THE ON-SITE INSPECTIONS, THE PHYSICIAN SUPERVISION, THE LIABILITY COVERAGE, THE CALIBRATION OF TESTING EQUIPMENT AND THE RECORD STORAGE STANDARDS

If CMS chooses to finalize the proposed performance standards for 2007, NCQDIS recommends that CMS make the following changes:

1. ***30 days notice standard.*** CMS should revise this standard to clearly indicate that IDTFs are only required to report any change of ownership within 30 days and all other changes to the CMS Form 855B should be reported within 90 days. Ninety days is a reasonable time frame for reporting changes in IDTF enrollment information (other than changes of ownership). Furthermore, CMS should clarify that IDTFs are not required to submit an entirely new application in order to report changes in their enrollment application unless required by their carrier. The OIG report identified IDTFs that failed to comply with existing requirements to update their enrollment information. It is unclear how a shorter notice period will have the desired result of minimizing fraud and abuse. On-site visits seem to be a more appropriate way of addressing a small group of IDTF providers' failure to comply with existing reporting requirements.

2. ***Non-solicitation standard.*** CMS should clarify the non-solicitation standard. This standard is vague and may violate the constitutional guarantee of freedom of speech. This proposed standard should be very limited in scope and only implemented after extensive discussions with the IDTF provider community to assure that educational efforts are encouraged, not hampered by regulation.

3. ***Unannounced inspections standard.*** CMS should clarify its intent with on-site inspections as well as clarify that beneficiaries only have access during regular business hours. This standard links unannounced, on-site inspections with maintaining normal business hours for Medicare beneficiaries.

4. ***One supervising physician for every three IDTF facilities standard.*** CMS should refine this standard. The proposed standard inappropriately expands a supervising physician's responsibilities to include oversight of the IDTF's business and administrative functions. This would constitute a significant change in the type of responsibility imposed on supervising physicians. We believe that a supervising physician should only be responsible for oversight of the clinical services provided by an IDTF because the supervision requirements set

forth in 42 C.F.R. § 410.32(b)(3) do not include responsibility for the operation and administration of an IDTF. Moreover, this is another example where more stringent supervision standards are already imposed on IDTFs as discussed in Section I.C. We urge CMS to develop more continuity in its physician standards for all imaging providers so that Medicare beneficiaries are provided with appropriate supervision for their imaging services regardless of the site of service.

5. ***Liability insurance standard.*** While NCQDIS is fully supportive of comprehensive coverage for all imaging providers, CMS should revise the proposed language to accommodate states which have already responded to concerns about adequate coverage for patients. The proposed comprehensive liability insurance policy appears to have been developed in the absence of knowledge about several state patient compensation funds that allow those providers who participate in the fund to have limited individual coverage. Moreover, it is impractical to tie the appropriate level of coverage to patient billings which fluctuate.

6. ***Calibration of testing equipment standard.*** NCQDIS recommends that CMS require that imaging IDTFs maintain their equipment in compliance with national accreditation standards. NCQDIS is highly supportive of consistent and high standards for calibration and maintenance of equipment. As discussed in Section I.A., imaging accreditation standards are already acknowledged through peer reviewed literature, and accepted by commercial payers, to be best practice.

7. ***Record storage standard.*** NCQDIS recommends that CMS clarify that IDTFs are only required to maintain records of the IDTF, not the medical records of any referring physician, and off-site storage of medical records is permitted so long as there is adequate access to the records. Moreover, CMS should define "current medical records." It is unclear whether this includes only the patients receiving services at a given time or whether medical records of past patients remain current for a period of time. Furthermore, CMS should refine these standards recognizing that significant developments in routing and storing of imaging tests have been made, including electronic portals made available to referring physicians. The use of these portals is best practice and they have negated the need for duplicative electronic storage or production of films.

III. ANY FINALIZED PERFORMANCE STANDARDS SHOULD APPLY TO ALL IMAGING PROVIDERS, NOT JUST IDTFS

NCQDIS urges CMS to follow MedPAC's recommendation to CMS that it apply quality standards to all imaging providers to improve the quality of imaging services and discourage the migration of imaging services to physician offices where there is less quality oversight.[7] We believe that Medicare beneficiaries should have access to safe and quality imaging services in all sites of imaging services. NCQDIS supports the use of written orders and existing imaging standards for all imaging providers to ensure that all Medicare beneficiaries receive safe and

[7] Medicare payment to physicians: *Testimony Before the Subcommittee on Health Committee on Ways and Means U.S. House of Representatives* (July 26, 2006) (Statement of Mark E. Miller, PhD, Executive Director, Medicare Payment Advisory Commission).

quality imaging services that represent best practices for the imaging community. The rationale for the proposed performance standards applies to all imaging providers, not just IDTFs. Moreover, application of performance standards to all imaging providers will help control utilization and fraud and abuse in all sites of service. Also, this will minimize any shift of site of service from IDTFs to the physician office to avoid stringent requirements.

NCQDIS urges CMS to be a leader in ensuring that safe and quality imaging services are provided to all Medicare patients in all sites of services. CMS should be diligent in its efforts to establish quality standards because its regulations influence the development of standards beyond the Medicare program. Many states link their regulatory requirements for non-Medicare recipients of health care to, and many commercial payers follow, CMS regulations and guidelines. Accordingly, by imposing consistent quality standards on all imaging providers, CMS is helping ensure that safe and appropriate imaging services are provided not only to Medicare beneficiaries, but all Americans.

DRA PROPOSALS

Section 5102 of the DRA includes two provisions that affect payments for imaging services under the physician fee schedule ("PFS"). DRA § 5102(a) requires CMS to exempt any savings attributable to multiple imaging procedure payment reductions implemented initially in the 2006 Physician Fee Schedule final rule[8] from the budget neutrality provision, effectively pulling those savings out of the pool of money available for physician reimbursement. DRA § 5102(b) limits payment amounts for the technical component of imaging services provided in a physician's office to the technical component rates available to hospital outpatient departments for the same services under the hospital outpatient prospective payment system ("OPPS") (the "OPPS Cap").

We urge CMS to mitigate the magnitude of changes in PET/CT payment rates for 2007 by making revisions to the "Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates Proposed Rule (the "2007 OPPS Proposed Rule") published in the *Federal Register* on August 23, 2006,[9] and to phase in the OPPS Cap in a more responsible fashion. Finally, we urge CMS to rescind the proposed 25% multiple-procedure reductions because it will result in duplicative cuts already achieved by the OPPS Cap.

IV. CMS SHOULD RESCIND THE PROPOSED 25% MULTIPLE-PROCEDURE REDUCTION

A. OPPS Cap achieves the same purpose of the multiple procedure reduction

NCQDIS believes it is inappropriate to apply a multiple procedure reduction to payments for imaging services that are subject to the OPPS Cap. The OPPS Cap achieves the same purpose of the multiple procedure reduction—avoid making payments for resources not utilized. In 2006, CMS implemented a 25% multiple-procedure reduction for the technical component of certain procedures when they were performed on contiguous body parts. The reduction was established because CMS thought it was making duplicate payment for some elements of practice expense

[8] 70 *Fed. Reg.* 70114 (Nov. 21, 2005).
[9] 71 *Fed. Reg.* 49504 (Aug. 23, 2006).

(e.g., staff time, certain supplies) when certain ultrasound, CT, or MRI procedures were performed on contiguous body parts during the same session.

In the Proposed Rule, CMS stated:

> the ACR (American College of Radiology) provided information for 25 code combinations supporting a reduction between 21 and 44 percent. Given the expected interaction between the multiple procedures imaging policy and the further imaging payment reductions mandated by section 5102(b) of the DRA . . . along with the new information we have received from the ACR . . . we believe it would be prudent to maintain the multiple imaging payment reduction at its current 25% level. . . . "[10]

Further, in the OPPS final rule for CY 2006 CMS stated:

> In calculating median costs for outpatient imaging procedures in the radiology families we proposed for discounting, for most hospitals' claims, we used a hospital-specific diagnostic radiology CCR for the conversion of charges to costs. Some hospitals reported costs and charges in nonstandard cost centers for ultrasound, CT, or MRI services, and, in general, those modality-specific CCRs were lower than their CCRs for diagnostic radiology. Those lower CCRs were not inconsistent with hospitals' experiences of particular efficiencies in providing multiple ultrasound, CT, or MRI services in a single setting, without reductions in charges for those multiple procedure sessions. . . . We found that the imaging procedures we identified as eligible for the proposed payment reductions accounted for approximately half of the total OPPS charges attributed by the OPPS to hospitals' diagnostic radiology cost centers. This result suggests that costs and charges related to ultrasound, CT, and MRI services in the 11 proposed families are significant contributors from the OPPS to hospitals' diagnostic radiology cost centers; . . . We have no way of knowing how patterns of costs and charges for those patients contribute to hospitals' diagnostic radiology CCRs, but we have no specific reason to believe that their patterns of services would be very different than those for Medicare beneficiaries in the hospital outpatient setting. Thus, it may be correct that our median costs for imaging services in the 11 families proposed for the reduction policy reflect a reduced median based, in part, on hospitals' provision of multiple scans in one session. . . . [O]ur analyses do not disprove the commenters' contentions that there are efficiencies already reflected in their hospital costs, and therefore, their CCRs and the median costs for the procedures. Further, the results of our initial analyses do support the recommendation that we should defer implementation of the proposed multiple imaging procedure reduction policy to perform additional analyses.[11]

We note that the conditions under which the multiple procedure reduction was created no longer exist. CMS implemented the multiple procedure reduction when payment was based on the PFS and where the first procedure would be paid at 100% of the PFS. That is no longer the case because the OPPS Cap applies to all procedures, not just subsequent procedures.

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[10] 71 *Fed. Reg.* 48996.
[11] 70 *Fed. Reg.* 68708.

The OPPS Cap takes into account the economic efficiencies of performing multiple procedures. OPPS costs are calculated in the aggregate over revenue centers so they already reflect efficiencies achieved from the performance of multiple procedures. Moreover, hospitals also are able to spread the cost of expensive capital equipment such as MRI, PET/CT, and CT scanners over all procedures with costs attributable to the diagnostic radiology revenue center. Hospitals then determine charges for procedures within a cost center based on aggregate costs for that cost center, expected utilization, and other factors. Costs are not determined on a "per procedure" basis. For these reasons, when charges are reduced to costs for hospital procedures where capital equipment accounts for a large portion of the cost, the actual cost will exceed the cost as calculated by CMS.

Costs for procedures performed under the PFS are calculated on a "per procedure" basis using direct cost inputs developed by CMS for clinical labor, supplies, and capital equipment. The cost of expensive capital equipment is not allocated over other procedures within a revenue center. The physician methodology results in a more accurate determination of the cost of a specific procedure. It also reflects the reality that physician offices do not spread costs over a large number of unrelated procedures because most physician offices do not perform a wide variety of procedures.

Given the methodological difference, it is not surprising the specifically reported "costs" of an imaging procedure (e.g., a CT, PET or MRI scan) as calculated using the PFS methodology are larger than the "cost" of the same procedure as calculated using the OPPS methodology.

B. Greater cost savings are achieved from the OPPS Cap

The OPPS Cap results in large reductions in payment to all CT and MRI procedures performed on contiguous body parts, not just the second or third procedure. It is unnecessary to continue the multiple procedure reduction in CY 2007 because the payment reductions mandated by the DRA in most cases exceed the reductions under the multiple procedure reduction. Not only does making payment at the OPPS rate take the efficiencies of performing similar procedures on contiguous body parts into account, the table below shows that the payment reduction is actually greater in a number of actual scenarios. We would also note that the OPPS Cap applies to single procedures as well as multiple procedures. This means that Medicare is paying less for almost all CT and MRI scans that it would if it were using its more accurate per procedure cost data under the PFS.

Cost Savings Comparison

CPT	Description	Proposed CY 2007 PFS Payment*	Proposed CY 2007 PFS Payment with 25% Reduction Only	Percentage Decrease in CY 2007 Payment if 25% Reduction Only	Proposed CY 2007 Payment applying the OPPS Cap Only without the Multiple Procedure Reduction	Percentage Decrease in CY 2007 Payment if OPPS Cap Only
71250	Ct chest w/o dye	$237.62	$237.62	0%	$194.69	-18%
74150	Ct abdomen w/o dye	$226.25	$169.69	-25%	$194.69	-14%
	TOTAL	**$463.87**	**$407.30**	**-12%**	**$389.38**	**-16%**
71551	Mri chest w/dye	$568.46	$568.46	0%	$385.24	-32%
74182	Mri abdomen w/dye	$563.16	$422.37	-25%	$385.24	-32%
	TOTAL	**$1,131.62**	**$990.83**	**-12%**	**$770.48**	**-32%**
72142	Mri neck spine w/dye	$552.92	$414.69	-25%	$385.24	-30%
72147	Mri chest spine w/dye	$532.46	$399.34	-25%	$385.24	-28%
72149	Mri lumbar spine w/dye	$552.92	$552.92	0%	$385.24	-30%
	TOTAL	**$1,638.31**	**$1,366.96**	**-17%**	**$1,155.72**	**-29%**

*Payment amount is calculated based on the current CY 2006 conversion factor.

Attached as Appendix III is an expanded table showing that the payment reduction due to the OPPS cap is greater than the payment reduction due to the 25% multiple procedure reduction for almost all common scenarios where CT or MRI is performed on contiguous body parts.

It has been well documented by MedPAC and CMS that physicians increase utilization in response to cuts in payment, therefore it is likely that physicians will make up for loss of "per procedure" payment for imaging by increasing volume.[12] To the extent physicians who can generate volume through self-referral may attempt to make up for loss of "per procedure" income due to the OPPS Cap and the 25% multiple procedure reduction, utilization will actually increase, thereby negating any cost savings and exacerbating inappropriate utilization of diagnostic imaging services. Furthermore, should CMS finalize its current proposal to drastically cut imaging services as described, NCQDIS advises that a significant number of IDTFs may convert their ownership and legal structure to allow billing under OPPS which will also negate any projected savings from the OPPS Cap.

[12] *See* Memorandum on Physician Volume & Intensity Response, from Volume-and-Intensity Response Team, Office of the Actuary, HCFA, to Richard S. Foster, Chief Actuary (Aug. 13, 1998), *available at* http://www.cms.hhs.gov/ActuarialStudies/downloads/PhysicianResponse.pdf; *see also* MedPAC Report To The Congress: Impact of Resource-Based Practice Expense Payments for Physician Services, at 13 (Dec. 2004) (discussing volume offsets).

V. CMS SHOULD ASSIGN PET/CTs TO APC 1514 FOR 2007 AND 2008

This recommendation echoes a discussion in our comments on the 2007 OPPS Proposed Rule. We will reiterate it here because the DRA § 5102(b) provision capping payments for the technical component of imaging services in IDTFs and radiology physician offices at the rates paid under OPPS has inextricably linked the two sets of rulemaking for CY 2007. NCQDIS strongly urges CMS to mitigate the magnitude of the DRA-mandated cap on PET/CT payment rates under the PFS by accepting the APC Panel's recommendation to keep PET/CT scans in APC 1514 and keeping PET/CT scans in APC 1514 for a minimum of two years to ensure that the cancer patients will continue to have access to this critical imaging service.

The OPPS Cap on payment for PET/CT scans will have a detrimental impact on beneficiary access to that service. PET/CT is a critically important part of the treatment plan for many cancer patients. The proposed OPPS payment amount of $862.29 represents, in many Carrier jurisdictions, a payment cut of over 50% for many IDTFs and physician offices.[13] The OPPS Cap unduly harms IDTF providers and radiology physician offices that have purchased PET/CT scanners to provide this state-of-the-art technology to cancer patients. These scanners were purchased with the expectation that revenue would remain stable. The useful life of these scanners is seven years and the scanners are depreciated over five years. IDTF and physician practices simply cannot adapt their practices to such an immediate and drastic cut in payment, especially when many still have outstanding financial obligations related to the purchase of the PET/CT scanner. More importantly, a decrease in PET/CT IDTF providers, many of which provide services to smaller hospitals and rural hospitals, will severely and detrimentally affect access to this service for cancer patients, including but certainly not limited to Medicare beneficiaries.

We are concerned that the OPPS rate underestimates the cost of the PET/CT scanner. We note that hospitals allocate the costs of expensive capital equipment over all procedures with costs attributable to a specific revenue center. In the case of PET/CT, the cost of a PET/CT scanner is allocated over all procedures in the diagnostic radiology (or nuclear medicine) revenue center. Under the PFS methodology, the cost of a PET/CT scanner is attributed to only PET/CT scans and more accurately reflects the actual cost of providing a PET/CT scan. The hospital "cost" of providing a PET/CT scan is underestimated because the cost of the scanner is spread out over all radiologic services. In essence, hospital cost reporting results in the cost of non-PET/CT services being overestimated and the cost of PET/CT underestimated.

As discussed at the APC technical advisory panel meeting, there is strong evidence that hospitals have not developed PET/CT specific charges and have just rolled over charges for PET to PET/CT. This significant flaw in the claims data should be addressed in setting the payment rate for PET/CT. In the past CMS has used external data when setting payments for OPPS services (e.g., insertion of defibrillators, cochlear implants) when the claims data are flawed. Therefore. we believe there is precedent for CMS to use its own external data (from the refined direct cost inputs used to establish practice expense RVUs under the PFS) to set payment rates for PET/CT.

[13] PET/CT scans are carrier priced.

If that external data is blended with OPPS claims data the payment rate would be significantly higher than the payment rate in the proposed rule. Such a result lends additional support to placing PET/CT in APC 1514.

CMS should keep PET/CT scans in APC 1514 for a minimum of two years to ensure the cancer patients will continue to have access to this critical imaging service. CMS has mitigated significant decreases in reimbursement by transitioning payment reductions over several years to allow providers to take steps to minimize the effect of reduced reimbursement on their ability to provide care to Medicare beneficiaries. In fact, CMS is doing precisely that with regard to transitioning payments under the new practice expense methodology from 2007 to 2010.

VI. CMS SHOULD REVISE CERTAIN IMAGING APCS

This recommendation echoes a discussion in our comments on 2007 OPPS Proposed Rule. We will reiterate it here because the DRA § 5102(b) provision capping payments for the technical component of imaging services in IDTFs and radiology physician offices at the rates paid under OPPS have inextricably linked the two sets of rulemaking for CY 2007. NCQDIS strongly urges CMS to revise CT, MRI, and MRA APC groupings to create greater internal clinical and resource consistency. Attached as Appendix IV is a listing of the proposed APC imaging groupings. It is critical that the imaging APCs be as refined as possible because the OPPS system is being used as the benchmark to limit reimbursement for imaging services under the PFS. We believe that refinement is appropriate for imaging services to ensure resource similarity of the procedures within imaging APCs and establish a more accurate payment rate for imaging services under PFS. Given the linkage between the OPPS and PFS with regard to payment for imaging services, we believe that CMS should refine the APCs for CT, MRI and MRA in a manner that more accurately reflects resource use than the current APC structure. In other words, because APC relative weights will now determine physician payment, and because physicians can not spread costs over unrelated procedures or make up payment shortfalls for CT and MRI by profits on other services like hospitals do, CMS should make every effort to restructure the CT and MRI APCs to take into account resource differences that are smaller than they have in the past.

