Standard PET imaging protocols and phantom test procedures and criteria: executive summary

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1. Introduction

The standard protocols described in this document cover subject preparation, injection activity, accumulation time, subject positioning, scan time and the criteria for determination of reconstruction parameters for each PET camera based on phantom data. The idea is to standardize the methods and conditions that would affect the PET image qualitatively or quantitatively. However, the image quality and quantitative capability depend on the camera model even with the same injection activity and scan time and further depend on the reconstruction parameters even for the identical data acquired in a PET scan on a particular subject. Therefore, Japanese Society of Nuclear Medicine (JSNM) provides standard procedures for a number of specific PET scans and methods of evaluating absolute quantitation, resolution, recovery coefficient, contrast, uniformity, image noise, etc., using appropriate phantoms, together with the phantom test criteria that should be satisfied, based on which reconstruction parameters and, if necessary, scan time could be determined for each PET camera for the purpose of qualification and harmonization among different camera models. *This document presents the executive summary of the standard protocols, and the procedures and criteria of the phantom test.* At this moment, JSNM has issued standard PET imaging protocol and phantom test criteria for the following PET scans.

- Brain PET with ¹¹C-methionine
- Brain PET with ¹⁸F-FDG
- Brain PET with amyloid agents (¹¹C-PiB, ¹⁸F-Florbetapir, ¹⁸F-Flutemetamol, ¹⁸F-Florbetaben)
- Whole-body PET with ¹⁸F-FDG for oncology

The injection activity described in this document is a standard. A particular research project may define a different injection activity, e.g. higher than the standard. However, care should be taken to the dosimetry of the subject, radiation exposure to workers and family, availability of the PET drug radioactivity, and count-rate performance of the PET camera. If the injection activity differs from the standard described here, the phantom test procedures should also be modified accordingly. Considering the variable sensitivity of PET camera models, the scan time (and, if necessary, the injection activity as well) for a particular PET camera is allowed to differ from the standard protocol if the phantom data acquired with the particular protocol satisfy the phantom test criteria.

2. ¹¹C-methionine PET for brain tumor

2.1. Standard protocol for brain PET with ¹¹C-methionine

The standard injection activity is $370 \text{ MBq} \pm 10\%$, the accumulation time is 20 minutes, and the scan time is 10 minutes [1–4]. (The scan time may be changed and determined by the phantom experiments).

2.2. Phantom test procedures and criteria for brain PET with ¹¹C-methionine

JSNM's brain tumor (BT) phantom is a cylinder with inner diameter and length of 200 mm and 185 mm, respectively, containing 6 spheres (the inner diameters of 5, 7.5, 10, 16, 27, and 38 mm) arranged circumferentially with a 120 mm diameter. The size of BT phantom resembles that of a human head, and the spheres mimic tumors. The background area of the phantom is filled with 2.65 kBq/mL \pm 5% of ¹⁸F (not ¹¹C) solution at the start of emission scan, and the spheres are filled with three times the activity concentration of the background. The "injection activity" and "body weight" sections of the DICOM header are filled in so that the true "SUV" is 1.00 in the background area. The emission scan is carried out in 3D in a dynamic or list mode. The list-mode acquisition data are sorted so as to extract images of 8.71-minute data acquisition, which is equivalent to 10 minutes of ¹¹C, or for a

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variable period if the appropriate scan time is to be searched for. The images are reconstructed with recommended parameters or with variable parameters if the appropriate parameters are to be searched for. The phantom data are analyzed to derive physical parameters including %contrast, relative recovery coefficient (RC), and accuracy and uniformity of SUV in the background area. A circular region-of-interest (ROI) with the same diameter as each hot sphere is placed over each hot spot to calculate maximum image activity of the hot spheres. Then, 10 circular ROIs of 100 mm² are placed on the background area.

The %contrast is calculated as follows:

$$\% \text{contrast} = \frac{\text{ROI}_H - \text{ROI}_{b,a}}{\text{ROI}_H + \text{ROI}_{b,a}} \times 100 \, [\%]$$
(1)

where ROI_H is the maximum activity of each sphere and $ROI_{b,a}$ is the mean activity of 10 background ROIs.

The relative RC is calculated as follows:

$$\mathrm{RC}_{j} = \frac{\mathrm{ROI}_{j}}{\mathrm{ROI}_{38mm}} \tag{2}$$

where *j* is sphere size, ROI_j is maximum activity of *j*-mm sphere and ROI_{38mm} is maximum activity of the 38-mm sphere.

