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Version 3.2  March 2013
PART A
CQIE QUALIFICATION PROGRAM

1. INTRODUCTION

1.1 Background
Advanced imaging methodologies play a pivotal role in cancer care, by providing the ability to detect tumors early and to guide therapy as well as in subsequent disease monitoring and surveillance. Advantages inherent in the imaging (in vivo) assays include the ability to obtain spatially localized information over large volumes of tissue or the entire body compared to the limited sampling required for in vitro assays and its inherent drawbacks. In addition, in vivo imaging assays have the ability to provide multiple evaluations of a molecular target or tumor metabolism over time allowing for adaptive therapy without invasive procedures.

Continued progress in research and development of imaging agents, methodologies and technologies holds promise for better cancer care, for example, with improved tumor detection and characterization. These new agents and approaches exploit various pathophysiologic and anatomic characteristics of tumors with evaluations of phenomena such as metabolism, proliferation, hypoxia, angiogenesis, essential signal pathway blockage(s) and other tumor microenvironment modifications. In addition, the use of validated molecular imaging agents is critical to the drug discovery and development process as well as the ongoing NCI commitment to further our understanding of cancer biology.

NCI Cancer Centers serve as centers for transdisciplinary, translational and clinical research and they link cancer research to health service delivery systems outside the center via proactive dissemination programs. They represent the optimal sites to support and promote advanced quantitative imaging for measurement of response. However, there are often delays in the conduct of multicenter trials with advanced imaging aims due to 1) site selection and qualification based on study-specific imaging requirements; 2) dissemination of relevant qualification and imaging standards and for molecular and/or functional imaging; and 3) lack of a coordinated collaboration among the imaging and medical treatment disciplines. NCI has committed significant funding and support to the development of studies which answer key questions related to advanced quantitative imaging and is interested in supporting processes which enhance the operations of such trials.

1.2 Scope and Objectives
The primary objective of the CQIE program is to establish a resource of 'trial ready' sites within the NCI Cancer Centers Program that are capable of conducting clinical trials in which there is an integral molecular and/or functional advanced imaging endpoint. In support of this objective, the CQIE program will focus on the qualification of NCI Cancer
Centers to serve as centers of excellence capable of conducting quantitative imaging in the following areas: volumetric CT body, volumetric MR brain, DCE-MRI body, DCE-MRI brain, PET body (dynamic and static), and PET brain (dynamic and static). The CQIE project has been designed and funded to provide an initial assessment of site qualification and annual re-evaluation, to maintain CQIE qualification, for an additional three years. A full description of CQIE requirements is provided in Section 3 of this document.

1.3 MOP Overview and Purpose

This Manual of Procedures (MOP) is intended to provide NCI designated Cancer Centers with a description of the CQIE program and a set of guidelines regarding CQIE participation. A copy of the CQIE MOP will be distributed by email to each NCI Cancer Center. Additionally, the document will reside on the ACRIN-CQIE web page for download and/or reference.

1.3.1 Document Revisions

Given the dynamic and complex nature of diagnostic imaging it is anticipated that this MOP, and/or supporting documents or forms, will undergo revisions during the course of the CQIE program. Minor corrections which will not affect CQIE procedures, such as grammatical changes, will be designated as a minor version change (i.e. Version 1.0 revised to Version 1.1). Changes which affect actual process will be designated by a change in version number (i.e. Version 1.0 to Version 2.0). Sites will be notified of document revisions. A summary of changes will accompany all MOP revisions and will reside on the ACRIN-CQIE web page with the MOP.
2. ORGANIZATIONAL OVERVIEW

2.1 NCI Role and Responsibilities

On behalf of NCI, SAIC-Frederick (SAIC-F) issued a solicitation for proposals in December, 2009 (S10-070 for the prequalification of Cancer Centers as Centers of Quantitative Imaging Excellence) which ultimately led to the current contractual agreement between SAIC-F and the American College of Radiology Imaging Network (ACRIN) to develop and perform site qualification procedures for the NCI-CQIE Program. NCI will maintain oversight of the program and, through the Cancer Centers Program and the Cancer Imaging Program, will serve as a liaison to the cancer center community to create awareness and promote participation in this project and in advanced imaging clinical research.

2.2 ACRIN and ACR Role and Responsibilities

Through the subcontract issued by SAIC-F, ACRIN is charged with developing and maintaining qualification guidelines and associated standard operating procedures which support qualification of imaging centers in the following imaging modalities: volumetric CT body, volumetric MR brain, MR diffusion, DCE MRI body, DCE MRI brain, PET body (dynamic and static), and PET brain (dynamic and static).

ACRIN is responsible for the development and dissemination of the CQIE qualification requirements and managing the qualification process. ACRIN will maintain this manual to serve as a resource for participating cancer centers. ACRIN will provide additional support for the CQIE program by providing the QC phantoms (on loan, as needed) required for the qualification testing, web-based learning modules related to CQIE qualification processes and quantitative imaging, and an initial on-site technical support visit. ACRIN will conduct the qualitative and quantitative analysis of submitted images. The ACRIN Imaging Core Laboratory within the ACR Clinical Research Center (ACR-CRC) will provide the support and infrastructure for collection and management of the images and data submitted by participating sites. ACR accreditation reviewers and ACRIN scientists will conduct the analysis of submitted images and data and provide feedback to the submitting institutions. Successful completion of the qualification process will result in NCI designation as a Center of Quantitative Imaging Excellence. ACRIN will administer a one-time payment to each CQIE-qualified cancer center in recognition of the cost associated with the time and effort required to complete and maintain CQIE qualification. A list of qualified CQIE sites will be published on both the ACRIN and NCI web sites. In addition, ACRIN will, at the direction of the NCI, perform annual requalification of participating institutions.

In developing the CQIE qualification requirements, ACRIN took advantage of the ACR's established and highly recognized accreditation programs by incorporating elements of the modality-specific accreditation programs. However, the ACRIN-managed CQIE program should not be confused with ACR Accreditation. The CQIE and ACR Accreditation programs are independent programs that differ significantly in both scope and purpose. The CQIE program was designed to focus specifically on factors relevant to experimental, advanced
quantitative imaging and preparing sites to participate in multicenter imaging trials. Although imaging accreditation is highly recommended, it is not a CQIE requirement.

2.3 Site Role and Responsibilities

Cancer centers will need to execute the CQIE Memorandum of Understanding (MOU); this document is not included in the MOP but will be distributed to all NCI Cancer Centers as part of a site initiation packet. The MOU serves as a participation agreement and provides a mechanism for ACRIN to provide payment to the cancer center upon successful completion of the qualification process. The organizational structure amongst the NCI Cancer Centers varies greatly, from single facility institutions to multi-hospital consortia, and many have multiple imaging sites (i.e. hospital, outpatient clinic, affiliated imaging centers, etc.). Initial implementation of the CQIE program will be limited to one imaging site per cancer center. For most cancer centers this will be the main hospital. Qualification of additional cancer center imaging sites will be addressed in the near future.

CQIE participation will require a collaborative effort between the cancer center and the imaging site. Throughout the remainder of this document the term “site” refers to the combined resources and efforts of both the cancer center and the imaging site.

Each site is asked to identify a project leader to serve as the primary point of contact with ACRIN and to help coordinate and oversee the qualification activities at the site. The site will need active participation and an ongoing commitment from all three imaging modalities (MR, CT and PET) to include completion of on-line learning modules, annual acquisition and submission of qualification imaging (CQIE-specified phantom scans and imaging test cases), and on-going quality control (QC) activities. Each participating site must be committed to completing the qualification process expeditiously and agree to conduct annual requalification for 3 years.

2.4 ACRIN Contact Information

Should you have any questions or require additional information please consult the CQIE web site at http://www.acrin.org/NCI-CQIE.aspx or contact one of the ACRIN CQIE project team at the following:

<table>
<thead>
<tr>
<th>PROJECT MANAGEMENT</th>
<th>IMAGING</th>
</tr>
</thead>
<tbody>
<tr>
<td><a href="mailto:CQIE-Manager@acr.org">CQIE-Manager@acr.org</a></td>
<td><a href="mailto:CQIE-MR-CT@acr.org">CQIE-MR-CT@acr.org</a></td>
</tr>
<tr>
<td>Telephone: 215-940-8921</td>
<td><a href="mailto:CQIE-PET@acr.org">CQIE-PET@acr.org</a></td>
</tr>
<tr>
<td>Fax: 215-717-0860</td>
<td></td>
</tr>
</tbody>
</table>

ACRIN hours of operation are 8:30 – 5:00 ET
3. CQIE QUALIFICATION REQUIREMENTS AND METHODOLOGY

As discussed in Section 1.2, the primary objective of the CQIE program is to establish a resource of ‘trial ready’ cancer centers capable of participating in multicenter quantitative imaging trials. In support of this objective, the CQIE program establishes benchmarks for quantitative imaging parameters involving PET, DCE-MRI and CT/ MR volumetric protocols, providing a foundation for the CQIE site qualification methodology. The qualification requirements were designed to qualify scanners and to qualify site imaging capabilities while promoting standardization and harmonization of imaging data in multicenter clinical trials. Evolving advancements, however, may necessitate additional imaging requirements at the trial-specific level. Therefore, these benchmarks may need to be met, or even exceeded by participating institutions for future trial-specific qualification.

The site qualification requirements can be divided into four main categories: 1) personnel qualifications, 2) CQIE learning modules, 3) baseline and annual qualification imaging, and 4) standardized, continuous quality control measures – each are discussed below.

3.1 Personnel Qualifications

Qualified and well trained personnel are central to producing high quality images and maintaining the scientific rigor required of multicenter quantitative imaging trials. Qualifications and responsibilities of CT, MR, and PET personnel—radiologists, physicists, and imaging technologists—involved in NCI-sponsored clinical trials are expected to conform to ACR recommendations, as described in the applicable ACR Practice Guidelines and Technical Standards. By executing the MOU, cancer centers attest to their compliance with personnel qualifications as set forth in the ACR guidelines listed below.

<table>
<thead>
<tr>
<th>Modality Personnel</th>
<th>Applicable ACR Practice Guidelines and Technical Standards*</th>
</tr>
</thead>
</table>
| CT                 | • ACR Practice Guideline for Performing and Interpreting Diagnostic Computed Tomography (CT)  
                     • ACR Technical Standard for Diagnostic Medical Physics Performance Monitoring of Computed Tomography (CT) Equipment |
| MRI                | • ACR Practice Guideline for Performing and Interpreting Magnetic Resonance Imaging (MRI)  
                     • ACR Technical Standard for Diagnostic Medical Physics Performance Monitoring of Magnetic Resonance Imaging (MRI) |
| PET                | • ACR-SNM Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals  
                     • ACR Technical Standard for Medical Nuclear Physics Performance Monitoring of PET Imaging Equipment |
| PET/CT             | • ACR-SNM-SPR Practice Guideline for Performing FDG-PET/CT in Oncology  
                     • ACR Technical Standard for Medical Nuclear Physics Performance Monitoring of PET Imaging/CT Imaging Equipment |

3.2 CQIE Learning Modules

Web-based learning modules have been developed to provide CQIE-relevant information. The purpose of the modules is to familiarize participating sites with the overall CQIE process and prepare the technologists to perform the required phantom scanning procedures. Although there has been an increased focus on imaging standardization in multicenter trials, imaging technologists are commonly not integrated into the clinical trial team or provided with formal clinical trial training. With this in mind, technologist-focused learning modules have been developed to provide educational content relevant to multicenter quantitative imaging trials. As part of the site initiation process sites are asked to identify at least two technologists, per modality, to be responsible for the modality-specific CQIE activities (this is discussed further in Section 4). These technologists are expected to complete the learning modules, as outlined below. However, all staff are welcome and encouraged to complete the learning modules.

<table>
<thead>
<tr>
<th>CQIE Learning Modules</th>
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<tbody>
<tr>
<td><strong>CT Technologists</strong></td>
</tr>
<tr>
<td>• CQIE Overview</td>
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<tr>
<td>• CQIE CT Procedures</td>
</tr>
<tr>
<td>• Introduction to Multicenter Imaging Trials</td>
</tr>
<tr>
<td>• Quantitative Imaging for Multicenter Trials: vCT</td>
</tr>
<tr>
<td><strong>MR Technologists</strong></td>
</tr>
<tr>
<td>• CQIE Overview</td>
</tr>
<tr>
<td>• CQIE MRI Procedures</td>
</tr>
<tr>
<td>• Introduction to Multicenter Imaging Trials</td>
</tr>
<tr>
<td>• Quantitative Imaging for Multicenter Trials: MR</td>
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<tr>
<td><strong>PET, PET-CT Technologists</strong></td>
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<tr>
<td>• CQIE Overview</td>
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<tr>
<td>• CQIE PET Procedures</td>
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<tr>
<td>• Introduction to Multicenter Imaging Trials</td>
</tr>
<tr>
<td>• Quantitative Imaging for Multicenter Trials: PET-PET/CT</td>
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http://www.acrin.org/CORELABS/NCICQIEQUALIFICATIONPROGRAM/SITEQUALIFICATIONMATERIALS.aspx

3.3 Qualification Imaging – Phantom Scans and Test Cases

The use of phantoms is a central component of the CQIE program. Standardized phantom testing allows for a standardized evaluation of equipment performance and image quality characteristics. Additionally, phantoms provide an opportunity to evaluate compliance with sample imaging acquisition protocols prior to participant recruitment and actual trial-specific protocols. This focus on standardization was the main consideration for phantom selection, and resulted in the selection of the modality-specific ACR phantoms for baseline imaging measures. In the case of PET and MR, these measures will be supplemented with a second phantom and sample clinical test cases. Collection of a standardized set of phantom and test images will allow ACRIN to make a thorough assessment of the site’s imaging capabilities. Phantom tests must be submitted for each scanner to be qualified. Though qualification of only one scanner per modality is required, sites are urged to qualify multiple scanners. All scanners to be used for NCI clinical trial imaging should be qualified.
3.3.1 CT Qualification Imaging
Qualification imaging for CT consists of a series of image acquisition protocols, including 2 volumetric protocols, using an ACR Accreditation CT phantom. The ACR CT phantom is relatively easy to use and is a widely employed QC phantom. ACRIN will provide an ACR CT phantom, on loan, to sites who do not own one. The phantom scans provide evaluation of a range of scanner and image quality parameters including: positioning accuracy, CT number accuracy, slice width, low contrast resolution, high contrast resolution, CT number uniformity, and image noise. Images will also be evaluated for compliance with the standardized acquisition protocols. Refer to the CT Technical Procedures (MOP-Part B) for additional details.

3.3.2 MR Qualification Imaging
Qualification imaging for MR consists of a series of image acquisition protocols, including sample vMR and DCE-MR protocols, using an ACR Accreditation MR phantom and a CQIE Body DCE-MR phantom. ACRIN will provide, on loan, a CQIE Body DCE_MR phantom to all sites. Additionally, ACRIN will provide an ACR MR phantom, on loan, to sites who do not own one. As with the ACR CT phantom, the ACR MR phantom is relatively easy to use and is a widely employed QC phantom. The phantom scans provide evaluation of a range of scanner and image quality parameters including: evaluation of geometric accuracy, high-contrast spatial resolution, slice thickness accuracy, slice position accuracy, image intensity uniformity, percent-signal ghosting, and low-contrast object detectability. Images will also be evaluated for compliance with the standardized acquisition protocols. Refer to the MR Technical Procedures (MOP-Part C) for additional details.

3.3.3 PET, PET/CT Qualification Imaging
Qualification imaging for PET and PET/CT consists of phantom scans acquired using the Uniform Cylinder Phantom and phantom scans acquired using the ACR Accreditation PET phantom. ACRIN will provide an ACR PET phantom, on loan, to sites who do not own one. The phantom scans provide evaluation of a range of scanner and image quality parameters including: contrast, spatial resolution, uniformity, scatter/attenuation, SUV calibration accuracy, and SUV analysis. Refer to the PET Technical Procedures (MOP-Part D) for additional details.