REASSIGNMENT AND PHYSICIAN SELF-REFERRAL

VII. CMS SHOULD ADOPT THE PROPOSED CHANGES TO THE PURCHASED DIAGNOSTIC TEST RULES AND APPLY THE ANTI-MARK UP PROVISION TO ALL CONTRACTUAL ARRANGEMENTS

We commend CMS for its efforts to clarify how the purchased diagnostic test and purchased interpretation rules apply in the case of a reassignment made under the contractual arrangement exception set forth at 42 C.F.R § 424.80(d)(3). There has been significant confusion in the imaging community about how the anti-markup provisions of the purchased diagnostic test rule apply when there is a reassignment pursuant to the contractual exception. The proposed changes are an important step to ensuring that providers abide by the anti-markup provisions in the purchased diagnostic rule.

Furthermore, we support the application of the anti-markup provision to situations where a reassignment has occurred pursuant to any contractual arrangement, including the billing of both the professional and technical components. This would be an important step towards avoiding fraud and abuse in all purchased services arrangements.

Lastly, the purchased diagnostic test and purchased interpretation criteria must apply to all imaging providers, not just IDTFs. The intent of the proposed requirements is to curb fraud and abuse and CMS can only achieve this goal if the requirements are imposed on all providers who purchase diagnostic test and interpretation services.

VIII. CMS Should Require Physicians Who Utilize the In-Office Ancillary Service Exception to Comply with the Physician Supervision and Registered Technologist Requirements Imposed on IDTFs

A physician or physician office that owns and operates diagnostic imaging equipment under the in-office ancillary exception has a financial incentive to create demand for imaging services. IDTFs and radiology physician practices, on the other hand, cannot create an independent demand for imaging services and instead must rely on physician orders ("referrals") to provide services to Medicare beneficiaries. As a result of the disparity in financial incentives and the ability to self-refer, the physician or physician office setting is far more likely to over-utilize imaging services than IDTFs and radiology physician practices.

The current regulatory structure pushes the vast majority of Medicare beneficiaries into the physician office setting to receive their imaging services. However, as explained under Section I.C., physicians and physician offices are not subject to the same regulatory standards aimed at ensuring that safe and quality imaging services are provided to Medicare beneficiaries. To rectify this bias toward lower standards for imaging services in the physician office setting, CMS should impose the quality standards currently imposed on IDTFs, and any performance standards should CMS choose to finalize these standards in the 2007 Physician Fee Schedule Final Rule, to imaging services provided in the physician office setting. In particular, NCQDIS strongly believes that the following two IDTF standards that are considered best practice in the imaging community should be required of all imaging providers to ensure appropriate and safe utilization of imaging services: (1) supervising physician qualifications and (2) technologist qualifications.

IX. CMS Should Initiate Regulations or Work Collaboratively with Congress to Develop Legislation to Curb Circumvention Arrangements

A growing number of physician practices are refusing to provide imaging services to Medicare patients at certain sites where they practice in an attempt to circumvent the Stark Law. Some physician practices have developed locations where they serve only Medicare beneficiaries and other locations where they serve patients with commercial insurance or self-pay patients. These physician practices also tend to make new imaging equipment available at the non-Medicare locations because the reimbursement rates are better. The devastating cuts to Medicare reimbursement set out in the Proposed Rule is likely to encourage the development of these arrangements. As a result of these circumvention schemes, Medicare beneficiaries may be

denied access to the most convenient and timely care available and these Medicare beneficiaries are likely to receive less than best practice imaging services.

We urge CMS to initiate regulations, or work collaboratively with Congress to develop legislation, aimed to curb these arrangements. Minnesota has developed legislation targeted at providers who do not accept Medicaid patients. The Minnesota law, Minn. Stat. § 256B.0644, states that health care providers who do not participate in state-subsidized programs shall not accept payment for services provided to state employees, local government employees, or those covered by the Minnesota Comprehensive Health Association, or workers compensation. NCQDIS is willing to assist CMS in understanding what provider group structures are currently developing in the country and why these structures may adversely affect health services for Medicare beneficiaries.

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NCQDIS thanks CMS for the opportunity to submit formal comments on the Proposed Rule. We are deeply concerned by the drastic reduction in reimbursement for imaging services and urge CMS to adopt the recommendations set forth in this comment letter so that Medicare beneficiaries continue to have access to safe and quality imaging services. We look forward to the opportunity to work with CMS on developing modality specific standards for IDTFs.

Sincerely,

Cherrill Farnsworth
President

Liz Quam
Policy Committee Chair

Appendix I

(Select ACR Accreditation Criteria)

CT Accreditation Program Requirements

Overview

The CT Accreditation Program involves the acquisition of clinical and phantom images, dose measurements, and the submission of scanning protocols. Every unit that performs head/neck, chest, or abdomen exams must go through testing for the site to be accredited. A site may apply for head only or body only if the scanner is used only for those body parts. For sites that perform only adult CT scanning, clinical images required for submission will be both basic and specialized examinations in the head/neck, chest, and abdomen regions. For sites that do occasional pediatric scanning in addition to adult work, an additional exam performed on a child will also have to be selected for submission. Sites that perform only pediatric exams will have to submit basic and specialized exams tailored to the pediatric population (see selection list under Clinical Images section for all three scenarios).

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 CT 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.

CT units that receive replacements or upgrades to any of the major subassemblies after accreditation is granted will be treated as new scanners and follow the procedures above. Facilities are only required to report modifications that change the scanner's model number. If the scanner changes from an adult- or pediatric-only scanner to an adult + pediatric scanner, an additional adult or pediatric exam must be submitted. If less than thirteen months are left on the facility's accreditation, it must renew the accreditation of all of its equipment at the same time.

Personnel Qualifications

Starting July 1, 2007, the physician's and the medical physicist's/MR scientist's ongoing qualifications (experience and education) will be required. All sites initially applying for accreditation after July 1, 2007 will be required to meet the full requirements for CME and continuing experience at the time of renewal (as listed below for sites renewing after July 2009). Sites accredited prior to July 2007 will have the option to meet the following phase-in plan:

Phase-In Plan for Continuing Education and Experience		
Sites renewing in:	**Continuing Education Requirement**	**Continuing Experience Requirement**
July 2007	Physicians and medical physicists/MR scientists must have earned at least 5 CME hours in the prior 12-month period. The 5 CME hours must be earned for each modality in which they are renewing (CT, MRI, nuclear medicine, PET and ultrasound).	• Physicians reading CT, MRI, and ultrasound examinations must have read an average of 9 exams per month over the prior 12-month period. • Physicians reading nuclear medicine examinations must have read an average of 15 exams per month over the prior 12-month period. • Physicians reading PET examinations must have read an average of 10 exams per month over the prior 12-month period.
July 2008	Physicians and medical physicists/MR scientists must have earned at least 10 CME hours in the prior 24-month period. The 10 CME hours must be earned for each modality in which they are renewing (CT, MRI, nuclear medicine, PET and ultrasound).	• Physicians reading CT, MRI, and ultrasound examinations must have read an average of 9 exams per month over the prior 24-month period. • Physicians reading nuclear medicine examinations must have read an average of 15 exams per month over the prior 24-month period. • Physicians reading PET examinations must have read an average of 10 exams per month over the prior 24-month period.
July 2009	Physicians and medical physicists/MR scientists must have earned at least 15 CME hours in the prior 36-month period. The 15 CME hours must be earned for each modality in which they are renewing (CT, MRI, nuclear medicine, PET and ultrasound).	• Physicians reading CT, MRI, and ultrasound examinations must have read an average of 9 exams per month over the prior 24-month period. • Physicians reading nuclear medicine examinations must have read an average of 15 exams per month over the prior 24-month period. • Physicians reading PET examinations must have read an average of 10 exams per month over the prior 24-month period.

Physician

A physician supervising and/or interpreting CT examinations will be required to meet the following minimum criteria:

Requirements for Physicians Supervising and Interpreting CT Examinations		
Qualifications	**Radiologists**	**Other Physician**
Initial	• Board certification in radiology or diagnostic radiology by: o ABR, o American Osteopathic Board of Radiology, o Royal College of Physicians and Surgeons of Canada, or o Le College des Medicins du Quebec, and • Supervision and/or performance of, as well as interpretation (and/or review) and reporting of, 300 CT examinations in the past 36 months.[1] OR • Completion of an accredited diagnostic radiology residency, and • Performance of, as well as interpretation and reporting of, 500 CT examinations in the past 36 months.[1]	• Completion of an accredited specialty residency, and • 200 hours of Category I continuing medical education (CME) in the performance as well as interpretation of CT in the subspecialty where CT reading occurs, and • Interpretation and reporting of 500 cases during the past 36 months in a supervised situation.
Continuing Experience	A minimum of 100 examinations per year is recommended in order to maintain the physician's skills. Alternatively, continued competency can be assured through monitoring and evaluation that indicates acceptable technical success, accuracy of interpretation, and appropriateness of evaluation. (recommended)	
Continuing Education	The physician's continuing education should be in accordance with the ACR Practice Guideline for Continuing Education (CME), including CME in CT that is appropriate to the physician's practice needs. (recommended)	

[1] Completion of an accredited radiology residency in the past 24 months will be presumed to be satisfactory experience for the reporting and interpreting requirement.

In addition, all physicians supervising and/or interpreting CT examinations must:

- Have completed an accredited diagnostic radiology residency or 80 hours of documented, relevant classroom instruction including diagnostic radiology and radiation safety physics. Otherwise, physicians must demonstrate training in the principles of radiation protection, the hazards of radiation exposure to both patients and radiological personnel, and appropriate monitoring requirements.
- Be thoroughly acquainted with the many morphologic and pathophysiologic manifestations and artifacts demonstrated on computed tomography. Additionally, supervising physicians should have appropriate knowledge of alternative imaging methods.
- Be knowledgeable of patient preparation, and training in the recognition/treatment of adverse effects of contrast materials[2] for these studies.
- Be responsible for reviewing all indications for the examination; specifying the use, dosage, and rate of administration of contrast agents,[2] specifying the imaging technique, including appropriate windowing and leveling; interpreting images; generating written reports; and maintaining the quality of both the images and interpretations.
- Be familiar with the meaning and importance to the practice of CT of: total radiation dose to the patient, exposure factors, conscious sedation principles that are performed in the practice, and post-processing techniques and image manipulation on work stations.

Radiologic Technologist and Medical Physicist

Requirements for Radiologic Technologist and Medical Physicist		
Qualifications	**Radiological Technologist**	**Medical Physicist**
Initial	• ARRT certified and currently registered and/or unrestricted state license, and • Documented training and experience in CT, and • Documented training and experience in operating CT equipment and radiation physics and protection. • Passing the advanced examination for CT certification is recommended.	• Board certification in diagnostic radiological physics or radiological physics (recommended)
Continuing Education	The technologist must be in compliance with the ARRT requirements for continuing education appropriate to his or her practice needs, which is 24 credits in a 2-year period.	Continuing education for a qualified medical physicist should be in accordance with the ACR Practice Guideline for Continuing Education (CME). (recommended)

In addition, the qualified medical physicist:

- Must be familiar with the principles of imaging physics and of radiation protection; the guidelines of the National Council on Radiation Protection and Measurements; laws and regulations pertaining to the performance of the equipment being tested; the function, clinical

[2] See the ACR Practice Guideline for the Use of Intravascular Contrast Media.

uses, and performance specifications of the imaging equipment; and calibration processes and limitations of the instruments used for performance testing.

- May be assisted by properly trained individuals in obtaining data. These individuals must be approved by the qualified medical physicist in the techniques of performing tests, the function and limitations of the imaging equipment and test instruments, the reason for the tests, and the importance of the test results. The qualified medical physicist is responsible for and must be present during initial and annual surveys and must review, interpret, and approve all data as well as provide a signed report of conclusions. The qualified medical physicist should be available for consultation regarding patient dosimetry issues within a reasonable period of time.

Equipment

CT equipment specifications and performance shall meet state and federal requirements and applicable ACR Practice Guidelines and Technical Standards.

Quality Control

A quality control (QC) program must be established and implemented under the supervision of a qualified medical physicist. Initial performance testing (acceptance testing) is required upon installation.

Annual Medical Physicist Survey

The medical physicist must evaluate the performance of each CT unit at least annually. This evaluation should include, but not be limited to, the following:

- Alignment light accuracy
- Alignment of Table to gantry
- Table/gantry tilt
- Slice localization from scanned projection radiograph (localization image)
- Table incrementation accuracy
- Slice thickness
- Image quality
  1.Hig h-contrast (spatial) resolution
  2.L ow-contrast resolution
  3.Im age uniformity
  4.Noise
  5.Art ifact evaluation
- CT number accuracy and linearity
- Other tests as required by state or local regulations
- Display devices
  1. Video display
  2. Hard-copy display
- Dosimetry
  1. Computed tomography dosimetry index (CTDI)
  2. Patient radiation dose for representative examinations
- Safety evaluation
  2. Visual inspection
  3. Audible/visual signals
  4. Posting requirements
  5. Scattered radiation measurements

Continuous Quality Control

A continuous quality control (QC) program must be established for all CT units with the assistance of a qualified medical physicist. The qualified medical physicist should determine the frequency of each test and who should perform it based on the facility and CT usage. An on-site radiological technologist should be identified to be responsible for conducting routine quality control.

The continuous QC program should include, but not be limited to, the following:

- Image quality
  1. High-contrast (spatial) resolution
  2. Low-contrast resolution
  3. Image uniformity
  4. Noise
  5. Artifact evaluation
- Alignment light accuracy
- Slice thickness
- CT number accuracy
- Display devices

All quality control testing must be carried out in accordance with written procedures and methods. Preventive maintenance must be scheduled, performed, and documented by a qualified service engineer on a regular basis. The results of the QC program must be monitored annually by the qualified medical physicist. If the results of a QC test fall outside the control limits, corrective action should be taken. A qualified medical physicist should be available to assist in prescribing corrective actions for unresolved problems. All deficiencies must be documented and service records maintained by the CT facility.

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 should 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.[3]

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[3] 2005 ACR Guidelines and Technical Standards. ACR Position Statement on Quality Control and Improvement, Safety, Infection Control, and Patient Education Concerns. Page IV.

Starting in April 2007, all sites initially applying for ACR accreditation and all sites renewing their accreditation must have a physician peer-review program in place. At that time, RADPEER™ or an equivalent peer review program will be required for accreditation. While currently this is not pass/fail criteria, there will be a section on the Quality Assurance questionnaire that will ask about your site's current physician peer-review status. You will receive the Quality Assurance questionnaire with your testing materials.

RADPEER™ is a simple process that allows peer review to be performed during the routine interpretation of current images. If, during interpretation of a new examination, there are prior images of the same area of interest, the interpreting radiologist will typically form an opinion of the previous interpretation while interpreting the new study. If the opinion of the previous interpretation is scored, a peer review event has occurred. In RADPEER™, the report of the previous interpretation is scored by the reviewer using a standardized 4-point rating scale.

An acceptable alternative physician peer review program must include:

- A peer review process that includes a double reading (2 MDs interpreting the same study) assessment.
- A peer review process that allows for random selection of studies to be reviewed on a regularly scheduled basis.
- Exams and procedures representative of the work of each physician's specialty.
- Reviewer assessment of the agreement of original report with subsequent review (or with surgical or pathological findings).
- A classification of peer review findings with regard to level of quality concerns (i.e. 4 point scoring scale).
- Policies and procedures for action to be taken on significantly discrepant peer review findings for purpose of achieving quality outcomes improvement.
- Summary statistics and comparisons generated for each physician by modality.
- Summary data for each facility/practice by modality.

For information on RADPEER™ or eRADPEER™ please go to the ACR Web site at www.acr.org.

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 must be in place to look at the diagnostic accuracy, and complication rate and outcome of CT-guided interventional procedures. Documentation may be requested as part of an on-site survey.

Accreditation Testing

Clinical Images

The clinical examinations will be of the head/neck, chest, and abdomen regions. One examination from each of the ***three categories*** and your ***facility's protocol*** for that examination must be submitted from each scanner. If a scanner does not perform all three examinations, i.e., a specialty scanner, the site must provide a description of the scanner and a signed attestation stating the scanner will not be used for other examinations. If the scanner is a specialty scanner, three exams are still required from that scanner.

The facility may choose which examinations it will submit for accreditation (see selection list below). At least one of the examinations chosen for each scanner must be a specialized examination. ***Asterisks denote the specialty examinations.*** If the scanner is also used for pediatric patients, one of the examinations must also be from a child between the ages of 0 and 15. ***Pediatric images should clearly reflect that the site has taken into account the child's age and body habitus in selecting the scanning parameters and contrast dosage. Please refer to the "FDA Public Health Notification: Reducing Radiation Risk from Computed Tomography for Pediatric and Small Adult Patients." All of the FDA health notifications can be found on the World Wide Web at http://www.fda.gov/cdrh/safety.html.***

Sites may not submit images performed on models or volunteers. Patient films will be returned with the final report. ***The reviewers assume that the images submitted are examples of your best work. All images must demonstrate adequate positioning, film contrast and exposure level, resolution, noise, patient and facility identification, and lack of artifacts.***

Required Images for CT Accreditation		
Adult Examination Choices		
Head/Neck	**Chest**	**Abdomen**
• Head (such as for headaches and to exclude neoplasm) • Temporal bones* • Cervical spine for known or suspected fracture*	• Chest (such as for evaluation of known or suspected lung cancer or cough) • Suspected pulmonary embolus* • High-resolution CT of chest (HRCT) for evaluation of diffuse lung disease* • Assessment of possible aortic dissection*	• Abdomen (such as for detection of possible liver metastases or lymphoma) • Known cirrhosis (R/O hepatoma)* • Evaluation of ***known*** renal mass (including ROI measurements)* • Evaluation of a patient with suspected pancreatic carcinoma*
Pediatric Examination Choices		
Head/Neck	**Chest**	**Abdomen**
• Pediatric head CT (such as for headaches, seizures, or suspected mass) • Pediatric sinus for infection • Pediatric cervical spine* • Pediatric temporal bones*	• Pediatric chest (such as for detection of metastatic disease, trauma, infection, or cough) • Pediatric high-resolution CT of chest (HRCT) for evaluation of diffuse lung disease*	• Pediatric abdomen (such as for blunt trauma, acute abdominal pain, or infection) • Pediatric CT for adrenal/renal mass*

Exam Identification and Labeling

Required Identification Labeling for Each Adult or Pediatric CT Image	
Identifying Demographic Data	**Scan and Display Parameters**
• Patient's first and last name • Medical record number • Institution name • Date and time of examination • Date of birth or age of patient • Gender of patient	• Anatomic orientation label • mA/kV • Table speed (pitch) • Scan time • Series number (if applicable) or image number • Size scale • Slice thickness • Table position • Window width/level

Recommended Identification and Labeling for CT	
On each image	**On at least one image of the exam**
• Contrast use • Field of view • Reconstruction algorithm	• Technologist's identification number, name, or initials

Clinical Protocols

The typical scanning protocols for the submitted images will be required for accreditation; the submitted clinical 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.