For the evaluation of quantitative accuracy and uniformity, 16 circular ROIs of 500 mm² are placed on a slice far off the sphere-containing section of the phantom and on two other slices \pm 10 mm apart, making a total of 48 ROIs. The average of SUV_{mean} for the 48 ROIs is calculated as SUV_{TOT} to evaluate quantitative accuracy of SUV. Standard deviation of relative error for the SUV_{mean} (SD_{Δ SUVmean}) is calculated for each ROI to evaluate uniformity as follows:

$$SD_{\Delta SUVmean} = \sqrt{\frac{1}{n-1} \sum_{i=1}^{n} \left(\frac{SUV_{mean}}{SUV_{TOT}} - 1\right)^2}$$
(3)

The phantom test criteria are presented below.

- (i) The 7.5-mm hot spot should be visible.
- (ii) %contrast should be higher than 13%.
- (iii) Relative RC for the 10-mm hot spot should be higher than 0.45, which corresponds to 8 mm FWHM.
- (iv) SUV_{TOT} should be within $1.00\pm0.05 (0.95 \sim 1.05)$.
- (v) Uniformity satisfies $SD_{\Delta SUVmean} \le 0.0249$, which corresponds to 95% of the SUV_{mean} of the ROIs being distributed within 1.00±0.05 assuming normal distribution. No significant (p<0.05) difference in SUV_{mean} between ROIs in inner area and those in outer area. No apparent tendency in SUV_{mean} along the angle of ROI localization.

3. Brain PET with ¹⁸F-FDG and amyloid agents for dementia

3.1. Standard protocol for brain PET with ¹⁸F-FDG for dementia

The subject should avoid hard exercise and fast for more than 4 hours before injection of ¹⁸F-FDG. ¹⁸F-FDG should be injected in the dimly lit quiet environment in the supine or semi-supine position on a bed or in a reclining chair, and the subject's posture and the environment should be kept until the emission scan. The standard injection activity is 185 MBq±10%, accumulation time is 30 minutes, scan time is 30 minutes [5–7] (The scan time is allowed to be changed and determined by the phantom experiments) (Table 1).

3.2. Standard protocol for brain PET with amyloid agents

The amyloid agents in this protocol include ¹¹C-PiB, ¹⁸F-Florbetapir, ¹⁸F-Flutemetamol and ¹⁸F-Florbetaben. The standard injection activity, accumulation time, and scan time is 555 MBq±10%, 50 minutes, 20 minutes for ¹¹C-PiB [5,8,9], 370 MBq±10%, 50 minutes, 20 minutes for ¹⁸F-Florbetapir [10–12], 185 MBq±10%, 90 minutes, 30 minutes for ¹⁸F-Flutemetamol [13,14], and 300 MBq±20%, 90 minutes, 20 minutes for ¹⁸F-Florbetaben [15–17] (The scan time may be changed and determined by the phantom experiments) (Table 1). The emission scan is carried out in 5-minute frame dynamic mode or list-mode, and the images are reconstructed with the parameters that are to be determined by the phantom experiments so that the physical parameters of the phantom images could meet the criteria shown below [18].

3.3. Phantom test procedures and criteria for brain PET with ¹⁸F-FDG and amyloid agents

A Hoffman 3D brain phantom is filled with 20 MBq±5% of ¹⁸F solution at the start of a 30-minute emission scan. A cylindrical phantom is also filled with 20 MBq ±5% of ¹⁸F solution at the start of a 30-minute scan. The "injection activity" and "body weight" sections of the DICOM header are filled in so that the true "SUV" is 1.00 in the cylindrical phantom. The emission scan is carried out in 3D in a dynamic or list mode with recommended or variable reconstruction parameters. The 30-minute acquisition list-mode data are sorted so as to extract multiple images of different intervals corresponding to each tracer as shown in Table 2 in which equivalent activity-time product is provided for each tracer considering the injection activity, brain uptake, accumulation time and scan time, physical decay and branching fraction. The phantom data are analyzed both visually and with ROIs to derive physical parameters including spatial resolution and gray/white matter contrast (%contrast) based on the Hoffman phantom and uniformity (SD_{uROImean}) and image noise (coefficient of variation; CV) based on the uniform cylindrical phantom.

Spatial resolution is estimated from visual similarity between the Hoffman phantom image and the digital phantom filtered with a 3D Gaussian of various FWHMs.