3.4 Standardized Quality Control
Quality control is an important function of image quality and patient safety and takes on even greater importance in multicenter quantitative imaging trials. The benefits of quality control include: verification of the operational integrity of the systems, consistent and high image quality, awareness of inherent image artifacts, early identification of potential problems, and consistent quantitative accuracy. As such, quality control of imaging equipment is fundamental to the goal of image standardization in imaging and therapy trials. All CQIE sites are required to have a documented quality assurance program in place and comply with a standardized set of quality control measures, as described within the CT, MRI, and PET Technical Procedures (MOP-Part B, C, and D). Note that the standardized CQIE
QC measures do not replace any QC measures required by law, accreditations, or those recommended by the manufacturer. Rather these QC measures were adopted for the CQIE program based on published recommendations by organizations and researchers involved in quantitative imaging and are intended to serve as a minimum QC standard. The purpose for establishing a standardized set of quality control activities is to help ensure the quantitative data generated is comparable within institutions, across institutions, and over time. However, that is not to say these tests represent an exhaustive list of all imaging-relevant QC activities. The level of imaging standardization within a given trial, including QC, may vary depending on trial design. Sites may be required to perform additional QC activities, or perform certain activities more frequently, to qualify for, or participate in, a given future clinical trial. Compliance with CQIE QC guidelines does not replace the responsibility for compliance with trial-specific requirements and vice-versa.

### 3.5 Summary of CQIE Procedures

<table>
<thead>
<tr>
<th>Procedures</th>
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<td>T0</td>
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<td>T2</td>
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<tr>
<td>Site Initiation Packet (Application, MOU, SAF)</td>
<td>Initial</td>
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<td>Site Initiation Visits (optional)</td>
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<td>CT</td>
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<td>Learning Modules (at least 2 technologists)</td>
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<td>Test Case - vCT Chest <em>(if requested)</em></td>
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<td>Phantom Tests - ACR CT Phantom</td>
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<td>Standardized Quality Control Testing</td>
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<td>MR</td>
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<td>Learning Modules (at least 2 technologists)</td>
<td>Initial</td>
<td>X</td>
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<td>X</td>
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<tr>
<td>Test Case - brain MR diffusion</td>
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<td>Phantom Tests - ACR MRI Phantom</td>
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<td>Phantom Tests - Body DCE-MRI Phantom</td>
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<td>Standardized Quality Control Testing</td>
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<td>PET</td>
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<tr>
<td>Learning Modules (at least 2 technologists)</td>
<td>Initial</td>
<td>X</td>
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<tr>
<td>Test Cases - 2 whole body, 2 brain</td>
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<td>Phantom Tests - ACR PET Phantom</td>
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<tr>
<td>Phantom Tests – Uniform Cylinder</td>
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<tr>
<td>Standardized Quality Control Testing</td>
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4. QUALIFICATION PROCESS

4.1 Site Initiation

ACRIN will provide each site with a Site Initiation Packet. This packet will include information the site needs to start preparing for CQIE qualification. The CQIE Application and execution of the MOU are the essential first steps in that they signify the organization’s commitment to complete all qualification requirements in a timely manner, adhere to CQIE guidelines, and provide a mechanism for ACRIN to administer a one-time CQIE payment (see Section 4.7 for additional information).

It is important to note that CQIE qualification will require active staff participation across multiple departments. Sites are expected to complete all initial qualification requirements expeditiously and in accordance with the timelines developed for the Group 1 and Group 2 implementation plans. The flow chart provided as Appendix A1 provides a visual representation of the qualification process.

4.1.1 CQIE Application

Sites will need to submit a completed CQIE Application to ACRIN; this document is not included in the MOP but will be distributed to all NCI Cancer Centers as part of a site initiation packet. An appropriate representative from both the NCI Cancer Center and the Imaging Department will need to be identified on the application. The CQIE Application also includes identifying a Project Leader to serve as liaison with ACRIN and coordinate the on-site team activities. The main purpose of the application is to formally notify ACRIN of your readiness to participate in the program and initiate communication and coordination efforts between the cancer center and the imaging department.

4.1.2 Site Agreement

Sites will need to agree to the general terms and conditions as delineated in the CQIE template Memorandum of Understanding (MOU); this document is not included in the MOP but will be distributed to all NCI Cancer Centers as part of a site initiation packet. The qualification process does not require submission of patient identifiers, so the template MOU should be the only legal instrument required between the participating sites and ACRIN. Sites will be expected to comply with the CQIE guidelines and qualification requirements as detailed in this manual. Regarding the guidelines for qualified personnel (Section 3.1), sites are expected to maintain qualified personnel throughout the length of CQIE participation. Sites will not be required to submit staff CVs or credentials. Instead, by signing the MOU, representatives of the cancer center and imaging department signify their understanding of, and agreement to comply with, CQIE personnel requirements.

4.1.3 Site Assessment Form

While the MOU is under administrative review, sites should complete the Site Assessment Form (SAF); this document is not included in the MOP but will be
distributed to all NCI Cancer Centers as part of a site initiation packet. The intent of the SAF is to provide ACRIN with detailed organizational and modality-specific information, such as equipment, quantitative imaging experience, and current QC practices. This information will enable ACRIN to begin development of a site-specific qualification plan and establish communications between the site team and the ACRIN-CQIE team.

4.1.4 Site Initiation Visits

As part of the site initiation process, ACRIN will conduct two on-site visits for each cancer center, one 2-day visit with the CT & MR site teams and one 1-day visit with the PET site team. These visits will be scheduled independently of each other based on site and ACRIN availability. The purpose of the visits is not to qualify the sites. The purpose is to familiarize the imaging team with the CQIE requirements and provide assistance with technical issues associated with standardizing imaging acquisition protocols for advanced quantitative imaging across multiple vendors and platforms. Therefore, site initiation visits are recommended but are not a mandatory requirement for CQIE qualification. Site assessment prior to the site visit will help to ascertain the site’s current imaging capabilities and clinical trial experience. As part of the determination of site readiness, an overall profile of the equipment to be utilized for qualification will be assessed. Based in part on this assessment, a Site Qualification Plan will be developed specifically for the site. This plan will outline the modality-specific qualification imaging required and identify vendor-/software-specific image acquisition considerations, as needed.

Site responsibilities prior to the ACRIN site initiation visit:
- Review of the CQIE MOP and appropriate modality-specific technical procedures (MOP-Parts B, C, and D).
- Identify two technologists, per modality, responsible for the modality-specific CQIE activities. CQIE responsibilities include participation in the appropriate modality-specific CQIE site visit, completion of the CQIE Learning Modules (as identified in Section 3.2), and compliance with CQIE-standardized QC (as detailed in CT, MR, and PET Technical Procedures—Part B, C, and D).
- Identify one scanner, per modality, for phantom scan demonstrations.
- Coordinate scanner and staff availability for the site visit training.
- Based on the technical parameters outlined in the phantom scanning instructions and vendor/platform-specific parameters provided in the Site Qualification Plan, create a CQIE phantom scan protocol and save to your scanner’s profile of routine acquisition protocols (to the extent capable, ACRIN will provide assistance as needed).

ACRIN responsibilities prior to the site initiation visit:
- Communicate with the project lead at the site, and modality technologists as needed, to schedule the site visits.
- Provide phantoms, on loan, as needed.
• An assessment of site equipment, quantitative imaging experience, and clinical trial imaging experience. This assessment will be based upon information provided by the site on the Site Assessment Form and any other relevant communications.

• Based on the above assessment, develop a customized Site Qualification Plan which will be provided to the site in advance of the site visit. The Site Qualification Plan will include a training agenda and relevant vendor-/platform-specific acquisition parameters for the qualification imaging.

Each site initiation visit will be organized around one scanner, selected by the site in advance of the site visit. The site initiation visit will include a review of the qualification guidelines, phantom scanning procedures, issues relevant to the performance of clinical protocol scans, and review of the CQIE standardized QC activities. Sites will be required to provide sufficient time for staff to participate in the site initiation visit and will need to block time on the scanner selected for the site initiation visit. The scanner and technologist time required for the site visit will vary but is expected to take approximately 3-4 hours for PET and 4-5 hours for MR and CT. As a general rule, at least four hours of scanner time should be allocated for each modality to ensure sufficient scanner time for demonstration of the phantom scans. The Site Assessment Form should provide ACRIN with enough information about on-site conditions to allow a more accurate estimate of required scanner and staff time; this will be addressed in the customized Site Qualification Plan.

Qualification imaging and associated data forms should be submitted to ACRIN within 2 weeks of the site visit. Site visits will not be conducted for the annual qualification renewals.

4.2 Annual CQIE Learning Modules

As part of the site initiation process, two technologists from each of the three modalities should be identified for the site’s CQIE project team. In addition to participating in the site initiation visit, these technologists are required to complete the appropriate CQIE Learning Modules, as identified in Section 3.2. However, it is recommended that all technologists working with clinical trial participants complete the learning modules. The first two learning modules, CQIE Overview and the modality-specific CQIE Procedures, should be completed prior to the site initiation visit. Additional learning modules, as listed above in Section 3.2, will be required annually.

4.3 Annual (T1-T3) Qualification Imaging

For each site, ACRIN will identify an annual testing window and timeline for completion of the annual qualification requirements based on the completion date of the initial (T0) qualification process. The annual qualification schedule is available on the CQIE web site but does not include the group assignments; ACRIN will communicate directly with each site regarding this. As with the initial qualification process, annual requirements include submission of a series of phantom and clinical scans to ACRIN. A detailed description of the
modality-specific requirements, with instructions for the phantom scans, is provided in Parts B, C, and D of this manual.

With the purpose of advancing standardization and harmonization of imaging data in multicenter clinical trials, all scanners to be used for NCI clinical trial imaging should be qualified. Sites are encouraged to qualify multiple scanners for each modality.

4.3.1 Phantom Loan
In order to minimize the financial burden on sites, ACRIN has acquired a small inventory of phantoms and will make these phantoms available, on loan, for qualification imaging. Details regarding the phantom loan procedures vary by modality and will be provided as part of the Site Qualification Plan, as needed.

4.4 Data Submission
All images must be submitted in DICOM format. Screen captures, where applicable, should be saved as a DICOM Secondary Capture. Patient identifiers must be scrubbed from the test case images before they are submitted to ACRIN. Image data should be transmitted to ACRIN electronically via secure file transfer protocol (FTP), if necessary images can be sent on CD-ROM. Download and installation instructions for FTP setup are provided as Appendix A2. Sites submitting images via CD-ROM should ship packages to ACRIN, mode of shipment should include package tracking. Additional data submission requirements are provided in the CT, MR, and PET Technical Procedures (MOP-Parts B, C, and D).

4.5 Evaluation of Image Data
Evaluation of the image data will be managed by the ACRIN-ACR Imaging Core Laboratory. Upon receipt of the image data, ACRIN will first perform a “submission-level” QC review to determine whether each modality-specific data set is complete and ready for evaluation. If a discrepancy is found, ACRIN will contact the site for resolution of the discrepancy. Once the modality-specific data set has passed the submission-level QC, the image data will be queued for evaluation. Phantom and test image data will be evaluated by ACR and/or ACRIN physicists as part of an overall assessment of image quality and will include qualitative and quantitative assessments. Review and evaluation of the images and associated data will be performed in accordance with standard and CQIE-specific operating procedures established by ACRIN.

Image data will be assessed per modality (CT, MR, PET) and will receive a ‘Pass’ or ‘Fail’ score based on modality-specific evaluation criteria. It is anticipated that the evaluation process will be completed within 2-4 weeks of submission. The CT, MR, and PET procedures (MOP-Parts B, C, and D) provide additional details regarding the evaluation of phantom and test image data.
4.6 Notification of Results

Sites will receive a report summarizing the result of the qualification evaluation. To be approved for CQIE qualification, sites must receive a ‘Pass’ score for all modalities. ACRIN will work with each site to identify and remedy deficiencies resulting in one or more ‘Fail’ scores. The specific action plan will depend upon the type of deficiency but may include submission of additional phantom or test images. Sites will be responsible for resolving discrepancies quickly to enable completion of the qualification process within the defined time periods.

Once the participating site has successfully submitted qualifying images in all three modalities, ACRIN will provide notification that the site is approved for qualification. Qualification notification will be sent to both the site and NCI, and the name of the site will be added to the list of qualified sites on the CQIE web page.

4.7 Site Payment

Upon successful completion of the initial qualification process sites will receive a one-time payment, as provided in the CQIE Memorandum of Understanding. The intent of this payment is to help off-set the costs incurred by the site to complete the CQIE-associated activities, such as scanner and staff time. No payment will be provided for the annual re-qualifications.
**QUALIFICATION PROCESS FLOWCHART**

**SITE INITIATION (T0 only)**

- NCI: Identify Cancer Centers Group 1 and 2
- **ACRIN: Contact Site (Cancer Center, Radiology)**
- **Submit to ACRIN: Application, SAF, MOU**

**SITE:**
- CQIE Application
- Site Agreement (MOU)
- Site Assessment Form (SAF)

**ACRIN:**
- Develop and Send Site Qualification Plan
- Ship Phantoms (as needed)
- Schedule Site Visits

**SITE:**
- Complete Learning Modules #1 and 2
- sFTP Set-up

**SITE INITIATION VISITS MR-CT PET**

**IMAGING (T0-T3)**

**SITE:**
- Perform Phantom Scans (CT, MR, PET)
- Complete Phantom Scan Data Forms

**ACRIN:**
- Determine Resolution Plan
- Imaging & Forms Pass QC

**EVALUATION (T0-T3)**

**ACRIN:**
- Schedule Site Visits
- Develop and Send Site Qualification Plan
- Ship Phantoms (as needed)
- Set-up sFTP

**SITE:**
- Complete Learning Modules #1 and 2

**ACRIN:**
- Determine Resolution Plan
- Imaging & Forms Pass QC

**SITE:**
- Implement Resolution Plan
- Deficiency Resolved

**ACRIN:**
- Determine Resolution Plan
- Imaging & Forms Pass QC

**SQ Requirements Met**

**SITE:**
- Implement Resolution Plan

**ACRIN:**
- Determine Resolution Plan
- Imaging & Forms Pass QC

**SITE QUALIFIED**
I. **WinSCP Software Installation**

1) Access the **software-download page** within the WinSCP website, via:

   ➜ Web Address: [http://winscp.net/eng/download.php](http://winscp.net/eng/download.php)
2) Select the software package with the *most current* "Released" date.

**IMPORTANT!!!** Do NOT download a **BETA** version of the software, even if the ‘released’ date is the most current. The selected installation package must *not* be a BETA version.

3) To start the download process, select "Installation Package" within the chosen software package’s information section.

→ **Installation package**

4) If an advertisement screen appears (versus an installation-module) that asks the user to install another program;
   → Select the **security warning bar** (as highlighted) in the header;
   → Select “Click here for options….”;
   → Select “Download file…”.

*EXAMPLE OF ADVERTISEMENT SCREEN*
5) A security warning appears, which asks “do you want to run or save this file?”. ➔ Select “RUN”.

![File Download - Security Warning](image1)

6) A 2nd security warning may appear, which asks if “you want to run this software?”. ➔ Select “RUN”.

![Internet Explorer - Security Warning](image2)
7) Choose the preferred language. ➔ Select “OK”.

**NOTE:** “English” will appear as the default. If a language other than English is preferred, choose the desired language by selecting it from the drop-down menu. After the preferred language is chosen, select “OK”.

8) The ‘WELCOME’ screen of the “WinSCP Setup Wizard” will appear ➔ Select “NEXT”.
9) The software’s “License Agreement” will appear.  
   ➔ After reading the agreement, select “NEXT”.

10) Select “TYPICAL Installation” setup-type.  ➔ Select “NEXT”. 
11) If an advertisement screen appears (versus an installation-module) that asks the user to install another program; 
   ➔ Select the “DO NOT INSTALL” option. ➔ Select “NEXT”.

**TWO (2) EXAMPLES OF ADVERTISEMENT SCREENS**

**Example #1**

**Example #2**
12) Select “COMMANDER Interface” style. → Select “NEXT”.

13) The software’s “Ready to Install” screen will appear. → Select “INSTALL”.
   ➔ Select “Launch WinSCP”
   ➔ Select “FINISH”.

Step 1

Step 2

Finish
15) The ‘WinSCP LOGIN’ screen will appear.

Please enter the following, which were provided to the Investigational Site (i.e. user) from ACR. The HOST NAME is unique to the sFTP account. The USER NAME & PASSWORD are uniquely assigned for each site.