A typical protocol should include the following elements:

- Indication
- Scanner settings
- Phase of respiration
- Slice thickness
- Table speed (pitch)
- Reconstruction algorithm
- Reconstruction interval
- Cranio-caudal extent
- IV contrast (with injection rate and scan delay)
- Necessity for preliminary non-contrast scans.

There are many published sources of information on scanning protocols and procedures in ACR documents and in radiological journals and textbooks.

Phantom Testing: Image Quality and Dose

A single ACR phantom (Gammex 464) may be used for all scanners accredited at a facility. When the testing materials are sent, the applicant will receive instructions on how to order the phantom directly from the manufacturer.

Specific performance criteria evaluated using the phantom include:

- Slice thickness and positioning
- CT number accuracy
- Low-contrast resolution
- High-contrast (spatial) resolution
- Image uniformity

A complete set of phantom images, along with dose measurements, from every CT scanner at the facility must be submitted.

For accreditation purposes, it will be necessary for your medical physicist to perform CTDI testing on every CT scanner at your facility. Using these CTDI measurements, your physicist will be able to calculate various descriptors of dose for your adult head, pediatric abdomen (5 year old), and adult abdomen examinations. These calculations will use the technique factors provided by your site. The appropriate equations and a calculation spreadsheet will be provided with the testing materials.

Currently, the ACR CT Accreditation Program does not have pass/fail criteria for dose. However, reference values, based on reports from the American Association of Physicists in Medicine (AAPM) and the International Commission on Radiological Protection (ICRP), will be incorporated as recommendations (see table below). These levels are to be used to identify situations where the level of patient dose is unusually high. If your dose for any of the three exams exceeds the respective reference value, we will strongly urge you to consult with your medical physicist to determine if it is possible to reduce the patient dose without sacrificing image quality. You will also be required to submit documentation to the ACR within 90 days detailing your investigation, corrective action if necessary, or justification of the higher dose level.

The recommended CTDIw reference values are as follows:

$CTDI_w$ Reference Values	
Examination	**$CTDI_w$ (mGy)**
Adult head	60
Adult abdomen	35
Pediatric abdomen (5 year old)	25

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. The charge for the phantom is paid directly to the manufacturer.

Accreditation Fees	
Cycle	**Fees**
Accreditation (Initial cycle and renewal)	$2100 for first unit. $2000 each additional unit at one site location.
Repeat	$700 per scanner for clinical or phantom images. $1400 per scanner if repeating both.
Reinstate/Corrective Action Plan	$2100 for first unit. $2000 each additional unit at one site location.
Add Units (mid cycle)	$1200 each unit
Replacement Certificate	$65 per certificate.
Phantom	$3205 for phantom. $445 for carrying case and stand (optional).

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 "Computed Tomography". A link to "Frequently Asked Questions" is available in the CT menu, along with other useful information about accreditation and many of the program's forms. To contact the ACR CT Accreditation Program office by phone, dial (800) 770-0145.

MRI Accreditation Program Requirements

Overview

The whole body MRI Accreditation Program involves the acquisition of clinical and phantom images and corresponding data for each magnet. The acquisition of the phantom images involves the use of a designated MRI phantom. The required clinical and phantom images and corresponding data must be obtained from each magnet at the site of the MR practice.

Personnel Qualifications

Physician

The physician shall have the responsibility for all aspects of the study including, but not limited to, reviewing all indications for the examination, specifying the pulse sequences to be performed, specifying the use and dosage of contrast agents, interpreting images, generating written reports, and assuring the quality of both the images and interpretations.

A physician supervising and interpreting MRI examinations will be required to meet the following minimum criteria (see Table 1).

Initial Qualifications

Physicians assuming these responsibilities for MR imaging of all anatomical areas should meet one of the following criteria:

- Certification in radiology or diagnostic radiology by the American Board of Radiology, the American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada, or Le College des Medicins du Quebec, and involvement with the supervision and/or performance of, as well as interpretation and/or review and reporting of, 300 MRI examinations within the last 36 months. [1]

OR

- Completion of an accredited diagnostic radiology residency program and involvement with the performance, interpretation, and reporting of 500 MRI examinations in the past 36 months.

Non-radiologist physicians assuming these responsibilities for MR imaging exclusively in a specific anatomic area should meet the following criteria:

[1] Board certification and completion of an accredited radiology residency in the past 24 months will be presumed to be satisfactory experience for the reporting and interpreting requirement.

Phantom Testing: Image Quality and Dose

A single ACR phantom (Gammex 464) may be used for all scanners accredited at a facility. When the testing materials are sent, the applicant will receive instructions on how to order the phantom directly from the manufacturer.

Specific performance criteria evaluated using the phantom include:

- Slice thickness and positioning
- CT number accuracy
- Low-contrast resolution
- High-contrast (spatial) resolution
- Image uniformity

A complete set of phantom images, along with dose measurements, from every CT scanner at the facility must be submitted.

For accreditation purposes, it will be necessary for your medical physicist to perform CTDI testing on every CT scanner at your facility. Using these CTDI measurements, your physicist will be able to calculate various descriptors of dose for your adult head, pediatric abdomen (5 year old), and adult abdomen examinations. These calculations will use the technique factors provided by your site. The appropriate equations and a calculation spreadsheet will be provided with the testing materials.

Currently, the ACR CT Accreditation Program does not have pass/fail criteria for dose. However, reference values, based on reports from the American Association of Physicists in Medicine (AAPM) and the International Commission on Radiological Protection (ICRP), will be incorporated as recommendations (see table below). These levels are to be used to identify situations where the level of patient dose is unusually high. If your dose for any of the three exams exceeds the respective reference value, we will strongly urge you to consult with your medical physicist to determine if it is possible to reduce the patient dose without sacrificing image quality. You will also be required to submit documentation to the ACR within 90 days detailing your investigation, corrective action if necessary, or justification of the higher dose level.

The recommended CTDIw reference values are as follows:

$CTDI_w$ Reference Values	
Examination	**$CTDI_w$ (mGy)**
Adult head	60
Adult abdomen	35
Pediatric abdomen (5 year old)	25

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. The charge for the phantom is paid directly to the manufacturer.

Accreditation Fees	
Cycle	**Fees**
Accreditation (Initial cycle and renewal)	$2100 for first unit. $2000 each additional unit at one site location.
Repeat	$700 per scanner for clinical or phantom images. $1400 per scanner if repeating both.
Reinstate/Corrective Action Plan	$2100 for first unit. $2000 each additional unit at one site location.
Add Units (mid cycle)	$1200 each unit
Replacement Certificate	$65 per certificate.
Phantom	$3205 for phantom. $445 for carrying case and stand (optional).

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 "Computed Tomography". A link to "Frequently Asked Questions" is available in the CT menu, along with other useful information about accreditation and many of the program's forms. To contact the ACR CT Accreditation Program office by phone, dial (800) 770-0145.

MRI Accreditation Program Requirements

Overview

The whole body MRI Accreditation Program involves the acquisition of clinical and phantom images and corresponding data for each magnet. The acquisition of the phantom images involves the use of a designated MRI phantom. The required clinical and phantom images and corresponding data must be obtained from each magnet at the site of the MR practice.

Personnel Qualifications

Physician

The physician shall have the responsibility for all aspects of the study including, but not limited to, reviewing all indications for the examination, specifying the pulse sequences to be performed, specifying the use and dosage of contrast agents, interpreting images, generating written reports, and assuring the quality of both the images and interpretations.

A physician supervising and interpreting MRI examinations will be required to meet the following minimum criteria (see Table 1).

Initial Qualifications

Physicians assuming these responsibilities for MR imaging of all anatomical areas should meet one of the following criteria:

- Certification in radiology or diagnostic radiology by the American Board of Radiology, the American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada, or Le College des Medicins du Quebec, and involvement with the supervision and/or performance of, as well as interpretation and/or review and reporting of, 300 MRI examinations within the last 36 months. [1]

OR

- Completion of an accredited diagnostic radiology residency program and involvement with the performance, interpretation, and reporting of 500 MRI examinations in the past 36 months.

Non-radiologist physicians assuming these responsibilities for MR imaging exclusively in a specific anatomic area should meet the following criteria:

[1] Board certification and completion of an accredited radiology residency in the past 24 months will be presumed to be satisfactory experience for the reporting and interpreting requirement.

- Completion of an accredited residency in the specialty practiced, plus 200 hours of Category I Continuing Medical Education (CME) in MRI to include, but not limited to: MRI physics, recognition of MRI artifacts, safety, instrumentation, and clinical applications of MRI in the subspecialty area where MRI reading occurs. In addition, 500 MRI cases in that specialty area shall have been interpreted and reported in the past 36 months in a supervised situation. For neurologic MRI, at least 50 of the 500 cases shall have been MRA or the central nervous system.

Continuing Experience

All physicians performing MRI examinations should demonstrate evidence of continuing competence in the interpretation and reporting of those examinations. If competence is assured primarily based on continuing experience, a minimum of 100 examinations per year is recommended in order to maintain the physician's skills. Because a physician's practice or location may preclude this amount of experience, continued competency can also be assessed through monitoring and evaluation that indicates acceptable technical success, accuracy of interpretation, and appropriateness of evaluation.

Continuing Education

The qualified physician's continuing education should be in accordance with the ACR Practice Guideline for Continuing Medical Education (CME) and should include CME in MRI as is appropriate to the physician's practice needs.

Table 1. Requirements for Physicians

	Radiologists	Other Physician
Initial	• Board certification, and • 300 MRI exams in past 36 months OR • Completion of a diagnostic radiology residency, and • 500 MRI exams in past 36 months	(MR imaging limited to a specific anatomic area) • Completion of a specialty residency • 200 hours of Cat 1 CME • 500 MRI exams in past 36 months
Continuing Experience	100 MRI exams per year (recommended)	100 MRI exams per year (recommended)
Continuing Education	150 hours every three years (recommended)	150 hours every three years (recommended)

Technologist

Initial Qualifications

- Be certified by the American Registry of Radiologic Technologists (ARRT) or the Canadian Association of Medical Radiation Technologists (CAMRT) as an MR technologist (RTMR) (see Table 2).

OR

- Be certified by ARRT and/or have appropriate state licensure ***and*** have six months of supervised clinical MRI scanning experience.

OR

- Have an associate's degree in an allied health field or a bachelor's degree ***and*** certification in another clinical imaging field ***and*** have six months of supervised clinical MRI scanning experience

OR

- Any technologist who began performing MRI prior to October 1996 and who does not meet the above criteria should be evaluated by the responsible physician to assure competence.

Any technologist practicing MRI scanning should be licensed in the jurisdiction in which he/she practices, if state licensure exists. To assure competence, all technologists must be evaluated by the supervising physician.

Continuing Education

Continuing education should involve 15 hours of Category A CME in MRI every three years. MRI technologists who have passed the ARRT MRI board exam will automatically satisfy the CME requirement. This exemption is only valid for three years starting on the date that they passed the examination. They should maintain 15 hours of CME during every 3-year period thereafter.

Medical Physicist/MR Scientist

Initial Qualifications

A qualified medical physicist/MR scientist ***should*** have the responsibility for overseeing the equipment quality control program and for monitoring performance upon installation and routinely thereafter.

- A qualified medical physicist is an individual who is competent to practice independently one or more of the subfields in medical physics. The ACR considers that certification and continuing education in the appropriate subfield(s) demonstrate that an individual is competent to practice one or more of the subfields in medical physics to be a qualified medical physicist. The ACR recommends that the individual be certified in the appropriate subfield(s) by the American Board of Radiology (ABR) (see Table 2).
- The appropriate subfields of medical physics are Diagnostic Radiological Physics and Radiological Physics.
- A qualified MR scientist is an individual who has obtained a graduate degree in a physical science involving nuclear MR (NMR) or MRI. These individuals should have three years of documented experience in a clinical MRI environment.

The qualified medical physicist/MR scientist must be familiar with the principles of MRI safety for patients, personnel, and the public; the Food and Drug Administration's guidance for MR diagnostic devices; and other regulations pertaining to the performance of the equipment being monitored. The qualified medical physicist/MR scientist shall be knowledgeable in the field of nuclear MR physics and familiar with MRI technology, including function, clinical uses, and performance specifications of MRI equipment, as well as calibration processes and limitations of the performance testing hardware, procedures, and algorithms. The qualified medical physicist/MR scientist shall have a working understanding of clinical imaging protocols and methods of their optimization. This proficiency shall be maintained by participation in continuing education programs of sufficient frequency to ensure familiarity with current concepts, equipment, and procedures.

The qualified medical physicist/MR scientist may be assisted in obtaining test data for performance monitoring by other properly trained individuals. These individuals must be properly trained and approved by the qualified medical physicist/MR scientist in the techniques of performing the tests, the function and limitations of the imaging equipment and test instruments, the reason for the tests, and the importance of the test results. The qualified medical physicist/MR scientist must review and approve all measurements.

Continuing Education

The continuing education of a qualified medical physicist/MR scientist should be in accordance with the ACR Practice Guideline for Continuing Medical Education (CME).

Table 2. Requirements for Radiological Technologist and Medical Physicist/MR Scientist

	Radiological Technologist	Medical Physicist/MR Scientist
Initial	• ARRT or CAMRT registered as an MR technologist OR • ARRT registered or unlimited state license, and • 6 months supervised clinical experience OR • Associate degree in allied health field or bachelor degree, and • Certification in another clinical imaging field, and • Supervised clinical experience OR • Performing MRI prior to October 1996, and • Evaluated by responsible physician to assure competence	• Board certification in diagnostic radiologic physics or radiologic physics (recommended) OR • Graduate degree in physical science involving nuclear MR or MRI, and • Three years documented experience
Continuing Education	15 credits in a 3-year period (recommended)	150 hours every three years (recommended)

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 should 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]

Starting in April 2007, all sites initially applying for ACR accreditation and all sites renewing their accreditation must have a physician peer-review program in place. At that time, RADPEER™ or an equivalent peer review program will be required for accreditation. While currently this is not pass/fail

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

criteria, there will be a section on the Quality Assurance questionnaire that will ask about your site's current physician peer-review status. You will receive the Quality Assurance questionnaire with your testing materials.

RADPEER™ is a simple process that allows peer review to be performed during the routine interpretation of current images. If, during interpretation of a new examination, there are prior images of the same area of interest, the interpreting radiologist will typically form an opinion of the previous interpretation while interpreting the new study. If the opinion of the previous interpretation is scored, a peer review event has occurred. In RADPEER™, the report of the previous interpretation is scored by the reviewer using a standardized 4-point rating scale.

An acceptable alternative physician peer review program must include:

- A peer review process that includes a double reading (2 MDs interpreting the same study) assessment.
- A peer review process that allows for random selection of studies to be reviewed on a regularly scheduled basis.
- Exams and procedures representative of the work of each physician's specialty.
- Reviewer assessment of the agreement of original report with subsequent review (or with surgical or pathological findings).
- A classification of peer review findings with regard to level of quality concerns (i.e. 4 point scoring scale).
- Policies and procedures for action to be taken on significantly discrepant peer review findings for purpose of achieving quality outcomes improvement.
- Summary statistics and comparisons generated for each physician by modality.
- Summary data for each facility/practice by modality.

For information on RADPEER™ or eRADPEER™ please go to the ACR Web site at www.acr.org.

Equipment

The MR equipment specifications and performance shall meet all state and federal requirements. The requirements include, but are not limited to, specifications of maximum static magnetic field strength, maximum rate of change of magnetic field strength (dB/dt), maximum radiofrequency power deposition (specific absorption rate), and maximum auditory noise levels.

Loaner Magnets

Accredited facilities may use a "loaner" magnet to temporarily replace an accredited magnet that is out of service for repairs, etc. for up to six months without submitting clinical and phantom images for evaluation (any loaner magnet that is in use for more than one month will be required to submit evidence of testing by a qualified medical physicist/MR scientist). However, the accredited facility must immediately notify the ACR of the installation date, manufacturer, and model of the loaner. 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.

MRI Equipment Quality Control

Acceptance Testing

Acceptance testing is intended to measure quantifiable system parameters, which may then be compared to the manufacturer's specifications. A complete evaluation of the system performance should be performed after completion of installation and prior to patient imaging.[3]

Quality Control Testing

All facilities applying for accreditation must maintain a documented quality control (QC) program and must comply with the minimum frequencies of testing outlined below. Weekly QC testing should be conducted by the technologist and reviewed on at least an annual basis by a qualified medical physicist/MR scientist and/or the supervising physician. Detailed instructions for each of the QC tests listed below are contained in the *2004 ACR MRI Quality Control Manual*. Upon acceptance of a facility's application, this manual and a video tutorial will be sent to the group practice supervising physician under separate cover.

The ongoing QC program assesses relative changes in system performance as determined by the technologist, service engineer, qualified medical physicist/MR scientist, or supervising physician. All facilities applying for accreditation or renewal must demonstrate compliance with the ACR requirements for quality control (QC) by including a copy of the facility's most recent **Annual MRI System Performance Evaluation** (must be dated within 1 year of the date of ACR MRI submission for accreditation) and copies of the facility's weekly on-site QC data (forms on pages 64, 65, and 66 of the *2004 ACR MRI Quality Control Manual*) for the most recent quarter. If the facility has been conducting QC for less than one quarter, the facility will submit whatever they have on these forms. Additionally, if the **Annual MRI System Performance Evaluation** and/or QC files show performance deficits (e.g. problems with the system and/or data outside of the action limits), the facility must state what steps it has taken to correct the problems. All QC testing must be carried out in accordance with the written procedures and methods outlined in the ACR *2004 MRI Quality Control Manual*.

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[3] A suggested protocol for acceptance testing is contained in "Acceptance Testing of Magnetic Resonance Imaging Systems: Report of American Association of Physicists in Medicine (AAPM) Nuclear Magnetic Resonance Task Group No. 6, Medical Physics. 1992; 19:217-219. This document is meant only to serve as a reference. The substance of this document is not intended to be incorporated by reference into the ACR Practice Guideline for Performing and Interpreting Magnetic Resonance Imaging (MRI).

Continuous Quality Control

The following is a list of QC tests and frequencies that must be performed by technologists and physicists/MR scientists:

Technologist's Weekly QC Tests

- Center Frequency
- Table Positioning
- Setup and Scanning
- Geometric Accuracy
- High-Contrast Resolution
- Low-Contrast Resolution
- Artifact Analysis
- Film Quality Control
- Visual Checklist

Physicist/MR Scientist's Annual QC Tests

- Magnetic Field Homogeneity
- Slice Position Accuracy
- Slice Thickness Accuracy
- Radiofrequency Coil Checks
- Inter-Slice Radiofrequency Interference
- Soft-Copy Displays (Monitors)

Preventive Maintenance

Preventive maintenance shall be scheduled, performed, and documented by a qualified service engineer on a regular basis. Service performed to correct system deficiencies shall also be documented and service records maintained by the MR site.

