

Requirements for PTBO Modality PET Qualification

1. All scanners for which a site is seeking scanner qualification must be a PET/CT scanner. PET-only scanners will no longer be accepted for qualification.
2. Phantom must be a water-filled cylinder injected with F-18. **Ga-68/Ge-68 solid cylinders are no longer acceptable.**
3. Uniform cylinder acquisition for trials involving PET/CT Body Scans must be acquired and reconstructed on a FOV of at least 500 mm diameter. A two bed position scan is required.
4. The phantom data submitted for qualification should be acquired within two or three weeks of the application submission.
5. The Test Patient Studies submitted for initial qualification should be acquired within the last 30 days of the application submission.
6. Test Patient Studies are only required for initial qualification. Requalification does not require new Test Patient Studies to be submitted.

REQUALIFICATION OF THE PET/CT SCANNER MUST OCCUR FOR ANY OF THE FOLLOWING SCENARIOS:

1. One year from the initial qualification.
2. A new scanner is installed that will be used to scan trial participants.
3. Any PET/CT system that undergoes a major upgrade (i.e., any upgrade that may affect quantitative (SUV) determination).

MATERIALS REQUIRED

Submit the following for every PET/CT scanner that will be used for research:

1. Application (online)
2. Uniform Phantom Images (DICOM)
3. Two Test Patient Studies (Body: skull base to mid-thigh)

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

UNIFORM PHANTOM SCAN REQUIREMENTS

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 $\pm 10\%$ 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:

$$\langle \text{Target Activity (mCi)} \rangle = \langle \text{Phantom Volume (ml)} \rangle * \langle \text{Target Concentration (uCi/ml)} \rangle / 1000$$

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.

The phantom should be scanned using your site's standard clinical protocol for Body PET, 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 $\geq 3x$ the phantom length, three acquisitions must be performed with the phantom center positioned at $\frac{1}{4}$ AFOV length, $\frac{1}{2}$ AFOV length and $\frac{3}{4}$ 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 mm² to 4 x 4 mm².

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 cm² of the center of each slice. The same ROI can then be copied and applied across all slices of the phantom. The SUV analysis of this region 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 to rdigati@acr.org but is not required.

For all Phantom studies, the site must submit:

1. PET attenuation corrected (PET AC)
2. PET non-attenuation corrected (PET NAC)
3. CT images used for attenuation correction (CTAC)

TEST PATIENT IMAGE REQUIREMENTS

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

1. Whole Body (torso) transmission CT
2. Whole Body (torso) PET attenuation corrected (PET AC)
3. Whole Body (torso) PET non-attenuation corrected (PET NAC)

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