- **Host Name** = sftp.acrin.org
- **User Name**
- **Password**

Once the above data-fields are complete, select “SAVE”. 

![WinSCP Login Screen with steps indicated](image-url)
16) If the user prefers to not use the default SESSION NAME, which will automatically appear in the ‘save session as’ data-field, then…
   ➔ Create & enter a new SESSION name in the data-field ➔ Click “OK”.

17) A warning appears, which advises that the server’s host key was not found in the cache. The module/screen asks if the user wishes to “continue connecting and add host key to the cache?”. ➔ Select “YES”.
18) The sFTP client will open.

Refer to the following section for instructions on how to upload electronic files.
II. Uploading Electronic Files to the sFTP Client

1) Using the LEFT panel, navigate to the location where the electronic files, which are to be uploaded to the sFTP folder, are saved.  

   **NOTE:** These files are uniquely located, per the institutional policies/procedures; e.g. network drive, ‘my documents’, desktop, etc.  

   **NOTE:** If the trial/study requires specific file-naming conventions to be used, please ensure the file is appropriately named prior to upload to the sFTP folder.

2) Once the files are located, perform the following:  

   - **Highlight** the chosen/selected files with the LEFT panel;  
   - **Drag & drop** the files into the sFTP folder in the RIGHT panel.

3) UPLOAD is COMPLETE.
PART B

CT TECHNICAL PROCEDURES

1. CQIE CT QUALIFICATION

1.1 Introduction

The purpose of this chapter is to provide detailed information regarding the CT phantom scanning and quality control activities required for CQIE qualification. For a full description of the qualification program refer to Part A of the CQIE Manual of Procedures (MOP). The CT procedures and guidelines outlined in this document apply to all scanners to be qualified. Though qualification of only one CT scanner is required, sites are urged to qualify multiple scanners. With the purpose of advancing standardization and harmonization of imaging data in multicenter clinical trials, all scanners to be used for NCI clinical trial imaging should be qualified.

As explained in Part A, Section 1.2, of the CQIE MOP, the primary objective of the CQIE program is to establish a resource of ‘trial ready’ sites within the NCI Cancer Centers that are capable of conducting clinical trials in which there is an integral molecular and functional advanced imaging endpoint. In support of this objective, the CQIE program is designed to qualify sites to participate in advanced imaging trials which include volumetric CT of the body.

1.2 Overview of CQIE CT Procedures

CT procedures for CQIE qualification include phantom tests with an ACR Accreditation CT phantom and compliance with a standardized set of quality control measures.

<table>
<thead>
<tr>
<th>Schedule of Procedures</th>
<th>Time Point</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>T0 Initial</td>
</tr>
<tr>
<td>ACR CT Phantom Tests</td>
<td>X</td>
</tr>
<tr>
<td>Standardized Quality Control</td>
<td>X</td>
</tr>
</tbody>
</table>

1.2.1 CT System Requirements: Although imaging for volumetric CT can be performed with a 1-data channel system, a multi-detector CT scanner with 16 or more data channels is highly recommended.

Number of channels:
- Ideal = 64 or greater
- Target = 16 or greater
- Acceptable = 1 or greater
1.3 Imaging Core Laboratory

The Imaging Core Laboratory is headquartered within the American College of Radiology Clinical Research Center in Philadelphia. The role of the Imaging Core Lab is to (1) develop guidelines and training materials for CQIE qualification imaging, (2) serve as a resource for site staff regarding technical and procedural issues associated with the qualification requirements and quantitative imaging, (3) collect and archive qualification imaging data, and (4) manage the qualitative and quantitative review of the qualification imaging data.

Should you have any questions or require additional information please consult the CQIE web site at http://www.acrin.org/NCI-CQIE.aspx or a member of the ACRIN CQIE project team.

<table>
<thead>
<tr>
<th>PROJECT MANAGEMENT</th>
<th>IMAGING</th>
</tr>
</thead>
<tbody>
<tr>
<td><a href="mailto:CQIE-Manager@acr.org">CQIE-Manager@acr.org</a></td>
<td><a href="mailto:CQIE-MR-CT@acr.org">CQIE-MR-CT@acr.org</a></td>
</tr>
<tr>
<td>Telephone: 215-940-8921</td>
<td><a href="mailto:CQIE-PET@acr.org">CQIE-PET@acr.org</a></td>
</tr>
<tr>
<td>Fax: 215-717-0860</td>
<td></td>
</tr>
</tbody>
</table>

ACRIN hours of operation are 8:30 – 5:00 ET
2. QUALIFICATION IMAGING

2.1 ACR CT Phantom Scans

For initial and annual qualification assessments, sites will need to perform phantom tests using an ACR CT phantom. Detailed phantom scanning instructions are provided as Appendix B1. If your site does not own an ACR-CT phantom ACRIN will provide a phantom, on loan, or you may purchase your own. Additional information regarding the phantom loan procedures will be provided as part of the Site Qualification Plan, as needed. For purchasing information refer to the ACR web site.

Phantom image data will be evaluated, per documented operating procedures, under the management of the Imaging Core Laboratory. Both a qualitative and quantitative review of the image data will be conducted. This review will include an evaluation of multiple CT performance and image quality characteristics and compliance with image acquisition protocols.

2.2 Clinical Test Case

For initial and annual qualification assessment sites may be asked to submit a volumetric Chest CT from a live subject or volunteer. If requested, the test case should be acquired within the past 90 days of the submission time point and can be with or without radiographic findings. Patient identifiers must be scrubbed from clinical images before transmission to ACRIN. Images must be submitted in DICOM format. The Test Cases will be qualitatively and quantitatively reviewed for overall technical image quality.
3. STANDARDIZED QUALITY CONTROL

3.1 Routine Quality Control

Quality control is an important function of image quality and patient safety and takes on even greater importance in multicenter quantitative imaging trials. The benefits of quality control include: verification of the operational integrity of the systems, consistent and high image quality, decreased chance of artifacts, early identification of potential problems, and consistent quantitative accuracy. As such, quality control of imaging equipment is fundamental to the goal of image standardization in imaging and therapy trials. In line with recommendations of the American College of Radiology, all CQIE sites are required to have a documented quality assurance program monitored by a medical physicist (or other qualified individual). For additional guidance, please reference ACR Technical Standard for Diagnostic Medical Physics Performance Monitoring of Computed Tomography (CT) Equipment and ACR Practice Guideline for Performing and Interpreting Diagnostic Computed Tomography (CT).

3.1.1 Acceptance Testing

The aim of acceptance testing is to verify that the equipment performs according to its specifications and clinical purpose. Acceptance testing should be performed according to manufacturer recommendations upon installation of imaging equipment and after major upgrades, before clinical use. The acceptance testing protocol should include an evaluation of all coils.

3.1.2 Routine Quality Control Testing

Routine performance tests and preventive maintenance are to be conducted according to performance measurements as outlined by the manufacturer and include regular testing procedures to insure proper operation on a daily basis. Federal standards require CT manufacturers to provide quality assurance testing instructions, recommended testing frequency, a QC phantom appropriate for the scanner and acceptable variations in parameter measurements. If any QC parameter being monitored falls outside of the control limits, corrective action should be taken.

3.2 CQIE Standardized Quality Control

To address the need of imaging standardization in multicenter and/or quantitative imaging trials, CQIE sites are expected to comply with the quality control testing (and frequency) identified in 3.2.1 below. These tests may already be part of your existing QC program. If not, these tests are to be incorporated into your continuous quality control activities. Note that the standardized CQIE QC measures do not replace any QC measures required by law, accreditations, or those recommended by the manufacturer. Rather these QC measures were adopted for the CQIE program based on published recommendations by organizations and researchers involved in quantitative imaging and are intended to serve as a minimum QC standard. The purpose for establishing a standardized set of quality control activities is to help ensure the quantitative data generated are comparable within institutions, across institutions, and over time. However, due to the nature of advanced/experimental imaging,
sites may be required to perform additional QC activities, or perform certain activities more frequently, to qualify for, or participate in, a given clinical trial. Compliance with CQIE QC guidelines does not replace the responsibility for compliance with trial-specific requirements and vice-versa.

CQIE sites are expected to adhere to these quality control standards to maintain CQIE qualification. As with all QC testing, performance of these procedures should be documented in your QC log and archived. A CT QC Questionnaire will be required for T2 and T3 qualification renewals. This questionnaire requires sites to attest to compliance with the CQIE standardized QC measures. Compliance with the CQIE QC standards is subject to audit.

### 3.2.1 Standardized QC Tests for CT

<table>
<thead>
<tr>
<th>Test</th>
<th>Minimum Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water CT Number &amp; Standard Deviation</td>
<td>Daily - Technologist</td>
</tr>
<tr>
<td>Artifacts</td>
<td>Daily - Technologist</td>
</tr>
<tr>
<td>Scout Prescription &amp; Alignment Light Accuracy</td>
<td>Annually</td>
</tr>
<tr>
<td>Imaged Slice Thickness (slice sensitivity profile, SSP)</td>
<td>Annually</td>
</tr>
<tr>
<td>Table Travel/Slice Positioning Accuracy</td>
<td>Annually</td>
</tr>
<tr>
<td>Radiation Beam Width</td>
<td>Annually</td>
</tr>
<tr>
<td>High-Contrast (Spatial) Resolution</td>
<td>Annually</td>
</tr>
<tr>
<td>Low-Contrast Sensitivity and Resolution</td>
<td>Annually</td>
</tr>
<tr>
<td>Image Uniformity &amp; Noise</td>
<td>Annually</td>
</tr>
<tr>
<td>CT Number Accuracy</td>
<td>Annually</td>
</tr>
<tr>
<td>Artifact Evaluation</td>
<td>Annually</td>
</tr>
<tr>
<td>Dosimetry/CTDI</td>
<td>Annually</td>
</tr>
</tbody>
</table>
4. DATA SUBMISSION

4.1 Qualification Data
Submit the following data for each scanner to be qualified.

<table>
<thead>
<tr>
<th>Time Point</th>
<th>Procedures</th>
<th>Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>T0–T3</td>
<td>ACR CT Phantom Tests</td>
<td>▪ Volumetric Chest Protocol data set</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▪ Volumetric Liver Protocol data set</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▪ Routine Abdomen Protocol data set</td>
</tr>
<tr>
<td>T0–T3</td>
<td>Clinical Test Case</td>
<td>▪ Volumetric Chest CT <em>(if requested)</em></td>
</tr>
<tr>
<td>T1–T3</td>
<td>Image Transmittal Worksheet</td>
<td>▪ Scanner specifications</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▪ Notification to ACRIN of data submission</td>
</tr>
<tr>
<td>T2–T3</td>
<td>Quality Control</td>
<td>▪ Quality Control Questionnaire</td>
</tr>
</tbody>
</table>

Clinical Test Cases
Images must be submitted in DICOM format. Patient identifiers must be scrubbed from the clinical images before transmission to ACRIN.

Data Submission
Images must be submitted in DICOM format. Imaging should be transmitted to ACRIN electronically via secure file transfer protocol (FTP), if necessary images can be sent on CD-ROM. Download and installation instructions for FTP setup are provided in Part A of this MOP, Appendix A2. An Image Transmittal Worksheet (ITW) should accompany each image submission. Refer to the CQIE web site, [http://www.acrin.org/NCI-CQIE.aspx](http://www.acrin.org/NCI-CQIE.aspx), for all qualification materials, including the ITW.

If necessary images can be sent on CD-ROM. Sites submitting images via CD should mail the package, including a copy of the ITW, to the ACRIN Imaging Core Lab at the address below. Method of shipment should include package tracking.

ACRIN Imaging Core Lab, # CQIE-CT
American College of Radiology
1818 Market Street, Suite 1600
Philadelphia, PA 19103
5 References

- American Association of Physicists in Medicine. AAPM Report No. 74: Quality Control in Diagnostic Radiology, 2002
- American College of Radiology. ACR Technical Standard for Diagnostic Medical Physics Performance Monitoring of Computed Tomography (CT) Equipment
- American College of Radiology. ACR Practice Guideline for Performing and Interpreting Diagnostic Computed Tomography (CT)
- Imaging Working Group (IWG), Clinical Translational Science Awards (CTSA).
- Quantitative Imaging Biomarkers Alliance (QIBA), Radiological Society of North America (RSNA).
CT PHANTOM TEST INSTRUCTIONS: ACR CT PHANTOM

This document provides detailed instructions for performing phantom tests with the ACR Accreditation CT phantom (Gammex 464). Though based on the ACR CT Accreditation testing, modifications were made for the purpose of CQIE qualification. If your site does not own an ACR-CT phantom, ACRIN will provide a phantom, on loan, or you may purchase your own. Additional information regarding the phantom loan procedures will be included in your site visit packet. For purchasing information refer to the ACR web site.

1. ACR CT Accreditation Phantom

The ACR CT accreditation phantom has been designed to examine a broad range of scanner parameters. These include:

- Positioning accuracy
- CT number accuracy
- Slice width
- Low contrast resolution
- High contrast (spatial) resolution
- CT number uniformity
- Image noise

The ACR CT accreditation phantom is a solid phantom containing four modules and is constructed primarily from a water-equivalent material. Each module is 4-cm in depth and 20-cm in diameter. There are external alignment markings scribed and painted white (to reflect alignment lights) on EACH module to allow centering of the phantom in the axial (z-axis, cranial/caudal), coronal (y-axis, anterior/posterior), and sagittal (x-axis, left/right) directions. There are also “HEAD”, “FOOT”, and “TOP” markings on the phantom to assist with alignment.

Figure 1: Diagram of the four modules of the ACR CT accreditation phantom.
**Phantom Module 1** is used to assess positioning and alignment, CT number accuracy, and slice thickness. The background material is water equivalent. For positioning, the module has 1-mm diameter steel BBs embedded at the longitudinal (z-axis) center of the module, with the outer surface of the BB at the phantom surface at 3, 6, 9, and 12 o’clock positions within the field of view (19.9-cm center to center). To assess CT number accuracy, there are cylinders of different materials: bone-mimicking material (“Bone”), polyethylene, water equivalent material, acrylic, and air. To assess slice thickness, two ramps are included which consist of a series of wires that are visible in 0.5-mm z-axis increments.

![Diagram](image)

Figure 2: Cross-sectional diagram of (a) module 1, (b) module 2, (c) module 3, and (d) module 4.

**Phantom Module 2** is used to assess low contrast resolution. This module consists of a series of cylinders of different diameters, all at 0.6% (6 HU) difference from a background material having a mean CT number of approximately 90 HU. The cylinder-to-background contrast is energy-independent. There are four cylinders for each of the following diameters: 2-mm, 3-mm, 4-mm, 5-mm, and 6-mm. The space between each cylinder is equal to the diameter of the cylinder. A 25-mm cylinder is included to verify the cylinder-to-background contrast level.
CT PHANTOM TEST INSTRUCTIONS: ACR CT PHANTOM

Phantom Module 3 consists of a uniform, tissue-equivalent material to assess CT number uniformity. Two very small BBs (0.28-mm each) are included for optional use in assessing the accuracy of in-plane distance measurements.

Phantom Module 4 is used to assess high contrast (spatial) resolution. It contains eight bar resolution patterns: 4, 5, 6, 7, 8, 9, 10 and 12 lp/cm, each fitting into a 15-mm x 15-mm square region. The z-axis depth of each bar pattern is 3.8-cm, beginning at the Module 3 interface. The aluminum bar patterns provide very high object contrast relative to the background material. Module 4 also has four 1-mm steel beads, as described for Module 1.

2. Test Preparation and Phantom Set Up

Calibrate the Scanner:
Prior to scanning the ACR-CT phantom, perform tube warm-up and any necessary daily calibration scans as recommended by the manufacturer. The ACR recommends that the site's water phantom be scanned and tested for accuracy of the CT number of water, absence of artifacts, and uniformity across the field of view prior to proceeding with the phantom test. If problems are found, contact your field engineer or medical physicist for resolution. Do not proceed with the phantom testing until the issues are resolved.

Required Testing Materials:
- ACR CT phantom
- Phantom base
- Level
- CQIE CT Phantom Data Worksheet

Phantom Set Up:
Pull back the table padding and position the ACR CT accreditation phantom so that it is “HEAD” first into the gantry. (Be sure to choose a patient orientation of “head first” on the scanner.) Carefully position the phantom so that the CT scanner's alignment lights are accurately positioned over the scribe line corresponding to the center of Module 1 (FOOT END of the phantom).