MR Safe Practice Guidelines

Safety guidelines, practices, and policies shall be written, enforced, reviewed, and documented at least annually by the MR supervising physician. These guidelines should take into consideration potential magnetic field interactions for ferromagnetic objects in the MRI environment. They should also consider potential hazards (i.e., from magnetic field interactions, heating, and induced electrical currents) posed by implanted objects and materials within the patient as well as other individuals in the MR environment.

For complete information regarding MR safety, see the ACR White Paper on MR Safety. In: Kanal E, Borgstede JP, Barkovich AJ, et al. American College of Radiology White Paper on MR Safety. AJR 2002; 178:1335-1347. Reprinted with permission from the American Roentgen Ray Society in the ACR Practice Guidelines and Technical Standards Book.

The ACR White Paper on MR Safety may be downloaded from the American College of Radiology website at www.acr.org.

Techniques and Indications

It is very important that each site offering MRI have documented procedures and technical factors to examine each anatomic site. Each site's procedures should be reviewed and updated at appropriate intervals. The final judgment regarding appropriateness of a given examination for a particular patient is the responsibility of the appropriate physicians. The indications for scanning a particular part of the human body depend on the MR software and hardware available and the relative cost, efficacy, and availability of competing imaging methods. The examination should provide images with suitable contrast characteristics, spatial resolution, signal-to-noise ratios, and section geometry appropriate to the specific clinical indications.

Exam Specifications

The examination should be performed within parameters currently approved by the FDA. Examinations that use techniques not approved by the FDA may be considered when they are judged to be medically appropriate.

Clinical Images

The site must provide the required clinical images from ***every*** magnet at its practice location to be evaluated for ACR MRI Accreditation (see Table 3). This is an accreditation process for general MRI services.

Please note the following:

- If your site routinely performs localizer or scout sequences with the clinical exams listed below, then include those with your clinical image submission.

- Sites cannot submit examinations performed on models or volunteers. The images submitted for each individual exam must be from the same patient (i.e., all brain images must be from the same brain study).

The following sets of images (which must be ***original*** 14 x 17-inch films or ***refilmed from original*** disks) are required for the MRI accreditation program:

Required images for whole body MRI accreditation:

- Routine brain examination (for headache)
  1. Sagittal short TR/short TE with dark CSF
  2. Axial or coronal long TR/short TE (or FLAIR) and long TR/long TE (e.g., long TR double echo)
- Routine cervical spine examination (for radiculopathy)
  1. Sagittal short TR/short TE with dark CSF
  2. Sagittal long TR/long TE or T2*W with bright CSF
  3. Axial long TR/long TE or T2*W with bright CSF

- Routine lumbar spine examination (for back pain)
  1. Sagittal short TR/short TE with dark CSF
  2. Sagittal long TR/longe TE or T2*W with bright CSF
  3. Axial short TR/short TE with dark CSF and/or long TR/long TE with bright CSF
- Complete routine knee examination (for internal derangement)
  1. To include sagittal(s) ***and*** coronal(s) with at least one sequence with bright fluid

Each set of clinical images will be evaluated for:

- Pulse sequences and image contrast
- Filming technique
- Anatomic coverage and imaging planes
- Spatial resolution
- Artifacts
- Exam ID (All patient information annotated on clinical exams will be kept confidential by the ACR.)

Please consider the following parameters when performing your examinations. The values shown below are intended to serve as recommendations. The numbers do not constitute a threshold for failure.

Table 3. Recommended Clinical Spatial Resolution Parameters

Sequence	Slice Thickness	Gap	Maximum In-Plane Pixel Dimension for Phase and Frequency
Brain – Sagittal & Axial and/or Coronal	≤5 mm	≤2 mm	≤1.2 mm
Cervical Spine - Sagittal	≤3 mm	≤1 mm	≤1 mm
Cervical Spine - Axial	≤3 mm	≤1 mm	≤1 mm
Lumbar Spine - Sagittal	≤5 mm	≤1.5 mm	≤1.5 mm
Lumbar Spine - Axial	≤4 mm	≤1 mm	≤1.5 mm
Knee – Sagittal & Coronal	≤4 mm	≤1 mm	≤.75 mm

MRI facilities should use the determinants and formulas listed below to determine the spatial resolution of their clinical MRI examinations. They can also be used in conjunction with any deficiencies noted on the site's final report to help determine which MRI scan parameters may need to be modified.

Spatial Resolution

There are five determinants of voxel dimensions in a MRI examination:

- Slice thickness (ST)
- Field of view along the phase encode axis (FOVp)
- Field of view along the frequency encode axis (FOVf)
- Number of phase encoding steps (Np)
- Number of frequency encoding steps (Nf)

Spatial Resolution Formulas

- In-plane pixel (phase) = (FOVp/Np)
- In-plane pixel (read) = (FOVf/Nf)

Alterations in any of these five parameters will alter the voxel volume, the signal-to-noise ratio (SNR) of the image, and the amount of partial volume averaging exhibited in the image. Alterations in the number of phase encoding steps (Np) affects scan time, while alterations in the number of frequency encoding samples (Nf) may affect the maximum number of slices as well as the minimum possible TE for the imaging sequence.

Phantom Testing and Image Quality

Clinical image review and phantom review are intended to complement each other for a comprehensive evaluation of the quality of MRI services. The criteria for evaluation are independent of field strength and can be applied uniformly so that all magnets are measured against a single standard.

Each site is required to submit phantom images using the ACR protocol ***and*** phantom images using its own routine T1- and T2-weighted scan protocol.

The images and testing data will be used to assess:
- Limiting high-contrast spatial resolution
- Slice thickness accuracy
- Distance measurement and accuracy
- Signal uniformity
- Image ghosting ratio
- Low-contrast detectability
- Slice positioning accuracy
- Image artifacts

Phantom data must be submitted in the form of film and DICOM CD-ROM. There may be additional costs associated with phantom data translation. If the facility is unable to convert their phantom data to DICOM CD-ROM, the facility must pay for a phantom on-site data analysis, and an ACR medical physicist will come to the site to review the phantom data.

Accreditation Fees

The fee for accreditation is $2100 for the first unit and $2000 for each additional unit (see Table 4). Checks should be made payable to the American College of Radiology (include modality accreditation ID#, if available). American Express, MasterCard, and Visa are accepted. The charge for the phantom is paid directly to the manufacturer. Phantom ordering instructions will be sent with the testing materials.

Table 4. Accreditation Fees	
Cycle	**Fees**
Accreditation (Initial cycle and renewal)	$2100 for first unit. $2000 each additional unit at one site location.
Repeat	$700 per unit for clinical or phantom images. $1400 per unit if repeating both.
Reinstate/Corrective Action Plan	$2100 for first unit. $2000 each additional unit at one site location.
Add units (mid cycle)	$1200
Replacement Certificate	$65 per certificate.
Phantom	$730 (includes shipping and handling).

Note: Fees subject to change without notice.

Appendix A: References

The following materials are revised periodically. Please contact the publisher to obtain the most current information.

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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 facility 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. 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.

Personnel Qualifications

Starting July 1, 2007, the physician's and the medical physicist's/MR scientist's ongoing qualifications (experience and education) will be required. All sites initially applying for accreditation after July 1, 2007 will be required to meet the full requirements for CME and continuing experience at the time of renewal (as listed below for sites renewing after July 2009). Sites accredited prior to July 2007 will have the option to meet the following phase-in plan:

Phase-In Plan for Continuing Education and Experience		
Sites renewing in:	**Continuing Education Requirement**	**Continuing Experience Requirement**
July 2007	Physicians and medical physicists/MR scientists must have earned at least 5 CME hours in the prior 12-month period. The 5 CME hours must be earned for each modality in which they are renewing (CT, MRI, nuclear medicine, PET and ultrasound).	• Physicians reading CT, MRI, and ultrasound examinations must have read an average of 9 exams per month over the prior 12-month period. • Physicians reading nuclear medicine examinations must have read an average of 15 exams per month over the prior 12-month period. • Physicians reading PET examinations must have read an average of 10 exams per month over the prior 12-month period.
July 2008	Physicians and medical physicists/MR scientists must have earned at least 10 CME hours in the prior 24-month period. The 10 CME hours must be earned for each modality in which they are renewing (CT, MRI, nuclear medicine, PET and ultrasound).	• Physicians reading CT, MRI, and ultrasound examinations must have read an average of 9 exams per month over the prior 24-month period. • Physicians reading nuclear medicine examinations must have read an average of 15 exams per month over the prior 24-month period. • Physicians reading PET examinations must have read an average of 10 exams per month over the prior 24-month period.
July 2009	Physicians and medical physicists/MR scientists must have earned at least 15 CME hours in the prior 36-month period. The 15 CME hours must be earned for each modality in which they are renewing (CT, MRI, nuclear medicine, PET and ultrasound).	• Physicians reading CT, MRI, and ultrasound examinations must have read an average of 9 exams per month over the prior 24-month period. • Physicians reading nuclear medicine examinations must have read an average of 15 exams per month over the prior 24-month period. • Physicians reading PET examinations must have read an average of 10 exams per month over the prior 24-month period.

Physician Qualifications

A physician supervising and/or interpreting nuclear medicine examinations will be required to meet the following minimum criteria:

<table>
<tr><th colspan="3">Requirements for 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 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">15 studies per month averaged over 24 months (recommended)</td></tr>
<tr><td>Continuing Education</td><td colspan="2">The physician's continuing education should be in accordance with the ACR Practice Guideline for Continuing Education (CME), including 15 hours of CME in nuclear medicine in the last three years. For non-nuclear medicine physicians interpreting cardiovascular nuclear medicine only, the 15 hours of CME should be in cardiovascular nuclear medicine. (recommended)</td></tr>
</table>

In addition, all physicians supervising and/or interpreting nuclear medicine examinations must:

- Have current Advanced Cardiac Life Support (ACLS) certification if monitoring cardiac stress studies.
- Satisfy all applicable state and federal regulations that pertain to the *in vivo* use of radiopharmaceuticals and performance of imaging procedures.

Nuclear Medicine Technologist and Medical Physicist Qualifications

Requirements for Nuclear Medicine Technologist and Medical Physicist		
Qualifications	**Nuclear Medicine Technologists**	**Medical Physicist for Nuclear Medicine**
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.	• Board certification in medical nuclear physics or radiologic physics (recommended), and • Familiarity with the principles of radiation protection; the guidelines of the National Council on Radiation Protection and Measurements; laws and regulations pertaining to the use of the equipment being tested;th e function, clinical uses,an d performance specifications of the imaging equipment; and calibration processes and limitations of the instruments and techniques used for testing performance.
Continuing Education	15 hours continuing education in nuclear medicine in the last three years (recommended)	Continuing education for a qualified medical physicist should be in accordance with the ACR Practice Guideline for Continuing Education (CME) and earn at least 15 hours of CME in the last three years that includes training appropriate to nuclear medicine for which physics services are provided. (recommended)

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.

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. **Multiple Window Spatial Registration** - Performed to verify that contrast is satisfactory for imaging radionuclides, which emit photons of more than one energy (e.g., Tl-201, Ga-67, In-111). Multiple window spatial registration is also important for dual radionuclide studies (e.g., Tc-99m/Tl-201).

8. **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.

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

10. **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.

11. **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

12. **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** (quarterly) - 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.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.

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 $2416.
2. Flangeless PET phantom (for PET only) for $1932.
3. The Jaszczak Deluxe Flangeless ECT phantom for (for SPECT only) for $1449.
4 The PET faceplate made to fit an existing flangeless or flanged Jaszczak Deluxe ECT phantom for $969.

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.**

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 should 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]

Starting in April 2007, all sites initially applying for ACR accreditation and all sites renewing their accreditation must have a physician peer-review program in place. At that time, RADPEER™ or an equivalent peer review program will be required for accreditation. While currently this is not pass/fail criteria, there will be a section on the Quality Assurance questionnaire that will ask about your site's current physician peer-review status. You will receive the Quality Assurance questionnaire with your testing materials.

RADPEER™ is a simple process that allows peer review to be performed during the routine interpretation of current images. If, during interpretation of a new examination, there are prior images of the same area of interest, the interpreting radiologist will typically form an opinion of the previous interpretation while interpreting the new study. If the opinion of the previous interpretation is scored, a peer review event has occurred. In RADPEER™, the report of the previous interpretation is scored by the reviewer using a standardized 4-point rating scale.

An acceptable alternative physician peer review program must include:

- A peer review process that includes a double reading (2 MDs interpreting the same study) assessment.
- A peer review process that allows for random selection of studies to be reviewed on a regularly scheduled basis.
- Exams and procedures representative of the work of each physician's specialty.
- Reviewer assessment of the agreement of original report with subsequent review (or with surgical or pathological findings).
- A classification of peer review findings with regard to level of quality concerns (i.e. 4 point scoring scale).
- Policies and procedures for action to be taken on significantly discrepant peer review findings for purpose of achieving quality outcomes improvement.
- Summary statistics and comparisons generated for each physician by modality.
- Summary data for each facility/practice by modality.

For information on RADPEER™ or eRADPEER™ please go to the ACR Web site at www.acr.org.

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.

[1] 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 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) **Plus one of the following:** • Whole body bone • Spot bone • Hepatobiliary • Perfusion lung • MUGA	• Bone SPECT (required) **Plus one of the following:** • Bone SPECT • Brain SPECT • Hepatic blood pool • Liver SPECT • SPECT myocardial perfusion	• SPECT myocardial perfusion (required) **Plus one of the following:** • MUGA • Gated SPECT

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 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.

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	$1200 facility fee Plus $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	$65 per certificate
Phantom	$2416 ECT phantom and the PET faceplate (can be used for both SPECT and PET acquisitions) $1449 ECT phantom (for SPECT only) $1932 PET phantom (for PET only) $969 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.

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 totalo f 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.

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 facility 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

Starting July 1, 2007, the physician's and the medical physicist's/MR scientist's ongoing qualifications (experience and education) will be required. All sites initially applying for accreditation after July 1, 2007 will be required to meet the full requirements for CME and continuing experience at the time of renewal (as listed below for sites renewing after July 2009). Sites accredited prior to July 2007 will have the option to meet the following phase-in plan:

Phase-In Plan for Continuing Education and Experience		
Sites renewing in:	**Continuing Education Requirement**	**Continuing Experience Requirement**
July 2007	Physicians and medical physicists/MR scientists must have earned at least 5 CME hours in the prior 12-month period. The 5 CME hours must be earned for each modality in which they are renewing (CT, MRI, nuclear medicine, PET and ultrasound).	• Physicians reading CT, MRI, and ultrasound examinations must have read an average of 9 exams per month over the prior 12-month period. • Physicians reading nuclear medicine examinations must have read an average of 15 exams per month over the prior 12-month period. • Physicians reading PET examinations must have read an average of 10 exams per month over the prior 12-month period.
July 2008	Physicians and medical physicists/MR scientists must have earned at least 10 CME hours in the prior 24-month period. The 10 CME hours must be earned for each modality in which they are renewing (CT, MRI, nuclear medicine, PET and ultrasound).	• Physicians reading CT, MRI, and ultrasound examinations must have read an average of 9 exams per month over the prior 24-month period. • Physicians reading nuclear medicine examinations must have read an average of 15 exams per month over the prior 24-month period. • Physicians reading PET examinations must have read an average of 10 exams per month over the prior 24-month period.
July 2009	Physicians and medical physicists/MR scientists must have earned at least 15 CME hours in the prior 36-month period. The 15 CME hours must be earned for each modality in which they are renewing (CT, MRI, nuclear medicine, PET and ultrasound).	• Physicians reading CT, MRI, and ultrasound examinations must have read an average of 9 exams per month over the prior 24-month period. • Physicians reading nuclear medicine examinations must have read an average of 15 exams per month over the prior 24-month period. • Physicians reading PET examinations must have read an average of 10 exams per month over the prior 24-month period.

Physician Qualifications

A physician supervising and/or interpreting PET examinations will be required to meet the following minimum criteria:

<table>
<tr><th colspan="3">Requirements for 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">Five studies per month averaged over 24 months (recommended)</td></tr>
<tr><td>Continuing Education</td><td colspan="2">Continuing education should be in accordance with the ACR Practice Guideline for Continuing Education (CME), including 15 hours of CME in PET in the last three years. (recommended)</td></tr>
</table>

In addition, all physicians supervising and/or interpreting PET examinations must:

- Have current Advanced Cardiac Life Support (ACLS) certification if monitoring cardiac stress studies.
- Satisfy all applicable state and federal regulations that pertain to the *in vivo* use of radiopharmaceuticals and performance of imaging procedures.

PET Technologist and Medical Physicist Qualifications

Requirements for PET Technologist and Medical Physicist		
Qualifications	**PET Technologists**	**Medical Physicist for PET**
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.	• Board certification in medical nuclear physics or radiologic physics (recommended), and • Familiarity with the principles of radiation protection; the guidelines of the National Council on Radiation Protection and Measurements; laws and regulations pertaining to the use of the equipment being tested; the function, clinical uses, and performance specifications of the imaging equipment; and calibration processes and limitations of the instruments and techniques used for testing performance, and • 40 hours of on-site practical experience providing physics support at established PET centers, each of which has performed a minimum of 500 cases. This requirement must be completed within the 12 months preceding submission of application.
Continuing Education	15 hours continuing education in PET in the last three years (recommended)	Continuing education for a qualified medical physicist should be in accordance with the ACR Practice Guideline for Continuing Education (CME) and earn at least 15 hours of CME in the last three years that includes training appropriate to nuclear medicine for which physics services are provided. (recommended)

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.

Quality Control

Acceptance Tests and Performance Tests

Acceptance tests must be performed on systems when they are installed. A qualified practicing medical physicist may perform these tests. Alternatively, the tests may be performed by a qualified PET 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. 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.

PET Performance Tests

The quality control testing should be performed in accordance with the ACR Technical Standard for Medical Nuclear Physics Performance Monitoring of PET Imaging Equipment. Data will be collected regarding the quality control tests performed by the facility for the first accreditation cycle. Based on this data, the ACR Committee on Nuclear Medicine Accreditation may establish QC requirements at the time of renewal.

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
- Constancy test
- Linearity
- Accuracy with NIST traceable standard
- Geometry

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.

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:

4. The Jaszczak Deluxe Flangeless ECT phantom and the PET faceplate (can be used for both SPECT and PET acquisitions) for $2416.
5. The Jaszczak Deluxe Flangeless ECT phantom (for SPECT only) for $1449.
6. Flangeless PET phantom (for PET only) for $1932.
7. The PET faceplate made to fit an existing flangeless or flanged Jaszczak Deluxe ECT phantom for $969.

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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 should 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]

Starting in April 2007, all sites initially applying for ACR accreditation and all sites renewing their accreditation must have a physician peer-review program in place. At that time, RADPEER™ or an equivalent peer review program will be required for accreditation. While currently this is not pass/fail criteria, there will be a section on the Quality Assurance questionnaire that will ask about your site's current physician peer-review status. You will receive the Quality Assurance questionnaire with your testing materials.