To derive the gray/white matter contrast, original ROI templates, which are defined on the digital Hoffman phantom and would provide true gray-to-white ratio of 4, are applied to the phantom image co-registered to the digital phantom. The %contrast is calculated as follows:

$$\% \text{contrast} = \frac{\text{GM}_P/\text{WM}_P - 1}{\text{GM}_d/\text{WM}_d - 1} \times 100 \, [\%]$$
(4)

where GM_P and WM_P are ROI activity of gray matter and white matter on the phantom PET image, GM_d and WM_d are ROI activity of gray matter and white matter on the digital phantom.

For uniformity evaluation, 17 circular ROIs of 500 mm² (uROI) are placed on the central slice and on two other slices \pm 40 mm apart from the central slice, making a total of 51 uROIs. The SD_{*uROImean*} is calculated as follows:

$$SD_{uROImean} = \sqrt{\frac{1}{n-1} \sum_{i=1}^{n} \left(\frac{uROI_{mean}}{uROI_{TOT}} - 1\right)^2}$$
(5)

where uROI_{mean} is the mean activity of uROI, n=51, and uROI_{TOT} is the average of the 51 uROI_{mean}.

For noise evaluation, a large circular ROI of 1300 mm in diameter (nROI) is placed on the central slice. The CV is calculated as follows:

$$CV = \frac{SD_{nROI}}{nROI_{mean}} \times 100 \,[\%]$$
(6)

where SD_{nROI} is the standard deviation of the voxel values within the nROI, and nROI_{mean} is the mean nROI activity.

The requested phantom test criteria are presented below [19].

- (i) 8 mm FWHM or better spatial resolution in the Hoffman 3D brain phantom.
- (ii) 55% or better gray/white matter contrast (%contrast) in the Hoffman 3D brain phantom.
- (iii) Uniformity of $SD_{uROImean} \le 0.0249$ in the uniform cylindrical phantom, which corresponds to 95% of the uROI_{mean} being distributed within 1.00±0.05 assuming normal distribution.
- (iv) Noise level of $CV \le 15\%$ in the uniform cylindrical phantom.

Radiotracer	Injection activity	Accumulation time	Scan time*	Estimated brain activity at the start of scan
¹⁸ F-FDG	185 MBq	30 minutes	30 minutes	20 MBq [<mark>7, 20</mark>]
¹¹ C-PiB	555 MBq	50 minutes	20 minutes	3 MBq [21–23]
¹⁸ F-Florbetapir	370 MBq	50 minutes	20 minutes	12 MBq [5 , 10 , 12 , 24]
¹⁸ F-Flutemetamol	185 MBq	90 minutes	30 minutes	3 MBq [13, 25, 26]
¹⁸ F-Florbetaben	300 MBq	90 minutes	20 minutes	6 MBq [15,21,27]

Table 1: Standard protocols for brain PET with ¹⁸F-FDG/amyloid agents and estimated brain activity at the start of scan.

* Note the scan time here is the standard and may be changed and determined based on the phantom experiments.

Table 2: Equivalent duration to be extracted from the Hoffman or pool phantom data (20 MBq of F-18 at start of scan) for each tracer according to the standard protocol.

Radiotracer	Equivalent duration for each tracer	
¹⁸ F-FDG ¹¹ C-PiB ¹⁸ F-Florbetapir	1800 seconds $125 \sim 135$ seconds $700 \sim 710$ seconds	
¹⁸ F-Flutemetamol ¹⁸ F-Florbetaben	$245 \sim 255$ seconds $345 \sim 355$ seconds	

4. Whole-body PET with ¹⁸F-FDG for oncology

4.1. Standard protocol for whole-body PET with ¹⁸F-FDG

The subject should avoid hard exercise and fast for at least 4 hours before injection of ¹⁸F-FDG. The measured serum blood glucose is recommended to be less than 150 mg/dL. The standard injection activity is $2.0 \sim 5.0$ MBq/kg, accumulation time is 60 ± 5 minutes, and scan time is 3 minutes per bed position [28, 29] (The scan time may be changed and determined by the phantom experiments).

4.2. Phantom test procedures and criteria for whole-body PET with ¹⁸F-FDG

NEMA IEC body phantom is used and the background area of the phantom is filled with ¹⁸F solution, of which the activity depends on the scanning protocol and is calculated as follows:

$$A_x = \frac{a}{60} \times \exp\left(\frac{-60}{109.8} \times \ln(2)\right) \times S \quad [kBq/mL]$$
(7)