Using the set of alignment lights (internal or external) that is used clinically, align the phantom in the sagittal, coronal and axial planes, and “zero” (or landmark) the table – all scans will be acquired in reference to this location (S0). While maintaining careful alignment, secure the phantom so it will not move (Figure 3).

Figure 3
CT PHANTOM TEST INSTRUCTIONS: ACR CT PHANTOM

3. Phantom Scans

For the CT portion of the CQIE qualification you are asked to scan the ACR CT phantom using three different acquisition protocols, as specified below. When setting up the scans, enter your institution name in the patient name field (see example below).

**Patient Name: CQIE Name of Your Cancer Center (ex. ACRIN Cancer Center)**

**Phantom Scan 1: CQIE Volumetric Chest Protocol**

**CQIE Volumetric Chest Protocol**

If your site is performing this test for the first time you will need to build an acquisition protocol and save it to your scanner’s protocol menu, this may require special user permissions.

- Start with a high resolution AXIAL chest protocol and modify the acquisition parameters to match those listed below in Table 1.
- Patient orientation should be head first.
- A topogram (scout) is optional and should not be necessary.
- Only a standard body reconstruction algorithm is required. Turn off (delete) any other reconstruction algorithms that may be part of the selected protocol.
- Turn off/do not use any type of automatic dose reduction technique.

**Phantom Scan**

- Position phantom and set landmark (“zero”) as described above in Section 2.
- Using the CQIE vCT Chest protocol, scan the phantom from I20 to S140 (-20 to +140).
- Save the image set for future QA/QC reference.

**Table 1: Volumetric Adult Chest CT Protocol**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>GE</th>
<th>Philips</th>
<th>Siemens</th>
<th>Toshiba</th>
</tr>
</thead>
<tbody>
<tr>
<td>Display FOV (Reconstruction FOV)</td>
<td>21 cm</td>
<td>210</td>
<td>210</td>
<td>21 cm</td>
</tr>
<tr>
<td>Reconstructed Slice Width</td>
<td>1.25 mm</td>
<td>1.25 mm</td>
<td>1 – 1.5 mm</td>
<td>1 – 1.5 mm</td>
</tr>
<tr>
<td>Reconstruction Algorithm</td>
<td>STD</td>
<td>B</td>
<td>B30f</td>
<td>FC10</td>
</tr>
<tr>
<td>Matrix</td>
<td></td>
<td></td>
<td>512 x 512</td>
<td></td>
</tr>
<tr>
<td>Scan FOV</td>
<td></td>
<td></td>
<td>Small Body</td>
<td></td>
</tr>
<tr>
<td>mAs</td>
<td></td>
<td></td>
<td>240 ± 20</td>
<td></td>
</tr>
<tr>
<td>kVp</td>
<td></td>
<td></td>
<td>120</td>
<td></td>
</tr>
<tr>
<td>Scan Mode</td>
<td></td>
<td></td>
<td>Axial</td>
<td></td>
</tr>
</tbody>
</table>
Phantom Scan 2: Adult Volumetric Liver Protocol
Start with your routine volumetric liver protocol then follow the bulleted steps below.

Phantom Scan 3: Routine Adult Abdomen Protocol
Start with your routine adult abdomen protocol then follow the steps below.

- Position the phantom and set landmark (“zero”) as described above in Section 2.
- Modify the selected acquisition protocol to match the parameters below in Table 2.
- Only the standard reconstruction algorithm is required. You can turn off (delete) any other reconstruction algorithms that may be part of the selected protocol.
- Turn off/do not use any type of automatic dose reduction technique.
- Patient orientation should be head first
- Scan the phantom from I20 to S140 (-20 to +140).
- Save the image set for future QA/QC reference.

Table 2: Acquisition Parameters for Phantom Scans 2 and 3

<table>
<thead>
<tr>
<th>Protocol</th>
<th>Scan FOV</th>
<th>Display FOV</th>
<th>Slice Width</th>
<th>Recon Algorithm</th>
<th>Scan Mode</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Volumetric Liver (or ~ 25 cm)</td>
<td>21-25 cm</td>
<td>2.5 – 3 mm</td>
<td>Per Routine Clinical Protocol</td>
<td>Helical</td>
</tr>
<tr>
<td>3</td>
<td>Adult Abdomen (or ~ 50 cm)</td>
<td>38 cm</td>
<td>5 mm</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4. Image Evaluation

Now that you have acquired all of the phantom scans you should evaluate the images for pass/fail criteria, as described below, before submitting the images to ACRIN for analysis. The CT Phantom Data Worksheet, provided as Appendix B2, is an optional tool for which you can document the results of your evaluation. The worksheet is not required as part of your data submission to ACRIN. If the images do not pass one or more of the tests you, should consult your physicist or supervising physician as corrective action and/or repeat imaging may be warranted.

4.1 Scanner Alignment Test

*Evaluate for the Volumetric Chest dataset only.* Display the image obtained at “0.0”. Manipulate the window and level settings to allow you to best visualize the phantom, a typical setting for this is WW=1000 and WL=0. Visually examine the images. All four BBs should be visible at S0 as well as S120, as depicted in Figures 4a-b.
4.2 CT Number Calibration

*Evaluate for all protocol data sets.* Select the best **Module 1** image, (~I4-S6) making sure that the image shows the longest wire ± 1 wire from the center of at least one of the top and bottom ramps. Place a circular region of interest (ROI), approximately 200-mm² in size, within each cylinder (as shown in Figure 5) and record the mean CT number for each material for your records. It is important to center the ROIs within each cylinder. For each of the other phantom image sets, measure only the mean CT number for water. To pass, the mean HU of the material must fall within the recommended range. The pass criteria for the CT Number Calibration test are shown in Table 3. **NOTE:** If the mean material HU from the abdomen protocol fails, try to rescan with a smaller FOV (21-25 cm).

![Figure 4a. BBs visible at scan location S0](image)

![Figure 4b. BBs visible at scan location S120](image)

![Figure 5: Cross-sectional image of Module 1 with properly placed ROIs.](image)

<table>
<thead>
<tr>
<th>Material</th>
<th>CT Number (HU)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bone</td>
<td>+850 to +970</td>
</tr>
<tr>
<td>Air</td>
<td>-1005 to -970</td>
</tr>
<tr>
<td>Acrylic</td>
<td>+110 to +135</td>
</tr>
<tr>
<td>Water</td>
<td>-7 to +7</td>
</tr>
<tr>
<td>Polyethylene</td>
<td>-170 to -87</td>
</tr>
</tbody>
</table>

Table 3: CT Number Pass Criteria
4.3 Low Contrast Criteria (Contrast-to-Noise Ratio) (CNR)

*Evaluate for Abdomen and Liver datasets only.* View the image located at the center of Module 2. Manipulate the window and level settings to allow you to best visualize the cylinders, a typical setting for this is a window and level setting of WW=100 and WL =100. Note that there are four cylinders for each of the following diameters: 2, 3, 4, 5, and 6-mm (as in Figure 2b). Place a ROI, approximately 100-mm² in size, over the large 25-mm diameter cylinder and next to the large cylinder (as in Figure 6).

Record the mean signal in the ROI inside the 25-mm rod (A), the mean signal in the ROI outside the 25-mm rod (B), and the Standard Deviation (SD) of the ROI outside the 25-mm rod (B) for your records.

Use this formula to calculate the Contrast to Noise Ratio (CNR): \[ \text{CNR} = \frac{|B-A|}{SD} \]

Use the absolute value- that is, **do not** take into consideration whether the CNR is a positive or negative number. *The CNR must be greater than 1.0 for the abdomen and greater than 0.75 for the liver.*

![Figure 6: Module 2 low contrast resolution image at WW = 100 and WL = 100 with correct ROI placement.](image)
4.1 Scanner Alignment Test (evaluate for volumetric chest data set only):

Are all four BBs visible at S0?

Are all four BBs visible at S120?

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>S0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>S120</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4.2 CT Number Calibration (evaluate for all protocol data sets):

Record the mean CT number for each material (HU)

<table>
<thead>
<tr>
<th>Material</th>
<th>Pass Criteria</th>
<th>Chest</th>
<th>Liver</th>
<th>Abd</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bone</td>
<td>+850 to +970</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Air</td>
<td>-1005 to -970</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acrylic</td>
<td>+110 to +135</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Water</td>
<td>-7 to +7</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Polyethylene</td>
<td>-170 to -87</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4.3 Low Contrast CNR (evaluate for abdomen and liver data sets only)

<table>
<thead>
<tr>
<th>Series</th>
<th>Mean A</th>
<th>Mean B</th>
<th>SD</th>
<th>CNR =</th>
<th>B – A</th>
<th>/ SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abd</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Liver</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Pass Criteria: Abd CNR > 1.0
Liver CNR > 0.75
1. CQIE MRI QUALIFICATION

1.1 Introduction
The purpose of this chapter is to provide detailed information regarding MR imaging and quality control activities required for CQIE qualification. For a full description of the qualification program refer to the CQIE Manual of Operating Procedures (MOP). The MR procedures and guidelines outlined in this document apply to all scanners to be qualified. Though qualification of only one MR scanner is required, sites are urged to qualify multiple scanners. With the purpose of advancing standardization and harmonization of imaging data in multicenter clinical trials, all scanners to be used for NCI clinical trial imaging should be qualified.

As explained in Part A, Section 1.2, of the CQIE MOP, the primary objective of the CQIE program is to establish a resource of ‘trial ready’ sites within the NCI Cancer Centers that are capable of conducting clinical trials in which there is an integral molecular and functional advanced imaging endpoint. In support of this objective, the CQIE program is designed to qualify sites to participate in advanced imaging trials which include the following MR imaging:

- Volumetric MR of the brain
- DCE-MRI of the body
- MR diffusion of the brain
- DCE-MRI of the brain

1.2 Overview of MRI Procedures
MRI procedures for CQIE qualification include clinical test images for diffusion imaging, phantom tests with an ACR Accreditation MR phantom, phantom tests with the CQIE Body DCE-MRI phantom, and compliance with a standardized set of quality control measures.

<table>
<thead>
<tr>
<th>Schedule of Procedures</th>
<th>Time Point</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>T0 Initial</td>
</tr>
<tr>
<td>Clinical Test Case - MR Diffusion Brain</td>
<td>X</td>
</tr>
<tr>
<td>ACR Phantom Test</td>
<td>X</td>
</tr>
<tr>
<td>DCE-MR Phantom Test</td>
<td>X</td>
</tr>
<tr>
<td>Standardized Quality Control</td>
<td>X</td>
</tr>
</tbody>
</table>

1.2.1 MRI System Requirements
CQIE qualification is intended for 1.5 Tesla MR Magnets; however, 3T imaging of the brain is permissible.
1.3 **ACRIN Imaging Core Laboratory**

The ACRIN Imaging Core Laboratory is headquartered within the American College of Radiology Clinical Research Center in Philadelphia. The role of the Imaging Core Lab is to (1) develop a manual of operations and training materials for the CQIE site qualification process (2) serve as a resource for technical and imaging protocol questions; (3) collect and archive qualification imaging data; and (4) provide qualitative and quantitative review of the qualification imaging data.

Should you have any questions or require additional information please consult the CQIE web site at [http://www.acrin.org/NCI-CQIE.aspx](http://www.acrin.org/NCI-CQIE.aspx) or a member of the ACRIN CQIE project team by telephone or email:

<table>
<thead>
<tr>
<th>PROJECT MANAGEMENT</th>
<th>IMAGING</th>
</tr>
</thead>
<tbody>
<tr>
<td><a href="mailto:CQIE-Manager@acr.org">CQIE-Manager@acr.org</a></td>
<td><a href="mailto:CQIE-MR-CT@acr.org">CQIE-MR-CT@acr.org</a></td>
</tr>
<tr>
<td>Telephone: 215-940-8921</td>
<td><a href="mailto:CQIE-PET@acr.org">CQIE-PET@acr.org</a></td>
</tr>
<tr>
<td>Fax: 215-717-0860</td>
<td></td>
</tr>
</tbody>
</table>

**ACRIN hours of operation are 8:30 – 5:00 ET**
2. QUALIFICATION IMAGING

2.1 Clinical Test Case – MR Diffusion

For initial and annual qualification assessment, sites will need to submit a diffusion-weighted MR series from a live subject or volunteer. The test case can be normal or abnormal. The test cases should be acquired within one month of the submission time point. Post-processed reconstructions of ADC maps are to be included with your submission. If eADC or FA maps are part of your institutional routine, these should also be included with your submission. Patient identifiers must be scrubbed from clinical images before transmission to ACRIN. Images must be submitted in DICOM format. The Test Cases will be qualitatively and quantitatively reviewed for overall technical image quality.

Note: Contact the CQIE team at the ACRIN Imaging Core Lab if your scanner cannot reconstruct ADC maps.

<table>
<thead>
<tr>
<th>Minimum Diffusion Guidelines for All Vendors</th>
</tr>
</thead>
<tbody>
<tr>
<td>2D EPI</td>
</tr>
<tr>
<td>Plane Axial</td>
</tr>
<tr>
<td>B-Value 1000, 100</td>
</tr>
<tr>
<td>FOV 240 mm</td>
</tr>
<tr>
<td>Slice Thickness 5 mm</td>
</tr>
<tr>
<td>Gap 1.5</td>
</tr>
<tr>
<td>Matrix 128 x 128</td>
</tr>
<tr>
<td>Phase A – P</td>
</tr>
<tr>
<td>Frequency L - R</td>
</tr>
</tbody>
</table>

2.2 ACR MR Phantom Scans

For initial and annual qualification assessments, sites will need to perform phantom tests using an ACR MRI phantom—detailed phantom scanning instructions are provided as Appendix C1. If your site does not own an ACR-MR phantom, ACRIN will provide a phantom, on loan, or you may purchase your own. Additional information regarding the phantom loan procedures will be provided as part of the Site Qualification Plan, as needed. For purchasing information refer to the ACR web site or contact the ACRIN-CQIE project manager.

Phantom image data will be evaluated, per documented operating procedures, under the management of the Imaging Core Laboratory. Both a qualitative and quantitative review of the image data will be conducted. This review will include evaluation of geometric accuracy, high-contrast spatial resolution, slice thickness accuracy, slice position accuracy, image intensity uniformity, percent-signal ghosting, low-contrast object detectability, and compliance with image acquisition protocols.
2.3 **DCE-MR Phantoms Scans**

For initial and annual qualification assessments, sites will need to perform phantom tests using a CQIE body DCE-MR phantom—detailed phantom scanning instructions are provided as Appendix C2. The DCE-MR phantom image data will be evaluated, per documented operating procedures, under the management of the Imaging Core Laboratory. Both a qualitative and quantitative review of the image data will be conducted. This review will include evaluation of T1 map error estimation, temporal resolution, image quality and compliance with image acquisition protocols.
3. **STANDARDIZED QUALITY CONTROL**

3.1 **Routine Quality Control**

Quality control is an important function of image quality and patient safety and takes on even greater importance in multicenter quantitative imaging trials. The benefits of quality control include: verification of the operational integrity of the systems, consistent and high image quality, decreased chance of artifacts, early identification of potential problems, and consistent quantitative accuracy. As such, quality control of imaging equipment is fundamental to the goal of image standardization in imaging and therapy trials. In line with recommendations of the American College of Radiology, all CQIE sites are required to have a documented quality assurance program monitored by a qualified medical physicist/MR scientist. For additional guidance, please reference ACR Technical Standard for Diagnostic Medical Physics Performance Monitoring of Magnetic Resonance Imaging Equipment and ACR Practice Guideline for Performing and Interpreting Magnetic Resonance Imaging.

3.1.1 **Acceptance Testing**

The aim of acceptance testing is to verify that the equipment performs according to its specifications and clinical purpose. Acceptance testing should be performed according to manufacturer recommendations upon installation of imaging equipment and after major upgrades, before clinical use. The acceptance testing protocol should include an evaluation of all coils.

3.1.2 **Routine Quality Control Testing**

Routine performance tests and preventive maintenance service are to be conducted according to performance measurements as outlined by the manufacturer and include regular testing procedures to insure proper operation on a daily basis. Federal standards require MR manufacturers to provide quality assurance testing instructions, recommended testing frequency, a QC phantom appropriate for the scanner and acceptable variations in parameter measurements. If any QC parameter being monitored falls outside of the control limits, corrective action should be taken.