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

RADPEER™ is a simple process that allows peer review to be performed during the routine interpretation of current images. If, during interpretation of a new examination, there are prior images of the same area of interest, the interpreting radiologist will typically form an opinion of the previous interpretation while interpreting the new study. If the opinion of the previous interpretation is scored, a peer review event has occurred. In RADPEER™, the report of the previous interpretation is scored by the reviewer using a standardized 4-point rating scale.

An acceptable alternative physician peer review program must include:

- A peer review process that includes a double reading (2 MDs interpreting the same study) assessment.
- A peer review process that allows for random selection of studies to be reviewed on a regularly scheduled basis.
- Exams and procedures representative of the work of each physician's specialty.
- Reviewer assessment of the agreement of original report with subsequent review (or with surgical or pathological findings).
- A classification of peer review findings with regard to level of quality concerns (i.e. 4 point scoring scale).
- Policies and procedures for action to be taken on significantly discrepant peer review findings for purpose of achieving quality outcomes improvement.
- Summary statistics and comparisons generated for each physician by modality.
- Summary data for each facility/practice by modality.

For information on RADPEER™ or eRADPEER™ please go to the ACR Web site at www.acr.org.

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.

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	$1200 facility fee Plus $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	$65 per certificate
Phantom	$2416 ECT phantom and the PET faceplate (can be used for both SPECT and PET acquisitions) $1449 ECT phantom (for SPECT only) $1932 PET phantom (for PET only) $969 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.

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 totalo f 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.

Breast Ultrasound Accreditation Program Requirements

Overview

The Breast Ultrasound Accreditation Program provides facilities performing breast ultrasound and ultrasound-guided breast biopsies peer review and constructive feedback on their staff's qualifications, equipment, quality control, quality assurance, accuracy of needle placement and image quality. The Breast Ultrasound Accreditation Program can accommodate a variety of practice settings. A facility that performs only breast ultrasound may apply for the Breast Ultrasound Accreditation Program; a facility that performs both breast ultrasound and ultrasound-guided breast biopsies must also apply for the Ultrasound-Guided Breast Biopsy Module. This document outlines the requirements a facility must meet in order to apply for breast ultrasound accreditation.

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.

Personnel Qualifications

All interpreting physicians and technologists working in breast ultrasound (including part-time and locum tenens staff) ***must meet and document*** specific requirements in order for their facility to be accredited by the ACR. If the interpreting physicians and technologists are working in mammography they ***must*** also meet the Mammography Quality Standards Act (MQSA) qualifications.

Interpreting Physician Qualifications

Physicians interpreting and supervising breast ultrasound examinations must:

- Have a thorough understanding of the indications for breast ultrasound examinations
- Be familiar with the basic physical principles and limitations of imaging ultrasound instrumentation and technology
- Be capable of correlating the results of mammographic and other examinations and procedures with the sonographic findings
- Be responsible for breast ultrasound examinations and procedures
- Be familiar with breast ultrasound anatomy

All physicians interpreting and supervising breast ultrasound examinations ***must*** meet the following ***minimum*** criteria in breast ultrasound:

Qualifications	Interpreting Physician - Breast Ultrasound
Initial	***Certification*** in Radiology or Diagnostic Radiology by the American Board of Radiology, the American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada, Le College des Medicins du Quebec, or an equivalent body that certifies in this discipline and is recognized by the American Board of Medical Specialties **AND** Meet the initial qualifications required under MQSA and specified in the ACR Practice Guidelines for Screening Mammography and Diagnostic Mammography, ***or*** If not qualified under MQSA: 1. Completed an approved residency program with (3 months of training in ultrasound), an appropriate fellowship, or post graduate training under the supervision of qualified individuals 2. Been involved with 500 ultrasound examinations in a broad spectrum of uses, including breast ultrasound 3. Passed written and oral board certification examinations, including sections pertaining to diagnostic ultrasound, ***or*** If completed training prior to 1982: 1. Performed and interpreted ultrasound examinations for at least 10 years 2. Generated film, electronic archives or other hard-copy records for studies performed, along with a written report, all of which have been retained according to hospital policy and consistent with state and federal laws, ***or*** In the absence of formal fellowship or postgraduate training: 1. 2 years of ultrasound experience during which a minimum of 500 general ultrasound or 100 breast ultrasound examinations were performed or supervised and interpreted 2. Generated film, electronic archives or other hard-copy records for studies performed, along with a written report, all of which have been retained according to hospital policy and consistent with state and federal laws 3. Documented quality improvement projects to improve patient care
Continuing Experience	Regular performance and interpretation of diagnostic breast ultrasound examinations (minimum of 30 breast ultrasound examinations per year ***recommended***), ***or*** Document acceptable continuing experience by monitoring acceptable technical success, interpretation accuracy and evaluation appropriateness
Continuing Education	150 hours of CME including CME in breast ultrasound, as appropriate to the physician's practice needs ***(recommended)***

Physicians performing and supervising ultrasound-guided biopsies must ***also*** meet the ultrasound-guided breast biopsy ***minimum*** criteria:

Qualifications	Interpreting Physician – Ultrasound-Guided Breast Biopsy
Initial	Perform 3 hands-on ultrasound-guided biopsy procedures under a qualified physician, ***or*** Have performed 12 ultrasound-guided breast biopsy procedures, ***or*** Completed a residency or fellowship that includes instruction in ultrasound-guided breast needle procedures **AND** Obtain 3 hours of Category 1 CME in ultrasound-guided breast biopsy
Continuing Experience	12 ultrasound-guided biopsy exams per year
Continuing Education	3 hours of Category 1 CME in ultrasound-guided breast biopsy every 3 years

Sonographer/Mammography Technologist Qualifications

All sonographers or mammography technologists performing breast ultrasound examinations are required to meet the following minimum criteria. This includes technologists assisting physicians with ultrasound-guided breast biopsy procedures:

Qualifications	Sonographer or Mammography Technologist - Breast Ultrasound
Initial	ARDMS certification and current registration, ***or*** ARRT post-primary certification and current registration in breast sonography, **or** ARRT certification and current registration (or unrestricted state license) ***and*** MQSA qualified **AND** 5 CEUs specific to breast ultrasound
Continuing Experience	Regular performance of breast ultrasound exams

The physician is not required to be present during breast ultrasound examinations performed by ARDMS sonographers or ARRT technologists with certification in breast sonography. However, the physician ***must*** be in the department during breast ultrasound examinations performed by ARRT technologists ***without*** an advanced registry in breast sonography. In all situations, ***the physician is ultimately responsible to see that the appropriate images are obtained.***

Equipment

Breast ultrasound procedures must be performed on appropriately equipped ultrasound units:

- High-resolution, real-time, linear arrays
- Center frequency of at least 7 MHz
- Capable of electronic focal zone(s) adjustment (recommended)
- Use highest frequency capable of adequate penetration to the depth of interest
- Use a standoff device for the evaluation of superficial lesions

Quality Control

Routine QC is recommended for all ultrasound units used for breast imaging. The following table describes the specific tests recommended for QC:

Recommended Quality Control for Breast Ultrasound		
Test	**Frequency**	**Performed By**
Maximum depth of visualization and hardcopy recording with a tissue-mimicking phantom	Semiannually	Service engineer/medical physicist
Vertical and horizontal distance accuracy	Semiannually	Service engineer/medical physicist
Uniformity	Semiannually	Service engineer/medical physicist
Electrical-mechanical cleanliness condition	Semiannually	Service engineer/medical physicist
Anechoic void perception	Semiannually	Service engineer/medical physicist
Ring down	Semiannually	Service engineer/medical physicist
Lateral resolution	Semiannually	Service engineer/medical physicist
Quality control checklist	Semiannually	Service engineer/medical physicist
Adherence to universal infection control procedures	After each biopsy	Technologist
Clean transducers	After each patient	Technologist
Distance calibration	Quarterly	Technologist
Grey-scale photography	Quarterly	Technologist

As part of accreditation, facilities must submit a copy of the service engineer's most recent preventive maintenance report or the medical physicist's most recent equipment survey. Although the ACR will not initially use this information to determine whether a facility passes or fails accreditation, it may be used in the future to set criteria.

Quality Assurance

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 should 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]

The ACR's RADPEER™ program is a simple tool that allows peer review to be performed during routine interpretation. If prior images of the same area of interest are available, the physician can review the previous interpretation while interpreting the current study. The physician can then score the previous interpretation (either on cards or on a computer) using a standardized 4-point rating scale:

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

1. Concur with interpretation
2. Difficult diagnosis, not ordinarily expected to be made
3. Diagnosis should be made most of the time
4. Diagnosis should be made almost every time – misinterpretation of finding

The facility periodically collects and sends these data to the ACR for confidential analysis. For more information on RADPEER™ or eRADPEER™ go to the ACR Web site at www.acr.org.

Starting in April 2007, participation in the ACR's RADPEER™ or an equivalent peer-review program will be required for accreditation. All facilities applying for ACR accreditation (whether for the first time or as a renewal) must have a program in place. Biopsy programs/modules are exempt from this requirement because outcomes are monitored as part of accreditation and RADPEER™ applies only to review of image interpretation. An acceptable alternative physician peer-review program must include:

- A peer-review process that includes a double reading assessment (2 MDs interpreting the same study)
- A peer-review process that allows for random selection of studies to be reviewed on a regular scheduled
- Exams and procedures representative of the work of each physician's specialty
- Reviewer assessment of the agreement of original report with subsequent review (or with surgical or pathological findings)
- A classification of peer-review findings regarding level of quality concerns (i.e. 4-point scoring scale)
- Policies and procedures for action to be taken on significantly discrepant peer-review findings for purpose of achieving quality outcomes improvement
- Summary statistics and comparisons generated for each physician by modality
- Summary data for each facility/practice by modality

While currently these are not pass/fail criteria, there will be a section on the accreditation modality's Quality Assurance Questionnaire that will ask about your site's current physician peer-review activities. You will receive the Quality Assurance Questionnaire with your testing materials.

Outcome Data – Ultrasound-Guided Breast Biopsy Accreditation Module Only

Each facility applying for the Ultrasound-Guided Breast Biopsy Module must submit outcome data. Although the ACR does not currently use this information as pass/fail criteria, it may be used in the future to help set criteria. The minimum data elements to be collected are:

- Total number of procedures
- Total number of cancers found
- Total number of benign lesions
- Total number of ultrasound-guided biopsies needing repeat biopsy, categorized by reason and type of biopsy (i.e., CNB, FNAC):

Reason for Repeat Biopsy	Data
Insufficient sample	• total # cases • # with repeat biopsy performed by core • # with repeat biopsy performed by excision
Discordance with imaging	• total # cases • # with repeat biopsy performed by core • # with repeat biopsy performed by excision
Cellular atypia, radial scar	• total # cellular atypia cases • total # radial scar cases (CNB only) • # with repeat biopsy performed by core • # with repeat biopsy performed by excision
Other	• total # cases • # with repeat biopsy performed by core • # with repeat biopsy performed by excision

- Complications categorized by type of biopsy (i.e., CNB, FNAC)

  1.T otal number
  2.Number w ith hematoma (requiring intervention)
  3.Num ber with infection
  4.Num ber with pneumothorax (CNB only)

Exam Identification and Labeling

All images are an important part of the medical record. The following information must be permanently recorded on each image of the study:

Required Examination Identification
• Facility name and location • Examination date • Patient's first and last name • Identification number and/or date of birth • Designation of right or left breast • Location of the mass in the breast (diagrammatic, clock or other consistent notation) • Scan plane

Accreditation Testing

Image quality and procedure performance assessments are the cornerstones of the ACR accreditation program. Facilities must apply for accreditation for all services provided. For example, if no biopsies are conducted, the facility should only apply for accreditation in breast ultrasound. If both core-needle biopsies (CNB) and fine needle aspiration cytology (FNAC) are performed, the facility must also apply for the Ultrasound-Guided Breast Biopsy Module and submit both types of cases. (For accreditation purposes, FNAC is the sampling for cytology of a solid mass. It is not intended for needle aspiration of a cyst/cyst drainage.)

Required Examinations	
Breast Ultrasound Module	**Ultrasound-Guided Biopsy Module**
• Simple cyst, ***and***	• Core needle biopsy, ***and/or***
• Solid mass	• Fine needle aspiration cytology

Facilities should select cases that are examples of their best work. The ACR Committee on Breast Ultrasound Accreditation understands that all images obtained during all ultrasound examinations or ultrasound-guided breast biopsy procedures may not meet these criteria. Consequently, sufficient time is allowed to select cases that are examples of "best work." ACR reviewers will evaluate them accordingly. All images should be submitted on film or high-quality photographic paper. (Contact the ACR for special instructions if you wish to submit images on CD.)

Clinical Images - Breast Ultrasound Accreditation

As part of accreditation testing for breast ultrasound, facilities must submit the following images:

Required Clinical Images – Breast Ultrasound Accreditation (both cases required)	
Simple Cyst	**Solid Mass**
1. 2-view mammogram with a single cyst (marked and visible on both views)	1. 2-view mammogram with a single mass (marked and visible on both views)
2. 2 orthogonal views (e.g., 1 transverse, 1 sagittal) with no calipers visible on the cyst	2. 2 orthogonal views (e.g., 1 transverse, 1 sagittal) with no calipers visible on the mass
3. 1 image with appropriate caliper measurements	3. 1 image with appropriate caliper measurements

If the cyst or mass is not marked, the facility will fail accreditation because the ACR reviewers will not be able to determine if the intended cyst or mass was imaged. Marking more than one will also result in accreditation failure because the ACR reviewers may be uncertain which cyst or mass is being evaluated. Evaluation of the quality of the mammogram is not part of the assessment.

Clinical Images - Ultrasound-Guided Breast Biopsy Accreditation Module

Films submitted for ultrasound-guided breast biopsy accreditation should demonstrate that physicians performing these procedures possess the skill necessary for appropriate needle positioning during these procedures. The position of the needle relative to the mass must be easily appreciated on the pre-biopsy sonogram and on the images obtained during the biopsy. Facilities must include the following images for each type of case submitted for accreditation review:

Required Clinical Images - Core Needle Biopsy (either case)	
Non-Vacuum Device	**Vacuum Suction Device**
1. 2-view mammogram with a single mass (marked and visible on both views)	1. 2-view mammogram with a single mass (marked and visible on both views)
2. Pre-biopsy sonogram showing mass in 2 orthogonal views (e.g., 1 transverse, 1 sagittal)	2. Pre-biopsy sonogram showing mass in 2 orthogonal views (e.g., 1 transverse, 1 sagittal)
3. Pre fire sonogram showing needle in the long axis	3. Sonogram showing the needle adjacent to the mass in the long axis
4. Post fire sonogram showing needle in the long axis	

And/Or

Required Clinical Images - Fine Needle Aspiration Cytology
1. 2-view mammogram with a single mass (marked and visible on both views)
2. Pre-biopsy sonogram showing mass in 2 orthogonal views (e.g., 1 transverse, 1 sagittal)
3. Sonogram showing the needle clearly within the mass in the long axis

If the mass is not marked, the facility will fail accreditation because the ACR reviewers will not be able to determine if the intended mass was biopsied. Marking more than one will also result in accreditation failure because the ACR reviewers may be uncertain which mass is being evaluated. Evaluation of the quality of the mammogram is not part of the assessment.

Accreditation Fees

The fees for accreditation are listed below:

Cycle	Fees*
Accreditation (Initial cycle and renewal)	$900 for breast ultrasound $1000 for breast ultrasound with biopsy
Repeat	$400 for one or both modules
Reinstate/Corrective Action Plan	$900 for breast ultrasound $1000 for breast ultrasound with biopsy
Replacement Certificate	$65 per certificate

** 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" then click on "Breast Ultrasound". A link to "Frequently Asked Questions" is available in the Breast Ultrasound Accreditation Program menu, along with other useful information about accreditation and many of the program's forms. To contact the ACR Breast Ultrasound Accreditation Program office by phone, dial (800) 770-0145.

Ultrasound Accreditation Program Requirements

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Overview

The Ultrasound Accreditation Program involves the acquisition of clinical images, submission of relevant physician reports corresponding to clinical images submitted, and quality control documentation. Sites should apply for accreditation in all categories of ultrasound services this site provides (e.g., OB, General, Gynecological, and/or Vascular).

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.

Personnel Qualifications

Starting July 1, 2007, the physician's and the medical physicist's/MR scientist's ongoing qualifications (experience and education) will be required. All sites initially applying for accreditation after July 1, 2007 will be required to meet the full requirements for CME and continuing experience at the time of renewal (as listed below for sites renewing after July 2009). Sites accredited prior to July 2007 will have the option to meet the following phase-in plan:

Phase-In Plan for Continuing Education and Experience	
Continuing Education Requirement	**Continuing Experience Requirement**
Sites renewing in July 2007	
Physicians and medical physicists/MR scientists must have earned at least 5 CME hours in the prior 12-month period. The 5 CME hours must be earned for each modality in which they are renewing (CT, MRI, nuclear medicine, PET and ultrasound).	Over the prior 12-month period, physicians reading: • CT, MRI, and ultrasound must have read an average of 9 exams per month. • Nuclear medicine must have read an average of 15 exams per month. • PET must have read an average of 10 exams per month.
Sites renewing in July 2008	
Physicians and medical physicists/MR scientists must have earned at least 10 CME hours in the prior 24-month period. The 10 CME hours must be earned for each modality in which they are renewing (CT, MRI, nuclear medicine, PET and ultrasound).	Over the prior 24-month period, physicians reading: • CT, MRI, and ultrasound must have read an average of 9 exams per month. • Nuclear medicine must have read an average of 15 exams per month. • PET must have read an average of 10 exams per month.
Sites renewing in July 2009	
Physicians and medical physicists/MR scientists must have earned at least 15 CME hours in the prior 36-month period. The 15 CME hours must be earned for each modality in which they are renewing (CT, MRI, nuclear medicine, PET and ultrasound).	Over the prior 24-month period, physicians reading: • CT, MRI, and ultrasound must have read an average of 9 exams per month. • Nuclear medicine must have read an average of 15 exams per month. • PET must have read an average of 10 exams per month.

Physician Qualifications

The physician must be a licensed medical practitioner with a thorough understanding of indications for ultrasound examinations and be familiar with the basic physical principles and limitations of the technology and ***meet at least one*** of the four initial qualifications criteria.

