FLT Body (FLTB) Qualification Requirements

A dedicated PET/CT scanner is mandatory. The PET/CT scanner must be capable of performing both emission and transmission (e.g., CT) images in order to allow for attenuation-corrected PET scan images. The ability to calculate standardized uptake values (SUVs) is also mandatory. The PET/CT scanner must be qualified prior to enrollment of any patients onto the protocol and must meet specific qualification criteria by the ACR Core Laboratory

The following must be submitted for each scanner to be used to scan trial participants: PET Qualification Application, two previous test patient studies (FDG or fluoride) acquired in the last 30 days, ^{18}F Water-filled Uniform Phantom images (DICOM) with the SUV measurement acquired within the last 2-3 weeks and completed ACR Phantom Forms.

For all qualification image submissions please include PET AC, PET NAC and CTAC series.

*Sites that choose not to acquire a new ACR PET phantom are required to submit the last ACR Phantom that was acquired as long as it was acquired in the last 6 months. If so, the ACR PET Phantom images (DICOM) with the corresponding forms need to be submitted using the QUIC utility.

The ACR strongly recommends quarterly testing but at a minimum of semi-annually. If needed, the instructions on filling, acquisition and reconstruction can be found in the appendix of the Site Imaging Manual.

Submit images of two unidentified patients consisting of three volumes or multi-slice files as follows:

- Whole body transmission CT
- Whole body emission with attenuation correction (AC)
- Whole body emission without attenuation correction (NAC)

Note: The two test patient images must have been acquired in the last 30 days.

If Whole-Body (top of head [vertex] to the bottom of the feet) is performed at the site (e.g., NaF Bone Scan), submission of these datasets are preferred.

**** Test cases are only required for initial qualification. Requalification does not require new Test Patient Studies to be submitted****

Uniform Cylinder Phantom Procedures

<u>UNIFORM PHANTOM SCAN REQUIREMENTS</u>

A. Preparing the 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 at least 18 cm - 22 cm, and be at least 20 cm long. Inject a known amount of FDG or F-18 fluoride into the phantom. The activity concentration at the time of phantom scanning should be ± 10% of the average activity concentration in a standard FDG patient at scan start. For example, assuming a 70 kg patient being scanned 60 minutes post-injection, if the standard FDG injection is 6 mCi then the target concentration in the phantom is approximately 60 nCi/ml. If the standard FDG injection is 10 mCi, the target concentration is approximately 100 nCi/ml. If the phantom scan will begin promptly after filling, then for manufacturer standard uniform phantoms the corresponding injection targets are:

		Target Activity for Standard Phantoms (mCi)		
Standard Dose (mCi)	Target Concentration (uCi/ml)	GE 5640 ml Phantom	Siemens 6283 ml Phantom	Philips 9293 ml Phantom
2	0.020	0.11	0.12	0.18
4	0.039	0.22	0.25	0.36
6	0.059	0.33	0.37	0.55
8	0.078	0.44	0.49	0.73
10	0.098	0.55	0.61	0.91
12	0.117	0.66	0.74	1.09
14	0.137	0.77	0.86	1.27
16	0.157	0.88	0.98	1.45
18	0.176	0.99	1.11	1.64
20	0.196	1.10	1.23	1.82

If you are not using one of the 3 standard phantoms listed above, the target activity can be calculated using this formula:
<Target Activity (mCi)> = <Phantom Volume (ml)> * <Target Concentration (uCi/ml)> / 1000

B. Scanning the phantom

Place the phantom on its side on the scanner table (not suspended in air). 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 transaxial FOV.

<u>The phantom should be scanned using your site's standard clinical protocol for Body PET</u>, in accordance with the manufacturer's recommendations. For the 'patient' weight enter the phantom's volume in liters, (i.e. 5.64 kg for a phantom with a volume of 5,640 ml). If the software requests a height, enter the internal length of the phantom in cm, e.g. 20 or 30 cm. The dose should be entered as the net dose obtained from the values recorded on the Application Form.

- If the uniform phantom's length is < 2x the scanner's Axial FOV (AFOV) then the scan length should be two bed-positions, with the phantom positioned in the center of the axial extent of the combined two bed positions. If your site's standard wholebody protocol includes the use of continuous bed motion (CBM), then the axial extent of the PET and CT must encompass the entire axial length of the phantom plus an additional 2 cm on either end.

- If, instead, the scanner's AFOV > 2x but < 3x the phantom's length, then two acquisitions must be performed; one with the phantom center positioned at ¼ AFOV length and the second with the phantom center positioned at ¾ AFOV length.
- If the scanner's AFOV ≥ 3x the phantom length, three acquisitions must be performed with the phantom center positioned at ¼ AFOV length, ½ AFOV length and ¾ AFOV length. Please label these acquisitions with their axial position.

The acquisition(s) should be reconstructed using your site's standard wholebody reconstruction parameters. For a Body FOV, typical slice thickness ranges from 2 - 5 mm and typical transverse pixel sizes are 2 x 2 mm^2 to 4 x 4 mm^2.
Note: The Uniform Phantom Cylinder must have been acquired in the last 2-3 weeks.

OPTIONAL ROI Analysis – On a transverse slice of phantom acquisition, draw a 2D circular ROI that encompasses an area of ~200 cm^2 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 0.90 and 1.10 with less than 10% axial variation across the entire axial field. An optional SUV analysis spreadsheet is available upon request (rdigati@acr.org) but is not required.
This Site Imaging Manual 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 Clinical Trial PET/CT Scanner Qualification and ACR Accreditation testing. Please read the instructions in full before preparing and scanning the phantom. If this testing will be used for ACR accreditation, please read both the Site Imaging Manual and ACR Instructions before preparing and scanning the phantom and contact the ACRIN PET Core Lab 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.

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 1x 25-mm Teflon cylinder. One of the 25-mm hollow cylinders will be filled with 'cold' water, one of the 25-mm cylinders will be let 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.

ACR PET Phantom Procedures

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. One acquisition will be a two-bed position acquisition using a Body 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)
Clock or Timer
ACR PET Phantom Dilution Worksheet
ACR PET Phantom Data Form
ACR PET Phantom SUV Analysis Form
>1.5 mCi 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 PET/CT scanner qualification for a clinical trial *and* ACR Accreditation

- The EA Trial PET form requests 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 EA Trial Phantom 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.

ACR Phantom Preparation

1. Empty the 4 'hot' cylinders of all water and leave the fill ports screws out to allow 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.
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 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 ACR 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 uCi scale and record the value and time on the ACR PET Phantom Dilution Worksheet; this should measure near 0 uCi.
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 ACR 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 ACR Phantom Dilution Worksheet; this should be near 0 uCi.
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 uCi 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.
24. Measure the activity of **Test Dose 1** using a uCi 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.

Positioning the ACR 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 trial 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 trial 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

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 acquisition should be reconstructed using the same protocol as is used for typical patient studies. In studies reconstructed on a Body FOV (50 – 70 cm in diameter), typical slice thickness range from 3 – 5 mm and typical transverse pixel sizes range in size from 3x3 – 4x4 mm^2. Using its preferred software package, the site will sum slices to produce 9 – 12 mm thick slices for the ROI analysis.

Optional ROI Analysis

ROI Analysis, as described below, should be performed for the Body FOV image set. Use the ACR PET Phantom SUV Analysis Form to record your SUV measurements.

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 transvers 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 the 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 ACR PET Phantom SUV Analysis Form