3.2 **CQIE Standardized Quality Control**

To address the need of imaging standardization in multicenter and/or quantitative imaging trials, CQIE sites are expected to comply with the quality control testing (and frequency) identified in 3.2.1 below. These tests may already be part of your existing QC program. If not, these tests are to be incorporated into your continuous quality control activities. Note that the standardized CQIE QC measures do not replace any QC measures required by law, accreditations, or those recommended by the manufacturer. Rather these QC measures were adopted for the CQIE program based on published recommendations by organizations and researchers involved in quantitative imaging and are intended to serve as a minimum QC standard. The purpose for establishing a standardized set of quality control activities is to help ensure the quantitative data generated are comparable within institutions, across institutions, and over time. However, due to the nature of advanced/experimental imaging, sites may be required to perform additional QC activities, or perform certain activities more frequently, to qualify for, or participate in, a given clinical trial. Compliance with CQIE QC
guidelines does not replace the responsibility for compliance with trial-specific requirements and vice-versa.

CQIE sites are expected to adhere to these quality control standards to maintain CQIE qualification. As with all QC testing, performance of these procedures should be documented in your QC log and archived. A MR QC Questionnaire will be required for the T2 and T3 qualification renewals. This questionnaire requires sites to attest to compliance with the CQIE standardized QC measures. Compliance with the CQIE QC standards is subject to audit.

### 3.2.1 Standardized QC Tests for MRI

<table>
<thead>
<tr>
<th>Test</th>
<th>Minimum Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Center Frequency</td>
<td>Weekly</td>
</tr>
<tr>
<td>Table Positioning</td>
<td>Weekly</td>
</tr>
<tr>
<td>Signal to Noise</td>
<td>Weekly</td>
</tr>
<tr>
<td>Artifact Analysis</td>
<td>Weekly</td>
</tr>
<tr>
<td>Geometric Accuracy</td>
<td>Weekly</td>
</tr>
<tr>
<td>High-Contrast Resolution</td>
<td>Weekly</td>
</tr>
<tr>
<td>Low-Contrast Resolution</td>
<td>Weekly</td>
</tr>
<tr>
<td>Magnetic Field Homogeneity</td>
<td>Quarterly</td>
</tr>
<tr>
<td>Slice Position Accuracy</td>
<td>Quarterly</td>
</tr>
<tr>
<td>Slice Thickness Accuracy</td>
<td>Quarterly</td>
</tr>
<tr>
<td>Radiofrequency Coil Checks</td>
<td>Annually</td>
</tr>
</tbody>
</table>
4. DATA SUBMISSION

4.1 Qualification Data
Submit the following data for each scanner to be qualified.

<table>
<thead>
<tr>
<th>Time Point</th>
<th>Procedure</th>
<th>Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>T0-T3</td>
<td>Clinical Test Cases</td>
<td>▪ Diffusion-weighted MR data set</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▪ ADC Maps</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▪ eADC or FA Maps (if applicable)</td>
</tr>
<tr>
<td>T0-T3</td>
<td>ACR MR Phantom Tests</td>
<td>▪ Scan 1: Modified ACR Protocol data set</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▪ Scan 2: 3D Volumetric data set</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▪ Scan 3: T1 Mapping for Brain DCE-MRI data set</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▪ Scan 4: Brain DCE-MRI data set</td>
</tr>
<tr>
<td>T0-T3</td>
<td>Body DCE-MR Phantom Tests</td>
<td>▪ Scan 1: T1 Mapping for Body DCE-MRI data set</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▪ Scan 2: Body DCE-MRI data set</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▪ Scan 3: Coil Maps</td>
</tr>
<tr>
<td>T1-T3</td>
<td>Image Transmittal Worksheet</td>
<td>▪ Scanner specifications</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▪ Notification to ACRIN of data submission</td>
</tr>
<tr>
<td>T2-T3</td>
<td>Quality Control</td>
<td>▪ Quality Control Questionnaire</td>
</tr>
</tbody>
</table>

**Clinical Test Cases**
Images must be submitted in DICOM format. Patient identifiers must be scrubbed from clinical images before transmission to ACRIN.

**Data Submission**
Images must be submitted in DICOM format. Image data should be transmitted to ACRIN electronically via secure file transfer protocol (FTP). Download and installation instructions for FTP setup are provided in Part A of this MOP, Appendix A2. An Image Transmittal Worksheet (ITW) should accompany each image submission. Refer to the CQIE web site, http://www.acrin.org/NCI-CQIE.aspx, for all qualification materials, including the ITW.

If necessary images can be sent on CD-ROM. Sites submitting images via CD should mail the package, including a copy of the ITW, to the ACRIN Imaging Core Lab at the address below. Method of shipment should include package tracking.

ACRIN Imaging Core Lab, # CQIE-MR
American College of Radiology
1818 Market Street, Suite 1600
Philadelphia, PA 19103
5. References

- American College of Radiology. MRI Quality Control Manual, 2004
- Imaging Working Group (IWG), Clinical Translational Science Awards (CTSA).
- Quantitative Imaging Biomarkers Alliance (QIBA), Radiological Society of North America (RSNA).
This document provides detailed instructions for performing the ACR Accreditation MR phantom tests. Though based on the ACR MR Accreditation testing, modifications were made for purpose of CQIE qualification. If your site does not own an ACR-MR phantom, ACRIN will provide a phantom, on loan, or you may purchase your own. Additional information regarding the phantom loan procedures will be included in your Site Qualification Plan. For purchasing information refer to the ACR web site.

1. **ACR Accreditation MR Phantom**

The ACR MRI phantom is a short, hollow cylinder of acrylic plastic closed at both ends. The inside length is 148 mm; the inside diameter is 190 mm. It is filled with a solution of nickel chloride and sodium chloride: 10 mM NiCl2 and 75mM NaCl. The outside of the phantom has the words “NOSE” and “CHIN” etched into it as an aid to orienting the phantom for scanning, as if it were a head. Inside the phantom are several structures designed to facilitate a variety of tests of scanner performance.

2. **Test Preparation and Set Up**

Please read the following instructions in full before scanning the phantom. The ACR MR phantom will be used for the following phantom scans:

- Phantom Sequence 1: ACR Protocol
- Phantom Sequence 2: CQIE 3D Volumetric Protocol
- Phantom Sequence 3: CQIE T1 Mapping Series for Brain DCE-MRI
- Phantom Sequence 4: CQIE Brain DCE-MRI Protocol

The position and alignment of the ACR MR phantom is the same for all 4 of the phantom scans in this section. The phantom should be scanned in the head coil with the cylindrical phantom aligned as a head would be in the coil. Transaxial slices should result in circular cross-sections of the phantom. The phantom should be positioned so that the word “Nose” is where the nose would be for a standard head study and the word “Chin” is where the chin would be located in a standard head study. The center of the phantom (the dark notch on the side of the phantom) should be placed in the center of the head coil and aligned with the positioning indicator light so that it will be in the isocenter of the scanner. Once grossly positioned, it is then necessary to “fine tune” the position of the phantom along all three axes. For this, you will need to use a non-metallic bubble level.

Place the level along the top of the phantom running in and out of the scanner (along the z-axis) to ensure that the phantom is horizontal. Place a gauze pad under either end of the phantom to level the phantom horizontally. Next, place the level on top of the plastic bar at the chin surface, rotating the phantom so that the plastic bar is horizontal. With the phantom then clamped or wedged inside the head coil, check to see that the sagittal laser alignment light is parallel to the line running along the “nose” surface of the phantom. (To see the laser light reflection, it may be necessary to place a piece of white paper on top of the phantom.) After each position adjustment, recheck that the top of the phantom and the
MR PHANTOM TEST INSTRUCTIONS: ACR MR PHANTOM

chin bar are still horizontal. In addition, you will want to confirm that the axial alignment light is parallel to the superior end of the geometric distortion grid (array of squares) as shown by the arrows in Figure 2.

After the phantom has been moved into the center of the magnet, verify its positioning by performing sagittal and, if desired, coronal plane localizer scans, until correct. (Please note, some systems require that a weight be entered in order to scan the phantom. The ACR recommends that your site enter a weight of 200 lbs.) Once correctly aligned, the phantom should be kept in the same position during the entire series of scans.

3. Phantom Scan

If your site is performing these tests for the first time you will need to build the acquisition and save it to your scanner’s protocol menu, this may require special user permissions. When setting up the scans, enter your institution name in the patient name field (see example below).

Patient Name: CQIE Name of Your Cancer Center (ex. ACRIN Cancer Center)

Phantom Sequence 1: Modified ACR Protocol

SERIES # 1: A sagittal locator sequence should be acquired with the acquisition parameters listed below as Series 1. The sagittal locator scan should result in an image similar to Figure 3 on the following page. If the pairs of 45° crossed wedges are not visible in the scan, the phantom must be repositioned and rescanned. A horizontal line used for slice prescription (see Figure 4) should be parallel to the low contrast disks located at the top of Figure 3 or Figure 4. If not, the phantom must be repositioned. If using a multi-channel head coil, pre-scan normalization (e.g. PURE, CLEAR) must be disabled.

<table>
<thead>
<tr>
<th>Modified ACR Protocol</th>
<th>Pulse Sequence</th>
<th>TR (ms)</th>
<th>TE (ms)</th>
<th>FOV (mm)</th>
<th># of Slices</th>
<th>Slice Thickness (mm)</th>
<th>Slice Gap (mm)</th>
<th>NEX</th>
<th>Matrix</th>
<th>Scan Time (min:sec)</th>
<th>Pre-Scan Normalization</th>
</tr>
</thead>
<tbody>
<tr>
<td>S-1 Sagittal Locator</td>
<td>Spin Echo</td>
<td>200</td>
<td>20</td>
<td>256 (25 cm)</td>
<td>1</td>
<td>20 mm</td>
<td>N/A</td>
<td>1</td>
<td>256 x 256</td>
<td>00:56</td>
<td>OFF</td>
</tr>
<tr>
<td>S-2 Axial T1</td>
<td>Spin Echo</td>
<td>500</td>
<td>20</td>
<td>256</td>
<td>11</td>
<td>5 mm</td>
<td>5</td>
<td>1</td>
<td>256 x 256</td>
<td>02:16</td>
<td>OFF</td>
</tr>
<tr>
<td>S-3 Axial T2 Double-Echo</td>
<td>Spin Echo</td>
<td>2000</td>
<td>20/80</td>
<td>256</td>
<td>11</td>
<td>5 mm</td>
<td>5</td>
<td>1</td>
<td>256 x 256</td>
<td>08:56</td>
<td>OFF</td>
</tr>
<tr>
<td>S-4 Axial T1 (multi-channel coils only)</td>
<td>Spin Echo</td>
<td>500</td>
<td>20</td>
<td>256</td>
<td>11</td>
<td>5 mm</td>
<td>5</td>
<td>1</td>
<td>256 x 256</td>
<td>02:16</td>
<td>ON</td>
</tr>
</tbody>
</table>

Note: Do not use post-process image leveling filters for image intensity correction (e.g. SCIC)
MR PHANTOM TEST INSTRUCTIONS: ACR MR PHANTOM

SERIES # 2-3: Acquisitions 2 and 3 are transaxial spin echo pulse sequences acquired with identical spatial parameters: 5mm slice thickness, 5 mm gap, 25 cm FOV, 256 x 256 matrix. At least 11 slices should be obtained, aligned using graphic prescription from the sagittal locator as shown in Figure 4 (Note: This is the preferred method for slice positioning). The center of slice #1 should be aligned with the vertex of the lower set of crossed wedges (visible on the lower left in Figures 3 and 4) and through the center of the dark chemical shift and resolution insert (visible on the lower right). Slice #1 should result in a transaxial image that looks like Figure 5. The centers of slices #8–11 should align with the four low-contrast discs shown toward the top in Figures 3 and 4. Your axial slices must be positioned as shown in Figure 4 in order for your images to be acceptable for evaluation. If using a multi-channel head coil, pre-scan normalization must be disabled.

SERIES # 4 (Multi-Channel Head Coils): This acquisition should be performed only if using a multi-channel head coil. The acquisition is a transaxial pulse sequence acquired with identical spatial parameters as Series # 2 and 3 but with pre-scan normalization enabled – Series #1-3 should have been performed with pre-scan normalization disabled. Calibration scans needed for PURE can be performed at any point prior to Series 4, as needed.
MR PHANTOM TEST INSTRUCTIONS: ACR MR PHANTOM

Phantom Sequence 2: CQIE Sagittal 3D Volumetric Protocol
Maintain the positioning of the ACR MR phantom as described above. Using slice 5 of the Axial T1 series, prescribe a sagittal 3D volumetric slab using a T1 weighted, spoiled gradient echo with an Inversion Recovery-preparatory pulse. The volume should be prescribed to sufficiently cover the entire phantom in the sagittal plane.

<table>
<thead>
<tr>
<th>3D Volumetric Protocol</th>
<th>Plane</th>
<th>TR (ms)</th>
<th>TE (min)</th>
<th>TI</th>
<th>Flip Angle</th>
<th>FOV (mm)</th>
<th>Phase FOV</th>
<th>Slice Thickness</th>
<th>Gap</th>
<th>Matrix</th>
<th>Phase</th>
<th>Freq</th>
<th>NSA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Siemens 3D MPRAGE</td>
<td>Sagittal</td>
<td>2500 - 2800</td>
<td>3.5</td>
<td>1100</td>
<td>7°</td>
<td>256 (25 cm)</td>
<td>100%</td>
<td>1.3 mm</td>
<td>None</td>
<td>256 x 256</td>
<td>A – P</td>
<td>S – I</td>
<td>1</td>
</tr>
<tr>
<td>Philips 3D TFE</td>
<td>Sagittal</td>
<td>Minimum</td>
<td>4 min.</td>
<td>870</td>
<td>8°</td>
<td>256</td>
<td>100%</td>
<td>1.3 mm</td>
<td>None</td>
<td>256 x 256</td>
<td>A – P</td>
<td>S – I</td>
<td>1</td>
</tr>
<tr>
<td>GE IR-FSPGR</td>
<td>Sagittal</td>
<td>~10 Min. Full</td>
<td>450</td>
<td>20°</td>
<td>256</td>
<td>100%</td>
<td>1.3 mm</td>
<td>None</td>
<td>256 x 256</td>
<td>A – P</td>
<td>S – I</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

Phantom Sequence 3 & 4: Brain DCE-MRI Protocol
Dynamic contrast-enhanced (DCE) MRI protocols are performed using a T1-weighted, 3D multi-phase spoiled gradient echo perfusion technique. Although no contrast media will be used for the phantom tests, when performed clinically on patients, the dynamic contrast-enhanced series is preceded by a series of non-contrast, single-phase acquisitions, each performed at a different flip angle. The non-contrast series make up the “T1 Maps;” these are essential to understanding the inherent T1 of the tissue and mapping the B1 magnetic field before the introduction of contrast media to the tumor and surrounding vasculature. The required flip angles are shown in the chart below. Note that the lowest flip angle must be 5 degrees or less; a 2 degree flip angle is ideal.