Requirements for Physicians Supervising and/or Interpreting Ultrasound Examinations		
Qualifications	**Radiologists/Physicians**	**Physician (without formal fellowship or postgraduate training)**
Initial	• Completion of an approved residency program including three months of training supervised by qualified individuals, and involvement with 500 ultrasound examinations, including a broad spectrum of uses. The physician should have successfully passed written and oral board certification examinations, including sections related to diagnostic ultrasound. OR • If residency did not include ultrasound, the physician must have had appropriate fellowship or postgraduate training including involvement with performance and interpretation of at least 500 ultrasound examinations, including a broad spectrum of ultrasound uses under the direct supervision of a qualified physician. OR • Physicians trained prior to 1982 must have performed and interpreted ultrasound examinations for at least 10 years, generating film or other hard-copy records for studies performed, along with a written report.	• Two years of ultrasound experience during which at least 500 ultrasound examinations were performed or supervised and interpreted. • Generation of film, videotape or other hard-copy records with written reports for studies performed. • Quality improvement projects to continuously improve patient care.
Continuing Experience	A minimum of 300 examinations per year is recommended in order to maintain the physician's skills. Alternatively continued competency can be assured through monitoring and evaluation that indicates acceptable technical success, accuracy of interpretation, and appropriateness of evaluation. (recommended)	
Continuing Education	The physician's continuing education should be in accordance with the ACR Practice Guideline for Continuing Education (CME), including 15 hours of CME in ultrasound and vascular ultrasound (as appropriate) in the last three years. (recommended)	

Technologist Qualifications

Requirements for Ultrasound Technologist		
	Initial Accreditation	**Renewal Accreditation**
Initial Qualifications	• Certified or eligible for certification by: o American Registry of Diagnostic Medical Sonographers (ARDMS), OR o American Registry of Radiologic Technologists, Sonography (ARRT) (S).	• All sonographers must be certified and currently registered as RDMS, RT(S), RT (VS), RVT, or RVS at the time of application for renewal of accreditation. (All sonographers should obtain certification within twenty-four months of graduation or cross training.)
	Both Initial and Renewal Vascular Accreditation	
	At least one technologist who is certified and currently registered as a Registered Vascular Technologist (RVT) by the ARDMS, a Vascular Sonographer (VS) by the ARRT, or as a Registered Vascular Specialist (RVS) (also known as RCVT) by Cardiovascular Credentialing International (CCI) must be working in vascular ultrasound if vascular accreditation is requested.	
Continuing Education	Sonographers should be in compliance with the ARDMS or ARRT(S) requirements for continuing education appropriate to their practices	

PRN technologists should meet all accreditation requirements. PRN technologists who are not certified may not be used at an accredited facility for more than two consecutive weeks and no more than a total of three weeks per calendar year.

Quality Control

A quality control (QC) program must be in place for each ultrasound unit in the facility and must:

- Have program documentation describing the goals and responsibilities of the QC program
- Be directed by a medical physicist or by the supervising radiologist/physician (who may appoint an appropriate designee to oversee the program).

Continuous Quality Control

Routine quality control testing must occur regularly; ***a minimum requirement is semiannually***. The same tests must be performed during each testing period so that changes can be monitored over time and effective corrective action can be taken. Testing results, corrective action, and the effects of corrective action must be documented and the documentation maintained on site. In the event of a site survey, reviewers will expect to see such documentation.

The QC program must evaluate at least the following items in gray-scale imaging mode:

- System sensitivity and/or penetration capability.
- Image uniformity.
- Photography and other hard-copy recording.
- Low-contrast object detectability (optional).
- Assurance of electrical and mechanical safety.

In addition, it is recommended that users verify the accuracy of vertical and horizontal distance measurement when a QC program is initiated for an ultrasound unit.

These items may be assessed using a commercially available phantom test object. At the present time, no one type of phantom is preferred; users should select one that is commercially available. Using a phantom will be helpful in responding to questions about low-contrast detectability in the quality control part of the testing material. However, the use of a phantom is ***optional*** at this time. Therefore, the part of the Quality Control section of the testing material, that addresses low-contrast object detectability, may be omitted. Questions relating to characteristics associated with system sensitivity, image uniformity, and safety may be answered without the use of a phantom as a test object.

Transducers

On an ongoing basis, tests should be done using two transducers commonly used with any unit employing more than one transducer. It is recommended that these be of different scan formats such as one linear (or curvilinear) array and one sector (mechanical, phased or vector).

QC Data to be Submitted for Accreditation

For each unit, submit a copy of your most recent physicist's or service engineer's report. The QC report should document results from testing the transducers (two probes with different formats). Data should be taken from testing of the transducers which are used for the ***most frequently occurring*** examination(s) at the site. None of the questions in the Quality Control section represent failure criteria. The data supplied by you will serve as a basis for the development of realistic quality control program for future inclusion in the Ultrasound Accreditation Program as well as criteria for use of a phantom.

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 should 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]

Starting in April 2007, all sites initially applying for ACR accreditation and all sites renewing their accreditation must have a physician peer-review program in place. At that time, RADPEER™ or an equivalent peer review program will be required for accreditation. While currently this is not pass/fail criteria, there will be a section on the Quality Assurance questionnaire that will ask about your site's current physician peer-review status. You will receive the Quality Assurance questionnaire with your testing materials.

RADPEER™ is a simple process that allows peer review to be performed during the routine interpretation of current images. If, during interpretation of a new examination, there are prior images of the same area of interest, the interpreting radiologist will typically form an opinion of the previous interpretation while interpreting the new study. If the opinion of the previous interpretation is scored, a peer review event has occurred. In RADPEER™, the report of the previous interpretation is scored by the reviewer using a standardized 4-point rating scale.

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

Ultrasound Accreditation Program Requirements

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Overview

The Ultrasound Accreditation Program involves the acquisition of clinical images, submission of relevant physician reports corresponding to clinical images submitted, and quality control documentation. Sites should apply for accreditation in all categories of ultrasound services this site provides (e.g., OB, General, Gynecological, and/or Vascular).

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.

Personnel Qualifications

Starting July 1, 2007, the physician's and the medical physicist's/MR scientist's ongoing qualifications (experience and education) will be required. All sites initially applying for accreditation after July 1, 2007 will be required to meet the full requirements for CME and continuing experience at the time of renewal (as listed below for sites renewing after July 2009). Sites accredited prior to July 2007 will have the option to meet the following phase-in plan:

Phase-In Plan for Continuing Education and Experience	
Continuing Education Requirement	**Continuing Experience Requirement**
Sites renewing in July 2007	
Physicians and medical physicists/MR scientists must have earned at least 5 CME hours in the prior 12-month period. The 5 CME hours must be earned for each modality in which they are renewing (CT, MRI, nuclear medicine, PET and ultrasound).	Over the prior 12-month period, physicians reading: • CT, MRI, and ultrasound must have read an average of 9 exams per month. • Nuclear medicine must have read an average of 15 exams per month. • PET must have read an average of 10 exams per month.
Sites renewing in July 2008	
Physicians and medical physicists/MR scientists must have earned at least 10 CME hours in the prior 24-month period. The 10 CME hours must be earned for each modality in which they are renewing (CT, MRI, nuclear medicine, PET and ultrasound).	Over the prior 24-month period, physicians reading: • CT, MRI, and ultrasound must have read an average of 9 exams per month. • Nuclear medicine must have read an average of 15 exams per month. • PET must have read an average of 10 exams per month.
Sites renewing in July 2009	
Physicians and medical physicists/MR scientists must have earned at least 15 CME hours in the prior 36-month period. The 15 CME hours must be earned for each modality in which they are renewing (CT, MRI, nuclear medicine, PET and ultrasound).	Over the prior 24-month period, physicians reading: • CT, MRI, and ultrasound must have read an average of 9 exams per month. • Nuclear medicine must have read an average of 15 exams per month. • PET must have read an average of 10 exams per month.

Physician Qualifications

The physician must be a licensed medical practitioner with a thorough understanding of indications for ultrasound examinations and be familiar with the basic physical principles and limitations of the technology and ***meet at least one*** of the four initial qualifications criteria.

Requirements for Physicians Supervising and/or Interpreting Ultrasound Examinations		
Qualifications	**Radiologists/Physicians**	**Physician (without formal fellowship or postgraduate training)**
Initial	• Completion of an approved residency program including three months of training supervised by qualified individuals, and involvement with 500 ultrasound examinations, including a broad spectrum of uses. The physician should have successfully passed written and oral board certification examinations, including sections related to diagnostic ultrasound. OR • If residency did not include ultrasound, the physician must have had appropriate fellowship or postgraduate training including involvement with performance and interpretation of at least 500 ultrasound examinations, including a broad spectrum of ultrasound uses under the direct supervision of a qualified physician. OR • Physicians trained prior to 1982 must have performed and interpreted ultrasound examinations for at least 10 years, generating film or other hard-copy records for studies performed, along with a written report.	• Two years of ultrasound experience during which at least 500 ultrasound examinations were performed or supervised and interpreted. • Generation of film, videotape or other hard-copy records with written reports for studies performed. • Quality improvement projects to continuously improve patient care.
Continuing Experience	A minimum of 300 examinations per year is recommended in order to maintain the physician's skills. Alternatively continued competency can be assured through monitoring and evaluation that indicates acceptable technical success, accuracy of interpretation, and appropriateness of evaluation. (recommended)	
Continuing Education	The physician's continuing education should be in accordance with the ACR Practice Guideline for Continuing Education (CME), including 15 hours of CME in ultrasound and vascular ultrasound (as appropriate) in the last three years. (recommended)	

Technologist Qualifications

Requirements for Ultrasound Technologist		
	Initial Accreditation	**Renewal Accreditation**
Initial Qualifications	• Certified or eligible for certification by: o American Registry of Diagnostic Medical Sonographers (ARDMS), OR o American Registry of Radiologic Technologists, Sonography (ARRT) (S).	• All sonographers must be certified and currently registered as RDMS, RT(S), RT (VS), RVT, or RVS at the time of application for renewal of accreditation. (All sonographers should obtain certification within twenty-four months of graduation or cross training.)
	Both Initial and Renewal Vascular Accreditation	
	At least one technologist who is certified and currently registered as a Registered Vascular Technologist (RVT) by the ARDMS, a Vascular Sonographer (VS) by the ARRT, or as a Registered Vascular Specialist (RVS) (also known as RCVT) by Cardiovascular Credentialing International (CCI) must be working in vascular ultrasound if vascular accreditation is requested.	
Continuing Education	Sonographers should be in compliance with the ARDMS or ARRT(S) requirements for continuing education appropriate to their practices	

PRN technologists should meet all accreditation requirements. PRN technologists who are not certified may not be used at an accredited facility for more than two consecutive weeks and no more than a total of three weeks per calendar year.

Quality Control

A quality control (QC) program must be in place for each ultrasound unit in the facility and must:

- Have program documentation describing the goals and responsibilities of the QC program
- Be directed by a medical physicist or by the supervising radiologist/physician (who may appoint an appropriate designee to oversee the program).

Continuous Quality Control

Routine quality control testing must occur regularly; ***a minimum requirement is semiannually***. The same tests must be performed during each testing period so that changes can be monitored over time and effective corrective action can be taken. Testing results, corrective action, and the effects of corrective action must be documented and the documentation maintained on site. In the event of a site survey, reviewers will expect to see such documentation.

The QC program must evaluate at least the following items in gray-scale imaging mode:

- System sensitivity and/or penetration capability.
- Image uniformity.
- Photography and other hard-copy recording.
- Low-contrast object detectability (optional).
- Assurance of electrical and mechanical safety.

In addition, it is recommended that users verify the accuracy of vertical and horizontal distance measurement when a QC program is initiated for an ultrasound unit.

These items may be assessed using a commercially available phantom test object. At the present time, no one type of phantom is preferred; users should select one that is commercially available. Using a phantom will be helpful in responding to questions about low-contrast detectability in the quality control part of the testing material. However, the use of a phantom is ***optional*** at this time. Therefore, the part of the Quality Control section of the testing material, that addresses low-contrast object detectability, may be omitted. Questions relating to characteristics associated with system sensitivity, image uniformity, and safety may be answered without the use of a phantom as a test object.

Transducers

On an ongoing basis, tests should be done using two transducers commonly used with any unit employing more than one transducer. It is recommended that these be of different scan formats such as one linear (or curvilinear) array and one sector (mechanical, phased or vector).

QC Data to be Submitted for Accreditation

For each unit, submit a copy of your most recent physicist's or service engineer's report. The QC report should document results from testing the transducers (two probes with different formats). Data should be taken from testing of the transducers which are used for the ***most frequently occurring*** examination(s) at the site. None of the questions in the Quality Control section represent failure criteria. The data supplied by you will serve as a basis for the development of realistic quality control program for future inclusion in the Ultrasound Accreditation Program as well as criteria for use of a phantom.

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 should 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]

Starting in April 2007, all sites initially applying for ACR accreditation and all sites renewing their accreditation must have a physician peer-review program in place. At that time, RADPEER™ or an equivalent peer review program will be required for accreditation. While currently this is not pass/fail criteria, there will be a section on the Quality Assurance questionnaire that will ask about your site's current physician peer-review status. You will receive the Quality Assurance questionnaire with your testing materials.

RADPEER™ is a simple process that allows peer review to be performed during the routine interpretation of current images. If, during interpretation of a new examination, there are prior images of the same area of interest, the interpreting radiologist will typically form an opinion of the previous interpretation while interpreting the new study. If the opinion of the previous interpretation is scored, a peer review event has occurred. In RADPEER™, the report of the previous interpretation is scored by the reviewer using a standardized 4-point rating scale.

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

An acceptable alternative physician peer review program must include:

- A peer review process that includes a double reading (2 MDs interpreting the same study) assessment.
- A peer review process that allows for random selection of studies to be reviewed on a regularly scheduled basis.
- Exams and procedures representative of the work of each physician's specialty.
- Reviewer assessment of the agreement of original report with subsequent review (or with surgical or pathological findings).
- A classification of peer review findings with regard to level of quality concerns (i.e. 4 point scoring scale).
- Policies and procedures for action to be taken on significantly discrepant peer review findings for purpose of achieving quality outcomes improvement.
- Summary statistics and comparisons generated for each physician by modality.
- Summary data for each facility/practice by modality.

For information on RADPEER™ or eRADPEER™ please go to the ACR Web site at www.acr.org.

Accreditation Testing

Clinical Images

Clinical images from four examinations for each type of ultrasound accreditation the facility is seeking must be submitted (see table below). Clinical images must be clearly labeled and obtained within the established time period. The time period is established using the date your application is processed by the ACR (two months before the date of the application and 45 days following the date of the application). Since we do not know exactly when the application will be processed, do not collect images until you have received instructions with the testing material.

Original films (transparencies preferred) or near-original-quality copies will be accepted. Normal examinations are requested. For vascular exams, both normal and abnormal exams are required. Examinations containing abnormal findings must be clearly documented in the accompanying physician report. The ACR is not responsible for abnormal evaluations. All views of an ultrasound examination must be from the same patient. ***Sites cannot submit images performed on models or volunteers.*** Films will be returned to the facility once the accreditation process is complete. The facility may choose which examinations it will submit for accreditation (see selection list in Clinical Image section). ***Note: The reviewers will assume that the images submitted are examples of your best work.***

Vascular Exam Diagnostic Criteria

Diagnostic physiologic and anatomic criteria for interpretation in each area being reviewed ***must*** be submitted with vascular exams.

Reporting of Results

Physician reports are requested to confirm the date and type of examination performed for all examinations. For vascular work, the reports must contain results from noninvasive pressure testing, where appropriate, obtained either from the referral source or from actual testing performed at your own site of practice. It is desirable that normal lab values for velocity measurements appear at the bottom of reports for reference; this is especially helpful with carotid examinations. If velocity measurements are not on the report, please include a copy of the measurements. Each ultrasound exam submitted must have a report that is clearly labeled; vascular reports must contain diagnostic physiologic and anatomic findings.

Types of Ultrasound Accreditation	
Categories	**Examinations Required**
Obstetrical	
• 1st trimester (Between 6-12 wks) • 2nd trimester (Between 13-<26 wks)* • 3rd trimester (>26 wks) *For ACR purposes, 2nd trimester exams should be 18 wks - <26 wks	1 exam 2 exams 1 exam
Trimester Specific Obstetrical **(Your site will only be accredited in the specific trimester(s) that you select.)**	
• One trimester only (1st, 2nd or 3rd trimester) **OR** • Any combination of two trimesters	4 exams (if 1st trimester, 2 of which must be endovaginal) 2 exams of each trimester (if 1st trimester, both exams must be endovaginal)
Gynecological	
• Female pelvis • Female pelvis	1 endovaginal 3 endovaginal or transabdominal
General	
• Complete Upper Abdominal Ultrasound • Select ***3 different exams*** from the following list: 1. Female pelvis 2. Renal/urinary 3. Transrectal/prostate 4. Pediatric neurosonology 5. Small parts ***(select only one exam)***: Scrotum **OR** Thyroid/parathyroid	1 exam 3 exams
Vascular (1 exam type from each category performed at this site: Peripheral, Cerebrovascular, Abdominal, and/or Deep Abdominal)	
• **Peripheral Exams:** ***Arterial*** 1. Arterial occlusive disease 2. Bypass graft 3. Soft-tissue abnormality 4. Abnormal vascular communication **OR** ***Venous*** 1. Thrombosis-lower extremities 2. Thrombosis-upper extremities 3. Vein mapping 4. Incompetence	1 normal and 1 abnormal exams 1 normal and 1 abnormal exams
• **Cerebrovascular Exam** Extracranial carotid (bilateral)	1 normal and 1 abnormal exams
• **Abdominal Exams:** ***Liver*** **OR** ***Renal*** 1. Liver vasculature — 1. Renal artery stenosis 2. Liver transplantation — 2. Renal vein thrombosis 3. TIPS — 3. Renal artery thrombosis	1 normal and 1 abnormal exams
• **Deep AbdominalEx ams:** Aorta and branches **OR** Inferior vena cava and draining veins	1 normal and 1 abnormal exams

Accreditation Fees

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

Accreditation Fees	
Cycle	**Fees**
Accreditation (Initial cycle and renewal)	$1000 OB antepartum ultrasound, only $1000 Trimester Specific Obstetrical, only $1000 Gynecological ultrasound, only $1000 General ultrasound, only $1000 Vascular only $1100 Combination accreditation (two types) $1200 Combination accreditation (three types) $1300 Combination accreditation (all types)
Repeat	$500
Reinstate/Corrective Action Plan	$1000 Single $1100 Two types $1200 Three types $1300 Four types
Add new module mid cycle	$1000 for one additional module $1100 for two additional modules $1200 for three additional modules
Replacement Certificate	$65 per certificate

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 "Ultrasound". A link to "Frequently Asked Questions" is available in the Ultrasound menu, along with other useful information about accreditation and many of the program's forms. To contact the ACR Ultrasound Accreditation Program office by phone, dial (800) 770-0145.

Appendix II

(IDTF Educational Efforts)

On September 20, 2006, an NCQDIS delegation met with CMS staff to discuss CMS-1321-P. During this discussion, the issue of how to assure appropriate utilization was addressed. NCQDIS Policy Committee chair, Liz Quam, offered to provide examples of the educational efforts undertaken by radiology groups/ IDTFs to educate treating/ referring physicians. The following is an example from one market of the types of education underway. It was chosen for the market's location as a rural regional center with a group of three radiologists. In this and similar geographic areas, data indicates that primary care providers drive utilization. NCQDIS would be pleased to provide other examples, based on geographic location, from around the country if CMS requests it.

St. Cloud Center for Diagnostic Imaging
2006 Educational Presentations for Referring Physicians

1. **January 3, 2006** Dr. Kerry Kallas met with Dr. [REDACTED]. Focus: musculoskeletal imaging guidelines that enhance imaging of stress fractures as well as other musculoskeletal conditions.