<table>
<thead>
<tr>
<th>Brain DCE-MRI Protocol</th>
<th>Plane</th>
<th>TR (ms)</th>
<th>TE (ms)</th>
<th>Flip Angles</th>
<th>FOV (mm)</th>
<th>Phase FOV</th>
<th>Thick</th>
<th>Gap</th>
<th>Matrix</th>
<th>Phase</th>
<th>NEX (NSA)</th>
<th>Time per Phase</th>
<th>Total Scan Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>T1 Maps 3D (5 series total)</td>
<td>Axial</td>
<td>3.0-6.5</td>
<td>Minimum</td>
<td>30, 20, 15, 10, ≤5°</td>
<td>256</td>
<td>75 - 100%</td>
<td>5 mm</td>
<td>None</td>
<td>256 x 128</td>
<td>R – L</td>
<td>1 – 2</td>
<td>Single Acq</td>
<td>Single Acq</td>
</tr>
<tr>
<td>DCE 3D</td>
<td>Axial</td>
<td>3.0-6.5</td>
<td>Minimum</td>
<td>20 – 35°</td>
<td>256</td>
<td>75 - 100%</td>
<td>5 mm</td>
<td>None</td>
<td>256 x 128</td>
<td>R - L</td>
<td>1</td>
<td>3 – 8 seconds</td>
<td>&gt; 6 minutes</td>
</tr>
</tbody>
</table>

1 Perform the T1 maps with 2 NEX if it is permitted by your system with the use of parallel imaging

Suggested imaging parameters are provided (above) to assist in building your DCE-MRI Brain protocol. The parameters for conducting DCE-MRI, and indeed many dynamic...
protocols of a specified spatial resolution, can vary greatly between scanner vendors, models, hardware, software versions and field strengths. Understanding these challenges is essential to understanding DCE-MRI implementation. It is for this reason that vendor and platform-specific parameters are not explicitly provided for this exercise. Rather, guidelines are provided and the spatial resolution requirements (matrix, slice thickness, field of view, etc.) for the DCE series and the associated T1 maps which precede it are required to fall within a provided temporal resolution limit for the given anatomical area (e.g. eight seconds or less per phase in the brain; ten seconds or less in the body per phase or “measurement”). The parameters in the shaded boxes in the table above will vary depending on the capabilities of your scanner. The remaining areas represent the required minimum settings for CQIE qualification for DCE-MRI of the brain.

**DCE-MRI Brain Pre-Scan Notes:**

- Scan the DCE-MRI protocol using the same coil and phantom set-up as in Phantom Sequences 1 & 2 above.
- For all series, do not use normalization or intensity correction filters such as CLEAR, SCIC or PURE.
- The slice locations and positioning for the T1 mapping and the dynamic series must be identical.
- The TR and TE for all six scan series (5 T1 maps plus a dynamic series) should be identical. For GE systems, reduce Turbo Factor to 1 or 0 if TR and TE do not match across series. If you still have difficulty with TR & TE, contact the CQIE technical team.
- If magnets and multichannel head coils are available to perform parallel imaging (e.g. ASSET, SENSE, IPAT), speed factors of 2 can be used. Do not use higher speed factors. If parallel imaging techniques are used, identical parallel imaging techniques must be used on all series.
- The total slab thickness must yield a 6 cm slab of reconstructed coverage. Therefore, a minimum of 12 slices must be reconstructed at 5mm. A minimum of 20% slice oversampling is recommended to reduce z-axis overlap into the evaluable volume.
- Images on the dynamic run should be acquired as a 3D FSPGR/FLASH true axial at a 20-35 degree flip angle; do not prescribe slabs as an oblique.
- Pre-scan calibration is completed for the first T1 mapping series only and is not repeated until after the dynamic series is completed.
- Perform a three-plane localizer per your institutional routine for a brain study, or you may use the localizer suggested in section one for the ACR series. (This localizer is not evaluated for qualification.)

**Phantom Sequence 3: T1 Mapping Series for DCE-MRI Brain**

- The five T1 mapping series, as well as the dynamic DCE series, are to be prescribed identically in the axial plane with the first slice being the inferior-most slice.
- Using the midline sagittal image, prescribe the first axial T1 mapping series axially with the center of the volume centered roughly to the center of the phantom (see Figure 6).
MR PHANTOM TEST INSTRUCTIONS: ACR MR PHANTOM

- Copy this slab prescription to the remaining T1 maps and the dynamic series.
- Run the T1 maps:
  - 30 degrees  Pre-scan per usual routine
  - 20 degrees  No pre-scan
  - 15 degrees  No pre-scan
  - 10 degrees  No pre-scan
  - 5 degrees  No pre-scan

**Phantom Sequence 4: DCE-MRI Brain Series**

- Run the DCE dynamic series; no pre-scan.

The temporal resolution (or time per phase/measurement) of the DCE dynamic series must be less than 8 seconds, and ideally 6 seconds or less. The total imaging time for the dynamic series must be at least 6 minutes. This amounts to 45 to 120 phases, depending upon the acquisition time per phase. The total number of images acquired should be 540 to 1,920 depending on the number of images per slab and the number of phases.

Example: Given a scan time of 5 seconds per phase/measurement...

<table>
<thead>
<tr>
<th>Time</th>
<th>Phases Calculation</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 minutes</td>
<td>360 seconds</td>
</tr>
<tr>
<td>360 seconds</td>
<td>72 phases</td>
</tr>
<tr>
<td>72 phases</td>
<td>864 slices</td>
</tr>
</tbody>
</table>
This document provides information about the CQIE Body DCE-MR phantom tests. The CQIE Body DCE-MRI phantom is not currently a commercially available phantom (see figure 1). The phantom contains 23 vials of varying concentrations of gadolinium and other solutions. The vials are surrounded by a loading solution consisting of a bath of distilled water. Note that the water level in the phantom will not appear full, this is normal. The phantom will be provided by ACRIN to all sites for baseline and annual qualification testing. Please read the following instructions in full before conducting your phantom tests.

1. **Body DCE-MRI Phantom**

   To reduce variance, a standardized imaging phantom designed specifically for body DCE-MRI will be used. ACRIN will conduct both a qualitative and quantitative review of the image data. This review will include evaluation of T1 map error estimation, temporal resolution, image quality and compliance with image acquisition protocols (via check of DICOM metadata).

2. **Phantom Set Up**

   If your site is performing this test for the first time you may want to build your CQIE Body DCE-MRI protocol before positioning the phantom, see Section 3 (below) for detailed instructions.

   - **Coronal acquisition plane.**
   - Use the surface array coil per your institutional routine for abdominal imaging (i.e. torso-array).
   - Place the CQIE Body DCE-MRI phantom in the center of the table, on top of the posterior elements of the torso-array coil with the vial lids facing upwards. The phantom should be positioned over the elements typically selected for a liver study. Assuming a feet-first entry into the bore, the large translucent lid on the outer diameter should represent the “foot” of the phantom (as illustrated in Figures 2 and 3).
   - Add the anterior torso array coil elements to the top (lid-side) of the phantom.
   - Pad either side of the phantom as necessary to ensure ideal alignment of the coil elements about the phantom.
   - Landmark to the center of the phantom.
3. Test Preparation – The CQIE Body DCE-MRI Protocol

If your site is performing this test for the first time you will need to build the acquisition protocol and save it to your scanner’s protocol menu, this may require special user permissions. The parameters for conducting DCE-MRI can vary greatly between scanner vendors, models, software versions and field strengths. Understanding these challenges is essential to understanding DCE-MRI imaging. It is for this reason that vendor and platform-specific parameters are not explicitly provided. The CQIE Body DCE-MRI Protocol Worksheet (Appendix C3) will assist you in optimizing a scanner-specific protocol to achieve the minimum required temporal and spatial resolution.

**Dynamic Series**
- Use the Body DCE-MRI Protocol Worksheet (Appendix C3) to define the acquisition parameters for a basic dynamic series.
- Add a CQIE Body DCE-MRI Phantom protocol to your scanner’s protocol menu. Enter/save the technical parameters for the basic dynamic series, based on the output of the above referenced protocol worksheet, and label as “Dynamic Series.”

**Single-Phase T1 Mapping Series**
- Copy and paste the parameters from the “Dynamic Series” for 30 degrees, 15 degrees and 5 degrees. Place these series to run immediately before the Dynamic Series.
- Rename each of the three series as “T1 Map – X” (where ‘x’ is the flip angle).
- Change the number of phases/measurements for each of the three T1 Maps to 1 (for GE systems, remove the multi-phase option) – change this only for the three T1 Maps.
- Change the NEX/NSA for each of the T1 Maps to 3 – again, change this only for the three T1 Maps. This will increase the scan time for the T1 Maps (this is normal).

**Coil Map Series**
- Copy the “T1 Map 15 degrees” series twice and place these two series immediately after the dynamic scan.
- Rename the first of these two series “Body Coil Map” and set the coil to body.
- Rename the second of these two series “Array Coil Map” and confirm that the torso array coil is selected as the receive coil.
- In all, your Body DCE-MRI protocol will have the following series prepared, in the order shown, to scan the CQIE DCE-MRI Body Phantom:

<table>
<thead>
<tr>
<th>Series</th>
<th>Flip Angle</th>
<th>Tuned/NOT Tuned</th>
<th>Pre-scan/No Pre-scan</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 plane localizer</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>T1 Map 30</td>
<td>30 degrees</td>
<td>Tuned</td>
<td>Pre-scan</td>
</tr>
<tr>
<td>T1 Map 15</td>
<td>15 degrees</td>
<td>Not Tuned</td>
<td>No Pre-scan</td>
</tr>
<tr>
<td>T1 Map 5</td>
<td>5 degrees</td>
<td>Not Tuned</td>
<td>No Pre-scan</td>
</tr>
<tr>
<td>Dynamic Series</td>
<td>30 degrees</td>
<td>Not Tuned</td>
<td>No Pre-scan</td>
</tr>
<tr>
<td>CQIE Body Coil Map</td>
<td>15 degrees</td>
<td>Tuned</td>
<td>Pre-scan</td>
</tr>
<tr>
<td>CQIE Array Coil Map</td>
<td>15 degrees</td>
<td>Not Tuned</td>
<td>No Pre-scan</td>
</tr>
</tbody>
</table>
MR PHANTOM TEST INSTRUCTIONS: BODY DCE-MR PHANTOM

4. Phantom Scans

When setting up the scans, enter your institution name in the patient name field (see example below).

Patient Name: CQIE Name of Your Cancer Center (ex. ACRIN Cancer Center)

Pre-Scan Notes

- Do not use normalization or intensity correction filters such as CLEAR, SCIC or PURE for any of the series.
- The slice locations and positioning for the T1 mapping and the dynamic series must be identical.
- The TR and TE for all six scan series (5 T1 maps plus a dynamic series) should be identical. For GE systems, reduce Turbo Factor to 1 or 0 if TR and TE do not match across series. If you still have difficulty with TR & TE, particularly at 30 degrees, contact the CQIE technical team.

Phantom Scan 1: T1 Maps for Body DCE-MRI

- Run a conventional 3 plane localizer to identify the phantom.
- Prescribe the 3D slab as a straight coronal acquisition centered to the phantoms.
- Run the T1 Map at 30 degrees, prescribing the 3D slab in the oblique/coronal plane through the center of the phantom, centered in all 3 planes (pre-scan as usual)
- Run the next T1 Map at 15 degrees, copying the position of the 3D slab from the previous series (no pre-scan).
- Run the next T1 Map at 5 degrees, copying the position of the 3D slab from the previous series (no pre-scan).

Phantom Scan 2: Dynamic Series for Body DCE-MRI

- Run the Dynamic Series at 30 degrees, again copying the position of the 3D slab from the previous series (no pre-scan). This is a multi-phase series – enable multi-phase (on GE systems) and increase the number of phases (or measurements) until the scan time is six minutes.

Example: If your scan time is 8 seconds per phase/measurement...

<table>
<thead>
<tr>
<th>6 minutes = 360 seconds</th>
</tr>
</thead>
<tbody>
<tr>
<td>360 seconds / 8 seconds = 45 phases</td>
</tr>
</tbody>
</table>

On an actual patient, contrast injection would occur after 10 baseline phases. For example, if your scan time is 8 seconds per phase/measurement, you would inject after 80 seconds. Typical injection rates are 3-5cc/second at 0.1mmol/kg followed by a 20cc saline flush at the same rate.

Phantom Scan 3: Coil Maps for Body DCE-MRI

- Run the Body Coil Map; ensure the integrated Body Coil is selected (pre-scan as usual).
- Run the Array Coil Map; ensure that the Torso Array Coil is selected (no pre-scan)
1. Enter the following scan parameters into your system:

| Body DCE-MRI Imaging Protocol | GE: 3D Fast SPGR  
|                             | Siemens: 3D FLASH  
<table>
<thead>
<tr>
<th></th>
<th>Philips: 3D TFE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plane</td>
<td>Oblique (coronal)</td>
</tr>
<tr>
<td>TE</td>
<td>minimum</td>
</tr>
<tr>
<td>Frequency FOV</td>
<td>40 cm</td>
</tr>
<tr>
<td>Flip Angles</td>
<td>30 degrees</td>
</tr>
<tr>
<td>Phase FOV</td>
<td>40 cm (100%)</td>
</tr>
<tr>
<td>Slice Thickness</td>
<td>6 mm</td>
</tr>
<tr>
<td>Frequency Matrix</td>
<td>256</td>
</tr>
<tr>
<td>Phase Matrix</td>
<td>128</td>
</tr>
<tr>
<td>Number of Locs (reconstructed)</td>
<td>12</td>
</tr>
<tr>
<td>Slice Oversampling (Siemens)</td>
<td>25% (if applicable)</td>
</tr>
<tr>
<td>Pixel Interpolation</td>
<td>Off</td>
</tr>
<tr>
<td>Spatial Saturation Bands</td>
<td>Anterior and Posterior</td>
</tr>
<tr>
<td>Slice Interpolation</td>
<td>Off</td>
</tr>
<tr>
<td>Fat Saturation</td>
<td>Off</td>
</tr>
<tr>
<td>Phase Direction</td>
<td>L - R</td>
</tr>
<tr>
<td>ASSET / IPAT / Parallel Imaging</td>
<td>Off</td>
</tr>
<tr>
<td>BW</td>
<td>62.5 kHz (GE)</td>
</tr>
<tr>
<td></td>
<td>250 Hz/px (Siemens/Philips)</td>
</tr>
<tr>
<td>TR</td>
<td>Minimum</td>
</tr>
<tr>
<td>Number of Acquisitions (NEX/NSA)</td>
<td>1 (do not use ZIP512, ZIPx2, or IRprep)</td>
</tr>
<tr>
<td>Delay before Acquisition (GE CV4)</td>
<td>0</td>
</tr>
<tr>
<td>Turbo Factor (GE CV)</td>
<td>0</td>
</tr>
<tr>
<td>Slice Resolution</td>
<td>100%</td>
</tr>
</tbody>
</table>

2. Based on the parameters above, record the scan time for the basic series:

___ . ___ seconds

- **If the scan time is less than 10 seconds → STOP.** These parameters will be the basis for your dynamic, multi-phase series. Go back to the phantom scan instructions.

- **If the scan time is longer than 10 seconds → Go to page 2, proceed step-by-step, in order, until the scan time is less than 10 seconds per phase.** In each step, indicate the new time. If the modification provided is not possible, indicate using the check box and re-enter the time from the previous step.
### Acquisition Parameters Adjustment

<table>
<thead>
<tr>
<th></th>
<th>Cannot Perform</th>
<th>Can Perform New series time</th>
</tr>
</thead>
</table>
| 3.1 | Increase BW to (a) or (b) then reset TR and TE to new minimum values  
(a.) GE = 83.3 kHz  
(b.) Philips or Siemens = 375 Hz/px | ☐ |  
| 3.2 | Change # locations to 8 | ☐ |  
| 3.3 | Change to 90% partial FOV (36 cm phase FOV) | ☐ |  
| 3.4 | Increase FOV to 42cm and change partial FOV to 80% (L/R phase FOV=35.7 cm) | ☐ |  
| 3.5 | Remove anterior and posterior saturation bands | ☐ |  
| 3.6 | Change NEX to equal 0.75 (or 6/8 partial fourier) | ☐ |  
| 3.7 | Turn on parallel imaging (acceleration factor of 2) | ☐ |  

---

**Acquisition Parameters Adjustment**

**Cannot Perform**

**Can Perform New series time**

3.1 Increase BW to (a) or (b) then reset TR and TE to new minimum values  
(a.) GE = 83.3 kHz  
(b.) Philips or Siemens = 375 Hz/px

3.2 Change # locations to 8

3.3 Change to 90% partial FOV (36 cm phase FOV)

3.4 Increase FOV to 42cm and change partial FOV to 80% (L/R phase FOV=35.7 cm)

3.5 Remove anterior and posterior saturation bands

3.6 Change NEX to equal 0.75 (or 6/8 partial fourier)

3.7 Turn on parallel imaging (acceleration factor of 2)
PART D
PET-PET/CT TECHNICAL PROCEDURES

1. CQIE PET-PET/CT QUALIFICATION

1.1 Introduction
The purpose of this chapter is to provide detailed technical information regarding the PET and PET/CT phantom scanning and QC activities required for CQIE qualification. For a full description of the qualification program refer to Part A of the CQIE Manual of Procedures (MOP). The PET procedures and guidelines outlined in this document apply to all scanners to be qualified. Though qualification of only one PET or PET/CT scanner is required, sites are urged to qualify multiple scanners. With the purpose of advancing standardization and harmonization of imaging data in multicenter clinical trials, all scanners to be used for NCI clinical trial imaging should be qualified.