2. **January 11, 2006** Dr. Kerry Kallas met with Dr. [REDACTED]. Focus: Imaging guidelines that promote best practices for musculoskeletal imaging.

3. **January 31, 2006** Dr. Kerry Kallas met with Dr. [REDACTED]. Focus: Appropriate utilization of musculoskeletal imaging, as it pertains to podiatry.

4. **February 1, 2006** Dr. Todd Cunningham's *Consult* clinical article "PET/CT Imaging in the Workup of the Solitary Pulmonary Nodule (SPN) was distributed to referring physicians in the community. Focus: appropriate utilization of PET/CT according to CMS guidelines.

5. **February 1, 2006** Dr. Todd Cunningham met with staff at the [REDACTED]. Focus: "Pain management." Appropriate utilization of therapeutic/diagnostic injections.

6. **February 2, 2006** CDI techs met staff at the [REDACTED]. Focus: General overview of nuclear medicine with an emphasis on patient appropriate care—guidelines for utilization of nuclear imaging vs. stress echo.

7. **February 6, 2006** Dr. Kerry Kallas met with Dr. [REDACTED]. Focus: Imaging guidelines that promote best practices for musculoskeletal imaging.

8. **February 9, 2006** Dr. Yair Safriel met the [REDACTED]. Focus: Dementia and the appropriate utilization of PET/CT in the diagnosis of the disease.

9. **February 14, 2006** Dr. Yair Safriel met the physicians of the [REDACTED]. Focus: "Imaging of the Aging Brain." Appropriate utilization of various imaging techniques in the elderly patient.

10. **February 15, 2006** Dr. Kerry Kallas met with Dr. [REDACTED]. Focus: Musculoskeletal imaging guidelines that promote best practices.

11. **February 17, 2006** Dr. Kerry Kallas met with Dr. [REDACTED]. Focus: Musculoskeletal imaging guidelines that promote best practices.

12. **February 20, 2006** Dr. Kerry Kallas met with Dr. [REDACTED]. Focus: Appropriate utilization of musculoskeletal imaging, as it pertains to podiatry.

13. **February 21, 2006** Dr. Kerry Kallas met with Dr. [REDACTED]. Focus: Appropriate utilization of musculoskeletal imaging, as it pertains to podiatry.

14. **February 24, 2006** Dr. Yair Safriel met with physicians of [REDACTED]. Focus: "Basic Pathology of Lumbar Spine." Appropriate utilization of imaging as a tool for diagnosis.

15. **March 3, 2006** Dr. Todd Cunningham met physicians of [REDACTED]. Focus: "Breast MRI Imaging." Utilization of Breast MRI as an adjunct to mammography and ultrasound to promote best practices.

16. **March 14, 2006** Dr. Kerry Kallas met with physicians of [REDACTED]. Focus: "Imaging of Stress Fractures." Imaging guidelines that promote best practices.

17. **March 9, 2006** Dr. Kerry Kallas met with physicians of [REDACTED]. Focus: Musculoskeletal imaging guidelines that promote best practices.

18. **March 14, 2006** Dr. Yair Safriel met physicians of [REDACTED]. Focus: "Imaging of the Aging Brain." Appropriate utilization of various imaging techniques in the elderly patient.

19. **March 14, 2006** Dr. Kerry Kallas met with Dr. [REDACTED]. Focus: Appropriate utilization of musculoskeletal imaging, as it pertains to podiatry.

20. **March 16, 2006** Dr. Yair Safriel met physicians of the [REDACTED]. Focus: "Chronic Back Pain and Weight Bearing Imaging." Appropriate utilization of various imaging techniques for the patient presenting with low back pain.

21. **March 17, 2006** CDI techs met with staff of the [REDACTED]. Focus: General overview of nuclear medicine with an emphasis on patient appropriate care—guidelines for utilization of nuclear imaging vs. stress echo.

22. **March 17, 2006** Dr. Yair Safriel met staff at [REDACTED]. Focus: "Imaging of the Aging Brain." Appropriate utilization of various imaging techniques in the elderly patient.

Appendix II: Example of Educational Effort by IDTFs regarding appropriateness criteria

23. **March 24, 2006** Dr. Yair Safriel met with staff at the [REDACTED]. Focus: "Imaging of the Aging Brain." Focus: Appropriate utilization of various imaging techniques in the elderly patient.

24. **March 30, 2006** Dr. Yair Safriel met with staff of [REDACTED]. Focus: "Pain Management." Focus: Appropriate utilization of therapeutic/diagnostic injections.

25. **April 1, 2006** Elizabeth Klodas, M.D., FACC's *In A Heart Beat* article "Resting Echocardiogram: when should I consider it for my patients?" was distributed to referring physicians/clinicians. Focus: appropriate utilization of echocardiograms based on patient indications.

26. **April 1, 2006** Dr. Kerry Kallas presented at the MN Academy of Physician Assistants conference. Focus: Advanced imaging guidelines that promote best practices for musculoskeletal imaging.

27. **April 4, 2006** Dr. Elizabeth Klodas met with staff of [REDACTED]. Focus: "Echocardiography and its Use in Primary Care."

28. **April 5, 2006** Dr. Todd Cunningham met with physicians of [REDACTED]. Focus: "Pain management." Appropriate utilization of therapeutic/diagnostic injections.

29. **April 6, 2006** Dr. Kerry Kallas met with staff of [REDACTED]. Focus: "Imaging of Stress Fractures." Imaging guidelines that promote best practices.

30. **April 8, 2006** Dr. Todd Cunningham presented at the MN Association of Physical Therapists annual conference. Focus: "Pain Management." Appropriate utilization of therapeutic/diagnostic injections.

31. **April 11, 2006** Dr. Kerry Kallas presented to staff of [REDACTED]. Focus: "Imaging of Stress Fractures" – imaging guidelines that promote best practices.

32. **April 25, 2006** Dr. Yair Safriel met the staff of [REDACTED]. Focus: "Imaging of the Aging Brain." Appropriate utilization of various imaging techniques in the elderly patient.

33. **May 1, 2006** Elizabeth Klodas, M.D., FACC's *In A Heart Beat* article "Hypertension: when is echocardiogram useful?" was distributed to referring physicians. Focus: appropriate utilization of echocardiograms for patients with hypertension.

34. **May 5, 2006** Dr. Elizabeth Klodas met with staff [REDACTED]. Focus: "Echocardiography and its Use in Primary Care."

35. **May 11, 2006** Dr. Todd Cunningham met with staff of [REDACTED]. Focus: "Breast MRI Imaging." Utilization of Breast MRI as an adjunct exam to mammography and ultrasound to promote best practices.

Appendix II: Example of Educational Effort by IDTFs regarding appropriateness criteria

36. **June 5, 2006** Dr. Kerry Kallas met with staff of [REDACTED]. Focus: "Imaging of Stress Fractures." Imaging guidelines that promote best practices.

37. **September 1, 2006** Elizabeth Klodas, M.D., FACC's *In A Heart Beat* article "Stress echo and nuclear: which test for what patient?" was distributed to referring physicians. Focus: appropriate utilization of echocardiograms and nuclear stress studies based on patient indications.

38. **September 28, 2006** CME presentation by Dr. Todd Cunningham to referring physicians in [REDACTED]. Focus: "Diagnostic and Therapeutic Spinal & Joint Injections for Pain Management: Indications and Review of Procedures." Appropriate utilization of spinal injections for patients presenting with back pain.

39. **October 26, 2006** CME presentation by Dr. Kerry Kallas to referring physicians in [REDACTED]. Focus: "Musculoskeletal Imaging Review." Imaging guidelines that promote best practices for musculoskeletal imaging.

40. **November 27, 2006** Dr. Kerry Kallas to meet with staff of [REDACTED]. Focus: "Imaging of Stress Fractures." Imaging guidelines that promote best practices.

41. **November 28, 2006** Dr. Todd Cunningham to meet with the staff of [REDACTED]. Focus: "Diagnostic and Therapeutic Spinal & Joint Injections for Pain Management: Indications and Review of Procedures." Appropriate utilization of spinal injections for patients presenting with back pain.

42. **November 30, 2006** CME presentation by Dr. Scott Swenson to referring physicians in [REDACTED]. Focus: "MR vs. CT: When to send to which modality." Imaging guidelines that promote best practices as well as appropriate modality utilization.

PET/CT Imaging in the Workup of the Solitary Pulmonary Nodule (SPN)

Todd Cunningham, M.D.
Medical Director & Body Radiologist

INSIDE THIS ISSUE

Todd Cunningham M.D. discusses how advancements in PET/CT imaging enable radiologists to evaluate and differentiate benign from malignant solitary pulmonary nodules (SPN) of the lung with more confidence.

PET/CT exams lead to a decrease in the false positives and false negatives inherent in PET alone, leading to faster, more accurate diagnoses, and better treatment planning and monitoring for patients.

Introduction

The finding of solitary pulmonary nodules (SPN) in patients is a common occurrence in clinical medicine and medical imaging. Most frequently, a nodule is found on chest x-ray (CXR) and is further investigated on CT. Some of these nodules have aggressive features and can have malignant potential proven or disproven via CT-guided lung biopsy. However, most do not have obviously aggressive features and turn out to be benign in the end.

The key has been to find a study that can help differentiate with more confidence malignant nodules from benign nodules of the lung.

PET/CT scanning has emerged as a tool in the investigation of pulmonary nodules. It has proven increasingly valuable in evaluation of such nodules to provide more confidence in declaring a nodule benign or warranting more invasive biopsy and surgery.

In cases in which a nodule is found to have little or no metabolic activity, it is presumed benign with higher confidence and the patient can avoid an unnecessary lung biopsy, with its associated risks and possible unnecessary thoracotomy.

Because of the value of PET imaging in the characterization of pulmonary nodules, it was approved by the Centers for Medicare and Medicaid Services in 1998. Specialists have most commonly ordered PET and now PET/CT exams. However, with increasing interest and participation in ongoing care by patients' internists and family practitioners, primary care providers are now ordering these exams more frequently. This article was written to further familiarize all providers about the exam itself, usefulness, and indications for pulmonary nodules.

PET/CT Background

PET (Positron Emission Tomography) has been an excellent institutional investigative tool in decades past. In recent years, newer technology has allowed PET scanning to become portable and more easily used in the community, as evidenced by PET scanners appearing in non-research hospitals and imaging centers.

PET scans have proven excellent at finding evidence of a malignancy, metastases, or tumor recurrence. It is therefore used for detection, staging,

(continued on page 2)

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(continued from page 1)

and restaging of many types of cancers. As a corollary, it is used to monitor treatment efficacy, and in planning radiation or surgical therapy.

With further advances and approaches in technology, one imaging exam now provides an excellent map of metabolic activity acquired by cross-sectional PET and merges this data with CT images. This is called PET/CT imaging and it has become the new standard of performing PET scanning in the community, replacing standalone PET. In PET/CT, the metabolic imaging of PET is fused electronically on a computer workstation with the CT images obtained at the same time.

The advantage of combining the highly specific anatomic resolution of CT with the sensitive metabolic image of PET is that it allows the exact anatomic location of the increased PET activity to be identified. PET/CT is also more accurate than a separate PET or CT exam. This combination approach leads to a decrease in the false positives and false negatives inherent in PET alone, leading to a faster, more accurate diagnosis, and better treatment planning and monitoring.

How PET/CT Works

PET provides a metabolic map of activity throughout the body, normal and abnormal, whereas CT maps the anatomic areas imaged.

PET scanning utilizes a radioactive Fluorine atom attached to a glucose analogue to monitor metabolic activity (utilization of glucose) throughout the body. The substance is called F-18 FDG (Fluoro-2-deoxy-D-glucose or "FDG") and is injected through a peripheral vein. Areas of inflammatory change and cancers in the body utilize glucose at a faster rate than normal tissues. So, any increase in utilization of glucose relative to the surrounding tissues shows up as bright or "hyper-metabolic" areas on images.

Factors are taken into account to monitor the ratio of a lesion to the background activity, such as the patient's body size, etc., to generate what is called a "SUV" or Standardized Uptake Value. An SUV of >2.5 for a pulmonary nodule is significant and would warrant further investigation.

The CT images are acquired during the same patient exam using a PET/CT scanner that has a built-in CT scanner and PET detection crystals. The images and data are viewed separately as well as fused. Images are viewed in all imaging planes (Figures 1 and 2).

Figure 1a: CT Exam

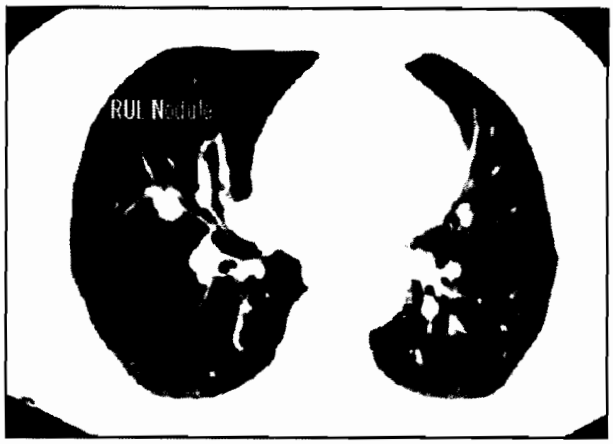
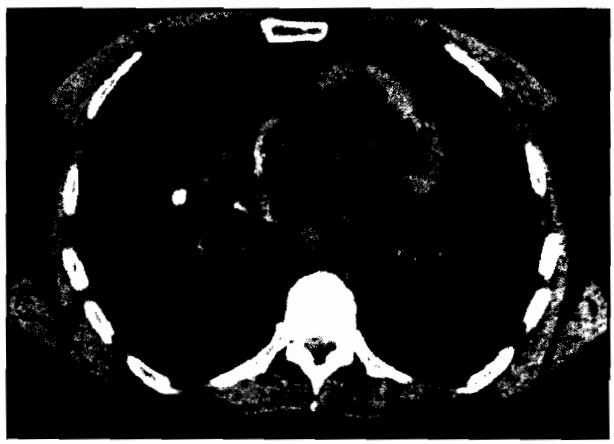


Figure 1b: PET/CT Exam



Figures 1a and 1b: Right upper lobe (RUL) nodule with increased PET metabolic activity. Dx: Non-small cell CA

Background of SPN

The difficulty of solitary pulmonary nodules (SPN) is that they are frequently found, and the majority, in the end, turn out to be benign. The key is to provide a sensitive and accurate diagnosis that indicates which nodules are more suspicious and need to be investigated further with biopsy and/or surgery.

A SPN study by Duke University from several years ago characterized this best.[1] The PET study found that:

- 20-30% of patients with lung cancer present with a SPN
- However, 60% of SPNs that warranted resection were benign
- They concluded that size is not very helpful:
  - 80% of benign nodules resected were <2 cm
  - 15% of malignant nodules resected were <1 cm

CT alone is frequently indeterminate and necessitates further investigation by needle biopsy or surgery. Needle biopsy alone may or may not provide

an accurate diagnosis and has a risk of pneumothorax and occasional need for hospitalization. PET performed on nodules 1cm or greater in size has shown results of:

- 92% sensitivity
- 90% specificity

A review of literature from the University of North Carolina sought to define the appropriate place for PET imaging in the diagnosis of pulmonary nodules or masses (Table 1).[1] Their conclusions were that PET imaging:

- For diagnosis of pulmonary lesions is most useful in patients with low to intermediate risk of lung cancer
- Has little to no role in patients with very low or high risk
- Has little role in patients with lesions <1 cm diameter, lesions suspected to be infection, atypical carcinoid, or bronchoalveolar carcinoma

PET limitations for SPN

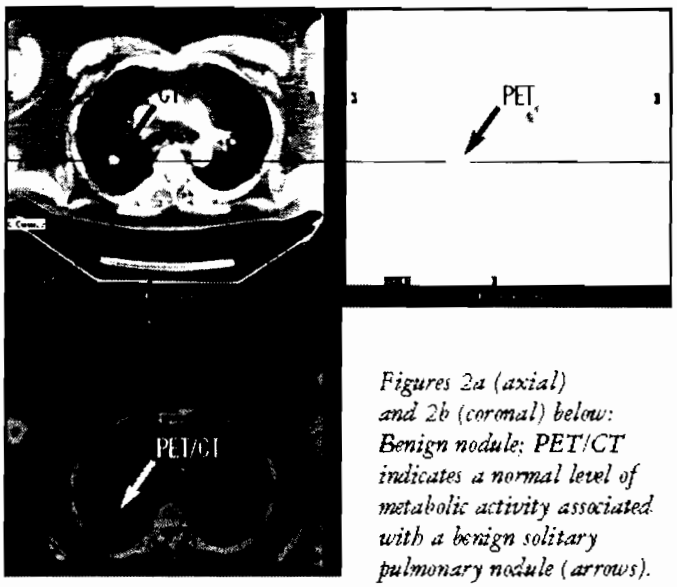
False Negatives:

- Decreased sensitivity in lesions <1 cm or high fibrous tissue content, limit <1 cm
- Bronchoalveolar carcinoma
- Carcinoid and rarely well-differentiated adenocarcinoma

False Positives:

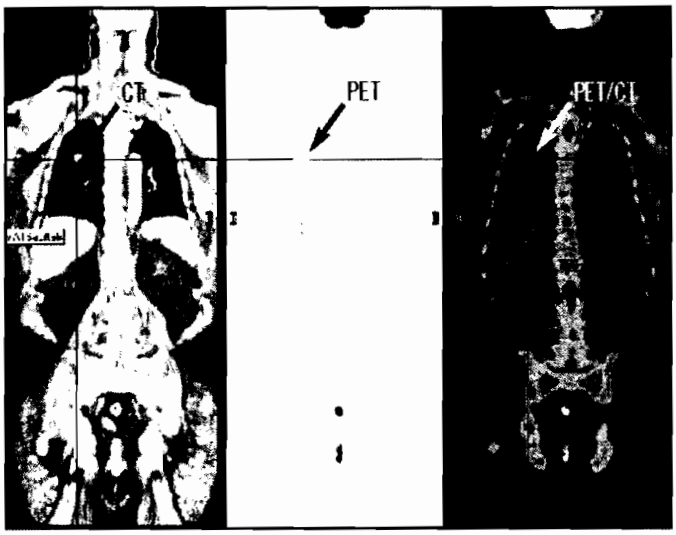
- Granulomatous diseases such as TB, histoplasmosis, sarcoidosis, coccidiomycosis
- Acute pneumonia, abscess
- Radiation pneumonitis
- Post-operative changes
- Healing fractures of the ribs and spinal column overlapping as false nodules

Figure 2a



Figures 2a (axial) and 2b (coronal) below: Benign nodule; PET/CT indicates a normal level of metabolic activity associated with a benign solitary pulmonary nodule (arrows).