As explained in Part A, Section 1.2, of the CQIE MOP, the primary objective of the CQIE program is to establish a resource of ‘trial ready’ sites within the NCI Cancer Centers that are capable of conducting clinical trials in which there is an integral molecular and functional advanced imaging endpoint. In support of this objective, the CQIE program is designed to qualify sites to participate in advanced imaging trials which include static and dynamic PET or PET/CT of the brain and body.

1.2 Overview of PET-PET/CT Procedures
PET procedures for CQIE qualification include phantom tests with both a uniform cylinder phantom and an ACR Accreditation PET phantom, and compliance with a standardized set of quality control measures.

<table>
<thead>
<tr>
<th>Schedule of Procedures</th>
<th>Time Point</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>T0 Initial</td>
</tr>
<tr>
<td>Clinical Test Cases</td>
<td>X</td>
</tr>
<tr>
<td>ACR PET Phantom Tests</td>
<td>X</td>
</tr>
<tr>
<td>Uniform Cylinder Phantom Tests</td>
<td>X</td>
</tr>
<tr>
<td>Standardized Quality Control</td>
<td>X</td>
</tr>
</tbody>
</table>

1.3 Imaging Core Laboratory
The Imaging Core Laboratory is headquartered within the American College of Radiology Clinical Research Center in Philadelphia. The role of the Imaging Core Lab is to (1) develop guidelines and training materials for CQIE qualification imaging, (2) serve as a resource for
site staff regarding technical and procedural issues associated with the qualification requirements and quantitative imaging, (3) collect and archive qualification imaging data, and (4) manage the qualitative and quantitative review of the qualification imaging data.

Should you have any questions or require additional information please consult the CQIE web site at http://www.acrin.org/NCI-CQIE.aspx or a member of the ACRIN CQIE project team.

<table>
<thead>
<tr>
<th>PROJECT MANAGEMENT</th>
<th>IMAGING</th>
</tr>
</thead>
<tbody>
<tr>
<td><a href="mailto:CQIE-Manager@acr.org">CQIE-Manager@acr.org</a></td>
<td><a href="mailto:CQIE-MR-CT@acr.org">CQIE-MR-CT@acr.org</a></td>
</tr>
<tr>
<td>Telephone: 215-940-8921</td>
<td><a href="mailto:CQIE-PET@acr.org">CQIE-PET@acr.org</a></td>
</tr>
<tr>
<td>Fax: 215-717-0860</td>
<td></td>
</tr>
</tbody>
</table>

ACRIN hours of operation are 8:30 – 5:00 ET
2. QUALIFICATION IMAGING

2.1 Clinical Test Cases

For initial and annual qualification assessments, sites are required to submit two test cases for the Brain and Body FOVs. The test cases can be any FDG study with or without abnormal findings. The test cases should be acquired and reconstructed according to the site’s standard protocols and be acquired within one month of the submission time point (initial qualification and annual requalification).

For each test case, sites need to submit the attenuation-corrected (AC) PET, non-attenuation-corrected (NAC) PET and CT image sets to the ACRIN Imaging Core Lab. All images must be in DICOM format. For initial qualification, the image sets should be submitted with or soon after submission of the Site Assessment Form and must be submitted prior to the ACRIN site visit. For annual requalification, the image sets should be submitted with the annual phantom testing data. Refer to Section 4 of this document for details regarding data submission.

The Test Cases will be qualitatively reviewed for overall technical image quality. This assessment will include a comparison of the technical parameters in the DICOM header with those recorded in Part D of the Site Assessment Form, an analysis of the quality of the PET and CT fusion, and an overall evaluation for anything that may hinder a reviewer’s ability to interpret the study.

2.2 Uniform Cylinder Phantom Scans

For initial and annual qualification assessments, sites will need to perform phantom tests using a uniform cylinder phantom – detailed phantom scanning instructions are provided as Appendix D1. Phantom image data will be evaluated, per documented operating procedures, under the management of the Imaging Core Laboratory. A physicist will conduct both a qualitative and quantitative review of the image data. The qualitative review includes evaluation of the uniformity and noise characteristics of the images. The quantitative review includes evaluation of the accuracy of the SUV calibration and the axial variation of the average SUV. Acceptance criteria for the uniform cylinder phantom tests are provided below.

<table>
<thead>
<tr>
<th>Acceptance Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Body and Brain FOV Static Acquisitions:</strong></td>
</tr>
<tr>
<td>• Volume-averaged SUV in phantom between 0.90 and 1.10</td>
</tr>
<tr>
<td>• Axial variation in phantom &lt; 10%</td>
</tr>
<tr>
<td><strong>Body FOV Dynamic Acquisition:</strong></td>
</tr>
<tr>
<td>• Volume-averaged SUV of each time frame varies by &lt; 10% over the course of the 25-minute acquisition</td>
</tr>
</tbody>
</table>
2.3 ACR PET Accreditation Phantom Scans

For initial and annual qualification assessments, sites will need to perform phantoms tests using the ACR PET accreditation phantom – detailed phantom scanning instructions are provided as Appendix D2. If your site does not own an ACR- PET phantom, ACRIN will provide a phantom, on loan, or you may purchase your own. Additional information regarding the phantom loan procedures will be included in your site visit packet. For purchasing information refer to the ACR web site or contact the ACRIN-CQIE project manager.

Phantom image data will be evaluated, per documented operating procedures, under the management of the ACRIN Imaging Core Lab. A core lab physicist will conduct both a qualitative and quantitative review of the image data. The qualitative review includes evaluation of the uniformity and noise characteristics of the images. The quantitative review consists of central SUV analysis. The SUV acceptance criteria are provided below.

<table>
<thead>
<tr>
<th>SUV Acceptance Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Based on the ACR’s New 2010 Pass/Fail Criteria</td>
</tr>
<tr>
<td>Mean Bkg: 0.85 – 1.15</td>
</tr>
<tr>
<td>25 mm cylinder: &gt; 1.8 – &lt; 2.8</td>
</tr>
<tr>
<td>16 mm / 25 mm ratio: &gt; 0.7</td>
</tr>
</tbody>
</table>
3. STANDARDIZED QUALITY CONTROL

3.1 Routine Quality Control

Quality control is an important function of image quality and patient safety and takes on even greater importance in multicenter quantitative imaging trials. The benefits of quality control include: verification of the operational integrity of the systems, consistent and high image quality, decreased chance of artifacts, early identification of potential problems, and consistent quantitative accuracy. As such, quality control of imaging equipment is fundamental to the goal of image standardization in imaging and therapy trials. In line with recommendations of the American College of Radiology, all CQIE sites are required to have a documented quality assurance program monitored by a medical physicist (or other qualified individual). For additional guidance, please reference ACR Technical Standard for Medical Nuclear Physics Performance Monitoring of PET Imaging Equipment, ACR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals, ACR Technical Standard for Medical Nuclear Physics Performance Monitoring of PET Imaging/CT Imaging Equipment, and ACR Practice Guideline for Performing FDG-PET/CT in Oncology.

3.1.1 Acceptance Testing

The aim of acceptance testing is to verify that the equipment performs according to its specifications and clinical purpose. Acceptance testing should be performed according to manufacturer recommendations upon installation of imaging equipment and after major upgrades, before clinical use.

3.1.2 Routine Quality Control Testing

Routine performance tests and preventive maintenance are to be conducted according to manufacturer recommendations and include regular testing procedures to insure proper operation on a daily basis. Federal standards require PET and PET/CT manufacturers to provide quality assurance testing instructions, recommended testing frequency, an appropriate QC phantom and acceptable variations in parameter measurements. For SUV measurements, assessment should include a comparison against a dose calibrator to ensure accuracy; that is, a comparison of the absolute activity measured versus the measured activity injected. If any QC parameter being monitored falls outside of the control limits, corrective action should be taken.

3.2 CQIE Standardized Quality Control

To address the need of imaging standardization in multicenter and/or quantitative imaging trials, CQIE sites are expected to comply with the quality control testing (and frequency) identified in 3.2.1 below. These tests may already be part of your existing QC program. If not, these tests are to be incorporated into your continuous quality control activities. Note that the standardized CQIE QC measures do not replace any QC measures required by law, accreditations, or those recommended by the manufacturer. Rather these QC measures were adopted for the CQIE program based on published recommendations by organizations and researchers involved in quantitative imaging and are intended to serve as a minimum
QC standard. The purpose for establishing a standardized set of quality control activities is to help ensure the quantitative data generated are comparable within institutions, across institutions, and over time. However, due to the nature of advanced/experimental imaging, sites may be required to perform additional QC activities, or perform certain activities more frequently, to qualify for, or participate in, a given clinical trial. Compliance with CQIE QC guidelines does not replace the responsibility for compliance with trial-specific requirements and vice-versa.

CQIE sites are required to adhere to these quality control standards to maintain CQIE qualification. As with all QC testing, performance of these procedures should be documented in your QC log and archived. A PET QC Questionnaire will be required for the T2 and T3 qualification renewals. This questionnaire requires sites to attest to compliance with the CQIE standardized QC measures. Compliance with the CQIE QC standards is subject to audit.

### 3.2.1 Standardized QC Tests for PET and PET/CT

<table>
<thead>
<tr>
<th>Test</th>
<th>Purpose</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical Inspection</td>
<td>To check gantry covers in tunnel and patient handling system</td>
<td>Daily</td>
</tr>
<tr>
<td>Daily QC Check</td>
<td>To test proper operation of scanner (per manufacturer's recommendations)</td>
<td>Daily</td>
</tr>
<tr>
<td>Normalization</td>
<td>To adjust system response to activity inside the field of view (FOV)</td>
<td>As recommended by manufacturer (at least every 3 months); after software upgrades and after hardware service</td>
</tr>
<tr>
<td>Uniformity</td>
<td>To assess Transverse and Axial Uniformity across image planes by imaging a uniformly filled object</td>
<td>At least every 3 months; after new setups and after software upgrades</td>
</tr>
<tr>
<td>Cross-Calibration</td>
<td>To monitor and identify discrepancies between the PET camera and the dose calibrator</td>
<td>At least every 3 months; after scanner upgrades, after new setups, and after modifications to the dose calibrator</td>
</tr>
<tr>
<td>Image quality</td>
<td>To check hot and cold spot image quality of standardized image quality phantom</td>
<td>At least annually</td>
</tr>
</tbody>
</table>

### 3.2.2 Standardized QC Tests for Dose Calibrator

<table>
<thead>
<tr>
<th>Test</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Constancy (precision)</td>
<td>Each day of use and after equipment repair</td>
</tr>
<tr>
<td>Clock Accuracy</td>
<td>Daily</td>
</tr>
<tr>
<td>Linearity</td>
<td>Quarterly</td>
</tr>
<tr>
<td>Accuracy</td>
<td>Annually and after equipment repair</td>
</tr>
<tr>
<td>Geometry (position and volume)</td>
<td>Upon installation and after replacement or repair of the chamber</td>
</tr>
<tr>
<td>Accuracy of F-18 Measurements</td>
<td>Upon installation; at least once since June 2009</td>
</tr>
</tbody>
</table>
### 3.2.3 Standardized QC Tests for CT (as part of PET/CT)

<table>
<thead>
<tr>
<th>Test</th>
<th>Minimum Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water CT Number &amp; Standard Deviation</td>
<td>Daily - Technologist</td>
</tr>
<tr>
<td>Artifacts</td>
<td>Daily - Technologist</td>
</tr>
<tr>
<td>Scout Prescription &amp; Alignment Light Accuracy</td>
<td>Annually</td>
</tr>
<tr>
<td>Imaged Slice Thickness (slice sensitivity profile, SSP)</td>
<td>Annually</td>
</tr>
<tr>
<td>Table Travel/Slice Positioning Accuracy</td>
<td>Annually</td>
</tr>
<tr>
<td>Radiation Beam Width</td>
<td>Annually</td>
</tr>
<tr>
<td>High-Contrast (Spatial) Resolution</td>
<td>Annually</td>
</tr>
<tr>
<td>Low-Contrast Sensitivity and Resolution</td>
<td>Annually</td>
</tr>
<tr>
<td>Image Uniformity &amp; Noise</td>
<td>Annually</td>
</tr>
<tr>
<td>CT Number Accuracy</td>
<td>Annually</td>
</tr>
<tr>
<td>Artifact Evaluation</td>
<td>Annually</td>
</tr>
<tr>
<td>Dosimetry/CTDI</td>
<td>Annually</td>
</tr>
</tbody>
</table>
4. DATA SUBMISSION

4.1 Qualification Data
Submit the following data for each scanner to be qualified. Refer to the CQIE web site to download the required data forms.

<table>
<thead>
<tr>
<th>Time Point</th>
<th>Procedures</th>
<th>Data</th>
</tr>
</thead>
</table>
| T0-T3      | Clinical Test Cases (Brain and Body FOV) | ▪ Attenuation-corrected PET data sets  
▪ Non-attenuation-corrected PET data sets  
▪ CT data sets  
▪ PET Routine Clinical Protocol Form (PT)  
▪ PET Test Cases Data Form (P1) |
| T0-T3      | Uniform Cylinder Phantom Tests | ▪ Attenuation-corrected data set  
▪ Non-attenuation-corrected data set  
▪ CT data set  
▪ Uniform Cylinder PET Phantom Data Form (P2) |
| T0-T3      | ACR PET Phantom Tests | ▪ Attenuation-corrected data set  
▪ Non-attenuation-corrected data set  
▪ CT data set  
▪ ROI Screen Capture(s)  
▪ ACR PET Phantom Data Form (P4)  
▪ ACR PET Phantom SUV Analysis Form (P5) |
| T1-T3      | Image Transmittal Worksheet | ▪ Scanner specifications  
▪ Notification to ACRIN of data submission |
| T2-T3      | Quality Control | ▪ Quality Control Questionnaire |

Clinical Test Cases
For initial qualification, test cases should be sent to ACRIN for review prior to the site visit and performance of the qualification imaging. For annual requalification, test cases should be sent with the annual phantom imaging. Patient identifiers must be scrubbed from clinical images before transmission to ACRIN.

Data Transmission
Images must be submitted in DICOM format. Image data should be transmitted to ACRIN electronically via secure file transfer protocol (FTP). Download and installation instructions for FTP setup are provided in Part A of this MOP, Appendix A2. An Image Transmittal Worksheet (ITW) should accompany each image submission. Refer to the CQIE web site, http://www.acrin.org/NCI-CQIE.aspx, for all qualification materials, including the ITW.

If necessary images can be sent on CD-ROM. Sites submitting images via CD should mail the package, including a copy of the ITW, to the ACRIN Imaging Core Lab. Method of shipment should include package tracking.
5. References

PET PHANTOM TEST INSTRUCTIONS: UNIFORM CYLINDER PET PHANTOM

This document provides detailed instructions for performing CQIE phantom tests with the uniform cylinder PET phantom.

1. Uniform Cylinder Phantom

The uniform cylinder can be any fill-able, cylindrical phantom that does not have any internal structure; the phantom should have an internal diameter of 18 cm – 22 cm and a length that is greater than the axial FOV of the scanner. On most systems, the ACR PET phantom can be used for the uniform phantom scans as long as the cold rods and cold spheres are removed and the “flat” lid is used, instead of the lid with the cylinders attached. However, manufacturers typically supply all PET scanners, at the time of installation, with a uniform cylinder that is used for routine QA and calibrations.

The uniform cylinder will be filled with a precise amount of radioactivity and scanned using standard acquisition and reconstruction protocols. There will be 3 sequential scans: (1) a two-bed-position Body FOV scan using the settings for a 70 kg (~24 BMI) patient; (2) a one-bed-position 10 or 20 minute Brain FOV scan; and (3) a one-bed-position dynamic Body FOV scan using a pre-defined acquisition protocol.

2. Phantom Test Preparation

Please read the following instructions in full before preparing and scanning the phantom.