Figure 2b



(continued on page 4)

Table 1

Very low	<1	CXR or CT in 6, 12, 24 months
Low	<1	CT in 3, 6, 12, or 24 months
Low	≥1	PET
Intermediate	<1	CT in 3, 6, 12, or 24 months
Intermediate	≥1	PET
High	<1	Staging as dictated by presentation

Summary

PET/CT has become a common and invaluable investigative imaging tool for primary care and specialty physicians in the workup of the solitary pulmonary nodule. PET/CT demonstrates a high sensitivity and specificity for pulmonary nodules 1 cm or greater in size. Since the majority of pulmonary nodules are benign, this can lead to limiting more invasive investigations of a nodule by biopsy or surgery and the respective risk to the patient. Nodules found can be more clearly defined as needing no further workup or non-invasive follow-up.

Interpretations and Locations

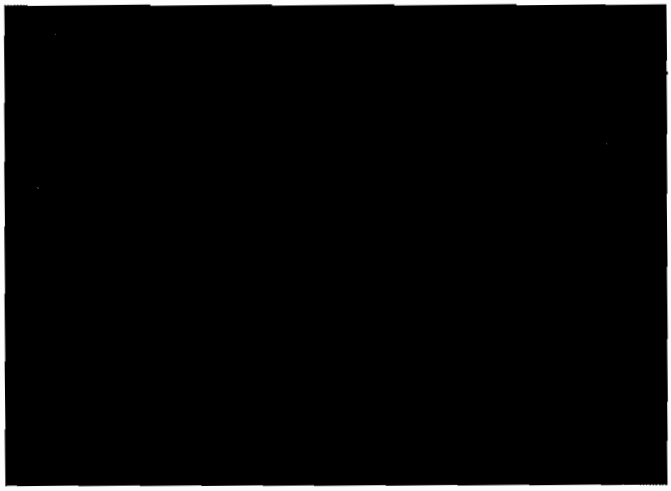
At CDI, we have dedicated PET/CT specialists who have undertaken further study in PET/CT imaging in order to provide more specific and valuable interpretations for your patients, including Body and Neuro/ENT imaging. This is in keeping with our subspecialization philosophy to provide the best interpretations possible.

We currently offer PET/CT imaging in our St. Cloud, St. Louis Park, and Mendota Heights locations. PET/CT is also available in Alexandria at our new location in the Douglas County Hospital for patients who live in the area.

References

1. Patz E, et al. "Positron emission tomography imaging in lung cancer." Clin Lung Cancer 1.1 (1999): 43-48.

2. Detterbeck FC, et al. "Seeking a home for a PET, part 1: Defining the appropriate place for positron emission tomography imaging in the diagnosis of pulmonary nodules or masses." Chest 125.6 (2004): 2294-2299.



If you have questions about what imaging exam to order for your patient, or questions about PET/CT exams or solitary pulmonary nodules, please call 320.251.0609 or 800.234.3055.

The mission of Center for Diagnostic Imaging (CDI) is to improve the lives of those we serve through the highest quality, care and safety in imaging services.

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CENTER FOR DIAGNOSTIC IMAGING

September 2006

In a Heart Beat

A PUBLICATION FROM CARDIOVASCULAR IMAGING CONSULTANTS AT CENTER FOR DIAGNOSTIC IMAGING

Question & Answer

Q: I am not sure when to choose a stress echo over a stress nuclear study.

Dr. Elizabeth Klodas

A: There are definite applications for each stress testing modality. These are not competitive tests, but complementary evaluations.

Stress Echo and Nuclear

Which test for what patient?

-Elizabeth Klodas, M.D., F.A.C.C.

A stress echocardiogram relies on evaluating wall motion response to stress (with either exercise or Dobutamine infusion). In the setting of physiologically significant coronary artery disease (CAD), the appearance of wall motion abnormalities precedes ECG changes during stress. Stress echocardiography therefore has a higher sensitivity than stress testing alone. A normal stress echocardiogram (with adequate exercise duration/heart rate attained), is also associated with a very good prognosis and a low risk (2-3%/year) of subsequent cardiac events. Stress echocardiograms are straightforward to perform, require no radiation exposure, and are significantly less expensive (1/3 to 1/2 the cost) as compared to nuclear stress procedures.

Nuclear stress studies evaluate myocardial perfusion/coronary blood flow in response to stress. This test depends upon coronary artery physiology and the ability of coronary arteries to dilate in proportion to myocardial metabolic demand. The diminished ability of coronary arteries to dilate in response to stress (reduced coronary "flow reserve") precedes wall motion changes, so stress nuclear studies have the highest sensitivity for picking up underlying CAD. Stress nuclear studies can also be used to effectively risk stratify patients into low, intermediate, and high risk groups. Patients with normal images, in the setting of adequate stress, have a very low risk of subsequent cardiac events (<1%/year). Those with markedly abnormal images (REGARDLESS OF THE ECG RESULTS) are at markedly increased risk of cardiac death, and benefit from revascularization. Patients with mildly abnormal scans can be safely managed medically, without excess risk. Stress nuclear studies involve a small radiation exposure and are relatively expensive.

A stress echocardiogram should be considered the primary stress imaging study for most patients. Under most circumstances, the sensitivity and prognostic capabilities of this type of evaluation are sufficient for patient management.

Stress nuclear studies should be utilized when the cost and radiation exposure associated with the test are justified and truly impact patient care. Patients who should be preferentially referred for stress nuclear studies are those with known coronary or vascular disease, and patients with diabetes. In these individuals, making the diagnosis of CAD is less relevant (all of these patients have CAD). The value of the study lies in defining near term prognosis, which can be of significant value to determining optimal care. Stress echo is less potent in terms of risk stratification.

Additional indications for stress nuclear studies include patients who:

- Require pharmacologic stress testing (in general, Adenosine infusion - utilized with nuclear - is safer than Dobutamine infusion used with echo).
- Have LBBB; Adenosine nuclear studies are preferred to reduce the possibility of a false positive result (as can be seen with plain treadmill stress, stress echo and exercise nuclear studies).
- Require a very high diagnostic sensitivity.
- Are candidates for stress echo studies, but are obese, have significant lung disease, chest wall deformity, or previous non-diagnostic echo evaluation (with the expectation that image quality on the stress echo study could be suboptimal for attaining a definitive diagnosis).

CVIC

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Comparison of Cost Savings

CPT	Description	APC	Proposed CY 2007 OPPS Payment Rate	Proposed CY 2007 PFS Payment*	Proposed CY 2007 PFS Payment with 25% Reduction Only	Percentage Decrease in CY 2007 Payment if 25% Reduction Only	Proposed CY 2007 Payment applying the OPPS Cap Only without the Multiple Procedure Reduction	Percentage Decrease in CY 2007 Payment if OPPS Cap Only	Proposed CY 2007 Payment applying the OPPS Cap after 25% Reduction	Percentage Decrease in CY 2007 Payment if OPPS Cap Applied After 25% Reduction
72193	Ct pelvis w/dye	283	$ 257.64	$ 276.27	$ 207.20	-25%	$ 257.64	-7%	207.20	-25%
74160	Ct abdomen w/dye	283	$ 257.64	$ 288.02	$ 288.02	0%	$ 257.64	-11%	257.64	-11%
	TOTAL			**$ 564.29**	**$ 495.23**	**-12%**	**$ 515.28**	**-9%**	**464.84**	**-18%**
72192	Ct pelvis w/o dye	332	$ 194.69	$ 233.45	$ 233.45	0%	$ 194.69	-17%	194.69	-17%
74150	Ct abdomen w/o dye	332	$ 194.69	$ 226.25	$ 169.69	-25%	$ 194.69	-14%	169.69	-25%
	TOTAL			**$ 459.70**	**$ 403.13**	**-12%**	**$ 389.38**	**-15%**	**364.38**	**-21%**
74170	Ct abdomen w/o and w/dye	333	$ 307.88	$ 369.50	$ 369.50	0%	$ 307.88	-17%	307.88	-17%
72194	Ct pelvis w/o and w/dye	333	$ 307.88	$ 350.17	$ 262.63	-25%	$ 307.88	-12%	262.63	-25%
	TOTAL			**$ 719.67**	**$ 632.13**	**-12%**	**$ 615.76**	**-14%**	**570.51**	**-21%**
71260	Ct chest w/dye	283	$ 257.64	$ 287.26	$ 215.45	-25%	$ 257.64	-10%	215.45	-25%
74160	Ct abdomen w/dye	283	$ 257.64	$ 288.02	$ 288.02	0%	$ 257.64	-11%	257.64	-11%
	TOTAL			**$ 575.28**	**$ 503.47**	**-12%**	**$ 515.28**	**-10%**	**473.09**	**-18%**
71250	Ct chest w/o dye	332	$ 194.69	$ 237.62	$ 237.62	0%	$ 194.69	-18%	194.69	-18%
74150	Ct abdomen w/o dye	332	$ 194.69	$ 226.25	$ 169.69	-25%	$ 194.69	-14%	169.69	-25%
	TOTAL			**$ 463.87**	**$ 407.30**	**-12%**	**$ 389.38**	**-16%**	**364.38**	**-21%**
74170	Ct abdomen w/o and w/dye	333	$ 307.88	$ 369.50	$ 369.50	0%	$ 307.88	-17%	307.88	-17%
71270	Ct chest w/o and w/dye	333	$ 307.88	$ 361.16	$ 270.87	-25%	$ 307.88	-15%	270.87	-25%
	TOTAL			**$ 730.66**	**$ 640.37**	**-12%**	**$ 615.76**	**-16%**	**578.75**	**-21%**
71551	Mri chest w/dye	0284	$ 385.24	$ 568.46	$ 568.46	0%	$ 385.24	-32%	385.24	-32%
74182	Mri abdomen w/dye	0284	$ 385.24	$ 563.16	$ 422.37	-25%	$ 385.24	-32%	385.24	-32%
	TOTAL			**$ 1,131.62**	**$ 990.83**	**-12%**	**$ 770.48**	**-32%**	**770.48**	**-32%**
74181	Mri abdomen w/o dye	336	$ 360.07	$ 450.22	$ 337.67	-25%	$ 360.07	-20%	337.67	-25%
71550	Mri chest w/o dye	336	$ 360.07	$ 489.64	$ 489.64	0%	$ 360.07	-26%	360.07	-26%
	TOTAL			**$ 939.86**	**$ 827.30**	**-12%**	**$ 720.14**	**-23%**	**697.74**	**-26%**

Comparison of Cost Savings

CPT	Description	APC	Proposed CY 2007 OPPS Payment Rate	Proposed CY 2007 PFS Payment	Proposed CY 2007 PFS Payment with 20% Reduction Only	Percentage Decrease in CY 2007 Payment if 20% Reduction Only	Proposed CY 2007 Payment applying the OPPS Cap Only without the Practice Expense Reduction	Percentage Decrease in CY 2007 Payment if OPPS Cap Only	Proposed CY 2007 Payment applying the OPPS Cap after 10% Reduction	Percentage Decrease in CY 2007 Payment if OPPS Cap Applied After 10% Reduction
72196	Mri pelvis w/dye	0284	$ 385.24	$ 544.97	$ 408.72	-25%	$ 385.24	-29%	385.24	-29%
74182	Mri abdomen w/dye	0284	$ 385.24	$ 563.16	$ 563.16	0%	$ 385.24	-32%	385.24	-32%
	TOTAL			$ 1,108.12	$ 971.88	-12%	$ 770.48	-30%	770.48	-30%
74181	Mri abdomen w/o dye	336	$ 360.07	$ 450.22	$ 337.67	-25%	$ 360.07	-20%	337.67	-25%
72195	Mri pelvis w/o dye	336	$ 360.07	$ 470.31	$ 470.31	0%	$ 360.07	-23%	360.07	-23%
	TOTAL			$ 920.53	$ 807.97	-12%	$ 720.14	-22%	697.74	-24%
72141	Mri neck spine w/o dye	336	$ 360.07	$ 457.04	$ 342.78	-25%	$ 360.07	-21%	342.78	-25%
72146	Mri chest spine w/o dye	336	$ 360.07	$ 493.80	$ 370.35	-25%	$ 360.07	-27%	360.07	-27%
72148	Mri lumbar spine w/o dye	336	$ 360.07	$ 494.18	$ 494.18	0%	$ 360.07	-27%	360.07	-27%
	TOTAL			$ 1,445.03	$ 1,207.32	-16%	$ 1,080.21	-25%	1,062.92	-26%
72142	Mri neck spine w/dye	0284	$ 385.24	$ 552.92	$ 414.69	-25%	$ 385.24	-30%	385.24	-30%
72147	Mri chest spine w/dye	0284	$ 385.24	$ 532.46	$ 399.34	-25%	$ 385.24	-28%	385.24	-28%
72149	Mri lumbar spine w/dye	0284	$ 385.24	$ 552.92	$ 552.92	0%	$ 385.24	-30%	385.24	-30%
	TOTAL			$ 1,638.31	$ 1,366.96	-17%	$ 1,155.72	-29%	1,155.72	-29%

*Calculated using the conversion factor for CY 2006, which is $37.8975.

Appendix IV

(Proposed APC Imaging Groupings)

CT APC Groupings

CPT	Proposed APC Grouping	Current APC
	CT EXTREMITIES/OTHER w/DYE	
70481	Ct orbit/ear/fossa w/dye	283
70487	Ct maxillofacial w/dye	283
70491	Ct soft tissue neck w/dye	283
73201	Ct upper extremity w/dye	283
73701	Ct lower extremity w/dye	283
76355	Ct scan for localization	283
76360	Ct scan for needle biopsy	283
	CT CORE w/DYE	
71260	Ct thorax w/dye	283
72193	Ct pelvis w/dye	283
74160	Ct abdomen w/dye	283
70460	Ct head/brain w/dye	283
72126	Ct neck spine w/dye	283
72129	Ct chest spine w/dye	283
72132	Ct lumbar spine w/dye	283
	CT EXTREMITIES/OTHER w/o DYE	
70480	Ct orbit/ear/fossa w/o dye	332
70486	Ct maxillofacial w/o dye	332
70490	Ct soft tissue neck w/o dye	332
73200	Ct upper extremity w/o dye	332
73700	Ct lower extremity w/o dye	332
	CT CORE w/o DYE	
70450	Ct head/brain w/o dye	332
71250	Ct thorax w/o dye	332
72192	Ct pelvis w/o dye	332
74150	Ct abdomen w/o dye	332
72125	Ct neck spine w/o dye	332
72128	Ct chest spine w/o dye	332
72131	Ct lumbar spine w/o dye	332
	CT CORE w/o & w/ DYE	
74170	Ct abdomen w/o & w/dye	333
71270	Ct thorax w/o & w/dye	333
70470	Ct head/brain w/o & w/dye	333
72127	Ct neck spine w/o & w/dye	333
72130	Ct chest spine w/o & w/dye	333
72133	Ct lumbar spine w/o & w/dye	333
72194	Ct pelvis w/o & w/dye	333

CT APC Groupings (continued)

CPT	Proposed APC Grouping	Current APC
	CT EXTREMITIES/OTHER w/o & w/DYE	
70482	Ct orbit/ear/fossa w/o&w/dye	333
70488	Ct maxillofacial w/o & w/dye	333
70492	Ct sft tsue nck w/o & w/dye	333
73202	Ct uppr extremity w/o&w/dye	333
73702	Ct lwr extremity w/o&w/dye	333
76362	Ct guide for tissue ablation	333
0067T	CT colongraphy; dx	333

MRA APC Groupings

CPT	Proposed APC Grouping	Current APC
	MRA CORE w/o DYE	
C8910	MRA w/o cont, chest	336
C8919	MRA w/o cont, pelvis	336
70547	Mr angiography neck w/o dye	336
70544	Mr angiography head w/o dye	336
	MRA EXTREMITIES/OTHER W/O DYE	
C8913	MRA w/o cont, lwr ext.	336
	MRA EXTREMITIES/OTHER W/DYE	
C8912	MRA w/cont, lwr ext	0284
	MRA EXTREMITIES/OTHER W/O & W/DYE	
C8914	MRA w/o fol w/ cont, lwr ext	337
	MRA CORE w/ & w/o DYE	
70546	Mr angiograph head w/o&w/dye	337
70549	Mr angiograph neck w/o&w/dye	337
C8902	MRA w/o fol w/cont, abd	337
C8920	MRA w/o fol w/cont, pelvis	337
C8911	MRA w/o fol w/cont, chest	337
	MRA CORE w/ DYE	
C8900	MRA w/cont, abd	0284
C8909	MRA w/cont, chest	0284
C8918	MRA w/cont, pelvis	0284
C8901	MRA w/cont, abd	336
70545	Mr angiography head w/dye	0284
70548	Mr angiography neck w/dye	0284

MRI APC Groupings

CPT	Proposed APC Grouping	Current APC
	MRI EXTREMITIES/OTHER w/o DYE	
C8908	MRI w/o cont, breast	337
C8904	MRI w/o cont, breast, uni	336
C8907	MRI w/o cont, breast, bi	336
73221	Mri joint upr extrem w/o dye	336
73721	Mri jnt of lwr extre w/o dye	336
73218	Mri upper extremity w/o dye	336
73718	Mri lower extremity w/o dye	336
	MRI CORE w/o DYE	
74181	Mri abdomen w/o dye	336
70557	Mri brain w/o dye	336
71550	Mri chest w/o dye	336
72195	Mri pelvis w/o dye	336
70551	Mri brain w/o dye	336
72141	Mri neck spine w/o dye	336
72146	Mri chest spine w/o dye	336
72148	Mri lumbar spine w/o dye	336
	MRI EXTREMITIES/OTHER w/o & w/ DYE	
73220	Mri uppr extremity w/o&w/dye	337
73223	Mri joint upr extr w/o&w/dye	337
73720	Mri lwr extremity w/o&w/dye	337
73723	Mri joint lwr extr w/o&w/dye	337
C8905	MRI w/o fol w/cont, brst, un.	337
	MRI CORE w/o & w/ DYE	
70543	Mri orbt/fac/nck w/o & w/dye	337
74183	Mri abdomen w/o & w/dye	337
70553	Mri brain w/o & w/dye	337
72156	Mri neck spine w/o & w/dye	337
72157	Mri chest spine w/o & w/dye	337
72158	Mri lumbar spine w/o & w/dye	337
70559	Mri brain w/o & w/dye	337
71552	Mri chest w/o & w/dye	337
72197	Mri pelvis w/o & w/dye	337
	MRI EXTREMITIES/OTHER w/ DYE	
73219	Mri upper extremity w/dye	0284
73222	Mri joint upr extrem w/dye	0284
73719	Mri lower extremity w/dye	0284
73722	Mri joint of lwr extr w/dye	0284
C8903	MRI w/cont, breast, uni	0284
C8906	MRI w/cont, breast, bi	0284

MRI APC Groupings (continued)

CPT	Proposed APC Grouping	Current APC
	MRI CORE w/ DYE	
70542	Mri orbit/face/neck w/dye	0284
70552	Mri brain w/dye	0284
70558	Mri brain w/dye	0284
71551	Mri chest w/dye	0284
72142	Mri neck spine w/dye	0284
72147	Mri chest spine w/dye	0284
72149	Mri lumbar spine w/dye	0284
72196	Mri pelvis w/dye	0284
74182	Mri abdomen w/dye	0284