Required Materials

- 1 - Uniform Cylinder phantom
- 1 - 60 mL syringe
- 1 - tuberculin syringe
- Clock or Timer
- CQIE Uniform Cylinder PET Phantom Data Form
- CQIE Uniform Cylinder SUV Analysis Form
- Dose: either FDG or F-18 fluoride are acceptable

Phantom Filling Procedure

Fill the phantom completely with water a few hours before scanning to allow for air bubbles to collect at the top of the phantom.

1. When ready to scan the phantom, ensure that the phantom is completely full, adding additional water with a syringe if necessary, to minimize any air bubble.
2. Using a 60 mL syringe, withdraw ~50 mL of water from the phantom to create a large air space to allow for better mixing.
3. Inject a known amount of FDG or F-18 fluoride; the activity injected should be within the range of 135 – 165 nCi/mL.
PET PHANTOM TEST INSTRUCTIONS: UNIFORM CYLINDER PET PHANTOM

- GE: 5,640 mL phantom, inject 0.76 – 0.93 mCi
- Siemens: 6,283 mL phantom, inject 1.0-1.5 mCi
- Philips: 9,293 mL phantom, inject 1.25 – 1.53 mCi

4. Record the activity in the syringe before injection on the Uniform Cylinder PET Phantom Data Form.
5. Repeatedly flush the syringe to ensure that there is little residual activity in the syringe.
6. Thoroughly combine the mixture by repeatedly inverting the phantom.
7. Inject the water that was removed from the phantom in step 2 until the phantom is completely full.
8. Measure the syringe in the dose calibrator and record the residual activity on the Uniform Cylinder PET Phantom Data Form.
9. The phantom scan should begin immediately after filling.

3. Data Acquisition and Reconstruction

When setting up the scans, enter your institution name in the patient name field (see example below).

   Patient Name: CQIE Name of Your Cancer Center (ex. ACRIN Cancer Center)

Positioning the Phantom

Place the phantom on its side on the scanner table. Some sheets may be used under the phantom to prevent the phantom from rolling and to assist in leveling. Align the phantom so that its long axis is parallel to the axis of the scanner. A bubble level should be used to ensure that the phantom is properly positioned in the horizontal plane. Adjust the table height so that the phantom is centered in the transverse FOV.

Body FOV Static Acquisition and Reconstruction

The scan length will be two-bed position with the phantom centered in the axial extent of the combined two bed positions. The phantom scan should be acquired using your site's standard clinical protocol for Body PET, in accordance with the manufacturer's recommendations. Typical imaging times, based on a 70 kg, 170 cm (~24 BMI) patient, vary from 2 – 5 minutes per bed position, depending on whether the scan acquisition is in 2D or 3D mode. Enter the “patient” weight as the phantom volume, in liters, (i.e. 5.64 kg for a phantom with volume 5,640 mL). If the software requests a height, enter 170 cm. The dose should be entered as the net dose obtained from the values recorded on the Uniform Cylinder PET Phantom Data Form.

The Body acquisition should be reconstructed using your site’s standard reconstruction procedure. For a Body FOV, typical slice thickness ranges from 3 – 5 mm and typical
PET PHANTOM TEST INSTRUCTIONS: UNIFORM CYLINDER PET PHANTOM

Transverse pixel size ranges from 3 x 3 – 4 x 4 mm. Record the start time of the body acquisition scan on the Uniform Cylinder PET Phantom Data Form.

**Brain FOV Static Acquisition and Reconstruction**

At the conclusion of the Body FOV acquisition, without moving the phantom on the bed, set up for a Brain FOV acquisition. The scan length will be one bed position centered on the axial extent of the phantom. The phantom image will be acquired for 10 minutes, if using 3D mode, and 20 minutes, if using 2D mode. Enter the same values for weight, height, and dose as for the Body FOV scan.

The Brain acquisition should be reconstructed using your site's standard reconstruction procedure. For a Brain FOV, typical slice thickness ranges from 2 – 5 mm and typical transverse pixel size ranges from 2 x 2 – 3 x 3 mm. Record the start time of the PET portion of the scan on the Uniform Cylinder PET Phantom Data Form.

**Body FOV Dynamic Acquisition and Reconstruction**

At the conclusion of the Brain FOV acquisition, without moving the phantom on the bed, set up a Body FOV Dynamic Acquisition. The scan length will be one bed position centered on the axial extent of the phantom. The phantom will be acquired using the following dynamic sequence: 16 bins of 5 seconds duration, 7 bins of 10 seconds duration, 5 bins of 30 seconds duration, 5 bins of 1 minute duration, and 5 bins of 3 minutes duration. Reconstruct the entire dynamic sequence with either a filtered back projection or an iterative algorithm. For Siemens scanners, it is suggested you use either a filtered back projection or 3D OSEM algorithm for reconstruction due to potential instability in the results of the 2D OSEM algorithm for the early time frames. Record the start time of the PET portion of the scan on the Uniform Cylinder PET Phantom Data Form.

**4. ROI Analysis**

On one transverse slice of each the Brain and Body FOV acquisitions, draw a 2D circular ROI that encompasses an area of ~200 cm² of the center of each slice. The same ROI can then be copied and applied across all slices of the phantom. The SUV value of this region in each slice should read between .90 and 1.10 with less than 10% variation across the entire axial field. An optional SUV analysis spreadsheet is available upon request ([CQIE-PET@acr.org](mailto:CQIE-PET@acr.org)) but is not required.

The site will need to submit the attenuation-corrected (AC) PET, non-attenuation-corrected (NAC) PET and CT image sets to the ACRIN Imaging Core Lab. All images must be in DICOM format. Refer to Part D, Section 4, of CQIE MOP (PET Technical Procedures) for details regarding data submission.
This document provides detailed instructions for performing phantom tests with the ACR Accreditation PET phantom. These instructions have been written to allow a site to use the phantom acquisition for both CQIE qualification and ACR Accreditation testing. Please read the following instructions in full before preparing and scanning the phantom. If this testing will be used for ACR accreditation, please read both the CQIE and ACR instructions before preparing and scanning the phantom and contact ACRIN with any questions. If your site does not own an ACR-PET phantom, ACRIN will provide a phantom, on loan, or you may purchase your own. Additional information regarding the phantom loan procedures will be included in your Site Qualification Plan. For phantom purchasing and ACR testing information refer to the ACR web site at http://www.acr.org/accreditation.aspx.

1. ACR Accreditation PET Phantom

The phantom is a cylinder with a 10.8-cm internal radius and may or may not be flanged at the top. The cylinder comes with a lid (Esser Lid) that has 3 fill ports and 7 cylinders hanging from the underside; 1x8-mm, 1x12-mm, 1x16-mm, and 3x25-mm hollow cylinders and 1x25mm Teflon cylinder. One of the 25-mm hollow cylinders will be filled with “cold” water, one of the 25-mm hollow cylinders will be left empty (air-filled) and the other 4 hollow cylinders will be filled with a “hot” solution. The lower portion of the cylinder contains six sets of acrylic rods arranged in a pie-shaped pattern.

Figure A. PET phantom viewed from side

Figure B. PET phantom viewed from above
2. Phantom Test Preparation

The following procedures are based on the ACR PET Accreditation phantom instructions, with minor modifications. The doses are based on the ACR Phantom Dose Chart for a 16 mCi injection, which approximates the concentration in a 70 kg patient. Two acquisitions will be acquired with a single fill of the phantom. The first acquisition will be a two-bed position acquisition using a Body FOV. The second acquisition will immediately follow the Body FOV scan and will be a one-bed position acquisition using a Brain FOV.

**Required Materials**

- 1 ACR-approved PET Phantom
- 1 - 1,000 mL bag or bottle of distilled water or saline solution
- 2 Tuberculin syringes (for measuring Doses A & B)
- 3 Large syringes (60 mL)
- 3 Large-bore needles (18 gauge)
- Clock or timer
- CQIE ACR-PET Phantom Dilution Worksheet
- CQIE ACR-PET Phantom Data Form (P4)
- CQIE ACR-PET Phantom SUV Analysis Form (P5)
- > 1.5mCi of FDG or F-18 fluoride are acceptable

**Testing Tips – Before you begin**

- Confirm hot lab clock and camera clock match.
- Ensure background of the dose calibrator is near 0 uCi at each measurement.
- Ensure residual activity readings are near 0 uCi at measurement; beware of external contamination of syringes and activity remaining in needle caps.

**Testing Tips – If testing will be used for CQIE qualification and ACR Accreditation**

- The CQIE PET forms request additional information about the filling of the phantom, like residual measurements of the doses, not requested by ACR. Therefore, it is recommended you use the CQIE forms then transfer relevant data to the ACR forms.
- Instructions for Dose A and B, below, are based on a 16 mCi patient dose from the ACR Phantom Dose Chart. If your standard patient dose is not 16 mCi, please refer to the ACR Phantom Dose Chart for the appropriate doses.

**Phantom Preparation**

1. Empty the 4 “hot” cylinders of all water and leave the fill port screws out to allow any excess water in the cylinders to evaporate.
2. Using the primary fill port, fill the main compartment of the phantom with water several hours prior to scanning to allow time for air bubbles to collect near the top of the phantom. Also fill the “Water” cylinder in the lid.
PET PHANTOM TEST INSTRUCTIONS: ACR PET PHANTOM

3. When ready to measure activity for the phantom, first add enough water to the body of the phantom to remove any air bubbles.

4. Draw up 0.56 +/- 0.05 mCi of \(^{18}\)F-FDG, or F-18 fluoride, in a tuberculin syringe and label it Dose A. For the CQIE ACR-phantom test, the Body FOV Scan must begin 60 minutes after the measurement of Dose A.

5. Record the assay amount and assay time of Dose A on the CQIE PET Phantom Dilution Worksheet.

6. Inject Dose A into the 1,000 mL bag or bottle of saline or distilled water, repeatedly flushing the syringe to ensure that there is little residual activity left in the syringe.

7. Measure the residual activity left in the syringe for Dose A on a µCi scale and record the value and time on the CQIE PET Phantom Dilution Worksheet; this should measure near 0 µCi.

8. Discard Dose A syringe.

9. Ensure that the saline bag or bottle with Dose A is properly sealed, then mix by repeatedly inverting.

10. Using a 60 mL syringe, draw out 60 mL of the resulting radioactive solution and label that syringe Test Dose 1.

11. Set aside the radioactive solution and Test Dose 1 in a shielded area.

12. Draw up 1.32 +/- 0.13 mCi in a tuberculin syringe and label it Dose B.

13. Record the assay amount and assay time of Dose B on the CQIE PET Phantom Dilution Worksheet.

14. Using a fresh 60 mL syringe, withdraw ~50 mL of water from the body of the phantom.

15. Inject Dose B into the body of the phantom, repeatedly flushing the syringe to ensure that there is little residual activity left in the syringe.

16. Measure the residual activity left in the syringes for Dose B and record the values on the CQIE PET Phantom Dilution Worksheet; this should be near 0 µCi.

17. Discard Dose B syringe.

18. Cap the fill port of the phantom and repeatedly invert the phantom to thoroughly mix.

19. Open the fill port and restore the ~50 mL of water withdrawn in step 14 until the phantom body is completely filled.

20. Cap the fill port then repeatedly invert the phantom to mix the water just added.

21. Using a third 60 mL syringe, withdraw 60 ml from the body of the phantom and label the syringe Test Dose 2.

22. Measure the activity of Test Dose 2 using a µCi scale (you will have to remove the syringe holder from the dose calibrator in order to measure the 60 mL syringes). Record dose activity and time on the ACR Phantom Dilution Worksheet.

23. Inject Test Dose 2 back into the body of the phantom and seal the phantom.
PET PHANTOM TEST INSTRUCTIONS: ACR PET PHANTOM

24. Measure the activity of Test Dose 1 using a µCi scale. Record dose activity and time on the ACR Phantom Dilution Worksheet.

25. Use Test Dose 1 to fill the 4 “hot” cylinders in the lid of the phantom.

3. Data Acquisition and Reconstruction

When setting up the scans, enter your institution name in the patient name field (see example below).

   Patient Name: CQIE Name of Your Cancer Center (ex. ACRIN Cancer Center)

Positioning the Phantom

Place the phantom on its side on the scanner table. Some sheets may be used under the phantom to prevent the phantom from rolling and to assist in leveling. Align the phantom so that its long axis is parallel to the axis of the scanner. A bubble level should be used to ensure that the phantom is properly positioned in the horizontal plane. Adjust the table height so that the phantom is centered in the transverse FOV.

Body FOV Data Acquisition

The Body FOV Scan should begin 60 minutes after the measurement of Dose A. The scan length will be two bed positions. The phantom should be centered in the axial extent of the combined two bed positions. The phantom should be acquired using a standard clinical protocol for Body in accordance with the manufacturers’ recommendations. Typical imaging times, based on a 70 kg, 170 cm (~24 BMI) patient, vary from 2 – 5 minutes per bed position, depending on whether the scan acquisition is in 2D or 3D mode. Use the following acquisition parameters for the phantom scan.

a. If acquiring phantom scan for CQIE qualification only (not for ACR Accreditation):
   - Dose = enter the sum of Dose B less the residual (Dose = Dose B – residual)
   - Assay Time = enter the time of the Dose B measurement
   - Weight = enter 5.78 kg
   - Height (if required by software) = 170 cm

b. If acquiring phantom scan for CQIE and ACR Accreditation:
   - Dose = enter 16 mCi
   - Assay Time = enter the time of the Dose A measurement
   - Weight = enter 70 kg
   - Height (if required by software) = 170 cm

Brain FOV Data Acquisition

Without moving the phantom on the bed, set up a Brain FOV acquisition. The scan length will be one bed position. Position the phantom so that the entirety of the “hot” cylinders are in the axial FOV, but include as much of the cold rod section as possible (some of the cold
rod section will be cut off). Acquire a single static view of the phantom for 10 minutes if using a 3D acquisition or for 20 minutes if using a 2D acquisition.

**Post Acquisition Processing (if scan acquired for ACR Accreditation)**

If the phantom scan was acquired per the ACR guidelines (i.e. dose of 16 mCi and patient weight of 70 kg) the images must be edited before reconstruction. For Philips scanners, the raw data will have to be edited and the images reconstructed after editing so that fields in the header used to calculate SUVs are properly adjusted. Required edits are as follows:

- Dose = enter the sum of Dose B less the residual (Dose = Dose B – residual)
- Assay Time = enter the time of the Dose B measurement
- Weight = enter 5.78 kg

**Reconstruction**

The Body and Brain acquisitions should be reconstructed using the same protocol as is used for typical patient studies. These protocols should be the same as those recorded on the Routine Clinical PET Protocol (PT) Form. In studies reconstructed on a Body FOV (50 – 70 cm in diameter), typical slice thicknesses range from 3 – 5 mm and typical transverse pixel sizes range in size from 3x3 – 4x4 mm². In studies reconstructed on a Brain FOV (25 – 30 cm in diameter), typical slice thicknesses range from 2 – 5 mm and typical pixel sizes range in size from 2x2 to 4x4 mm². Using its preferred software package, the site will sum slices to produce 9 – 12 mm thick slices for the ROI analysis (for both the Brain and Body FOVs).

**4. ROI Analysis**

ROI analysis, as described below, should be performed for both the Body and Brain FOV image sets. Use the CQIE ACR PET Phantom SUV Analysis Form (P5) to record your SUV measurements.
PET PHANTOM TEST INSTRUCTIONS: ACR PET PHANTOM

**Step 1:** Select the 9 – 12 mm transverse slice that best shows the four “hot” cylinders.

**Step 2:** Draw a 2D, circular background ROI of diameter 6 – 7 cm in the center of the chosen transverse slice (avoiding cylinders). Draw a 2D, circular ROI just inside the boundaries (as visualized on PET) of the largest “hot” cylinder (25 mm cylinder). Place copies of this smaller ROI over the other visible cylinders, including the air, water and bone cylinders. All of the smaller ROIs must be the same size regardless of cylinder size.

**Step 3:** Save a screen capture of the image from step 2; all ROIs must be visible. The screen capture should be saved as a DICOM Secondary Capture and submitted with the image set.

**Step 4:** Record the mean and max SUVs in the appropriate section of the CQIE ACR PET Phantom SUV Analysis Form (P5), using separate forms for Brain and Body FOVs.