where A_x is the activity of the background area, *a* is the assumed injection activity (MBq) for subject with 60 kg, and *S* is the specific gravity of human body that is set at 1.0 (g/mL). If the assumed injection activity is 3.7 (MBq/kg), *a* is equal to $3.7 \times 60 = 222$ (MBq). The six hot spheres are filled with solution of four times the activity concentration of the background. The "injection activity" and "body weight" sections of the DICOM header are filled in so that the true "SUV" is 1.00 in the background area. A 30-minute emission scan is carried out in a dynamic or list mode. The list-mode acquisition data are sorted so as to extract three images of the planned clinical scan duration, starting at 0, 1, 2 min from the start of the 30-minute list-mode data, or of a variable duration if the appropriate scan time is to be searched for. Both the 30-minute image and the images of clinical scan duration are reconstructed with the parameters that are determined so that the physical parameters of the phantom images could meet the criteria shown below. The phantom data are analyzed both visually and quantitatively to derive physical parameters including noise equivalent count (NEC_{phantom}), N_{10mm}, Q_{H,10mm}/N_{10mm}, CV_{background}, SUV_{B,ave}, RC_{10mm}, SUV_{max} of each hot sphere, and SD_{Δ SUVmean} [28,30]. It is noted that NEC_{phantom}, N_{10mm}, Q_{H,10mm}/N_{10mm} are optional.

NEC_{phantom} is a raw-data quality metric and is calculated as follows:

$$NEC_{\text{phantom}} = (1 - SF)^2 \frac{(T + S)^2}{(T + S) + (1 + k)fR}$$
 [Mcounts] (8)

$$f = \frac{S_a}{\pi r^2} \tag{9}$$

where T, S, and R represent true, scatter, and random coincidences acquired in the raw-data of the clinical acquisition duration. SF, k, and f represent scatter fraction, random scaling factor, and ratio of object size to scanning axial field-of-view. S_a and r represent the cross-sectional area of the phantom and the radius of the detector ring diameter. SF is the intrinsic value based on NEMA NU-2 standard because real-time measurement of the scatter fraction is currently impossible for most camera.

A circular ROI with a 10-mm diameter is placed over the 10-mm hot sphere on the slice of the sphere center. Twelve ROIs of the same size are placed over the background area on the slice of the sphere centers and on the slices ± 1 and ± 2 cm off the sphere centers, making a total of 60 ROIs. The percent background variability of N_{10mm} is calculated using the data of 10-mm ROIs as follows:

$$N_{10\rm mm} = \frac{SD_{10\rm mm}}{C_{B,10\rm mm}} \times 100 \quad [\%]$$
(10)

where $C_{B,10mm}$ is the mean of the mean activity for the 10-mm ROIs in the background area and SD_{10mm} is the SD of the mean activity for the background 60 ROIs. The percent contrast for the 10-mm hot sphere is calculated as follows:

$$Q_{H,10\text{mm}} = \frac{C_{H,10\text{mm}}/C_{B,10\text{mm}} - 1}{a_H/a_B - 1} \times 100 \quad [\%]$$
(11)

where $C_{H,10mm}$ and $C_{B,10mm}$ are the mean activity in the ROI for the 10-mm sphere and the mean activity in all the background 10-mm ROIs, respectively, and a_H/a_B is the activity concentration ratio for the hot sphere to the background.

For noise evaluation, twelve circular ROIs with a 37-mm diameter are placed over the background on the slice of the sphere centers and on the slices ± 1 and ± 2 cm off the sphere centers as defined above (a total of 60 ROIs). The CV_{background} is calculated using the data of the 37-mm ROIs as follows:

$$CV_{\text{background}} = \text{mean of} \left[\frac{SD_{37\text{mm}}}{C_{B,37\text{mm}}} \times 100 \right] \quad [\%], (n=60)$$
(12)

where $C_{B,37mm}$ is mean activity for each 37-mm ROI in the background area, and SD_{37mm} is SD of the pixel values within each ROI. $CV_{background}$ is calculated as the coefficient of variation (SD/mean) averaged across the background ROIs.

For evaluation of background SUV accuracy, SUV_{B,ave} is calculated using the data of 37-mm ROIs as follows:

$$SUV_{B,ave} = \frac{\sum_{k=1}^{K} SUV_{B,37\text{mm},k}}{K}$$
(13)

where $SUV_{B,37mm}$ is the mean activity for the 37-mm background ROIs on the slice of the sphere centers, and n=12.

The relative recovery coefficient for a 10-mm-diameter hot sphere (RC_{10mm}) is calculated as follows:

$$RC_{10mm} = \frac{C_{10mm}}{C_{37mm}}$$
(14)

where C_{10mm} and C_{37mm} are the maximum activity of the 10-mm and 37-mm diameter hot sphere, respectively.

For SUV harmonization, SUV_{max} of each hot sphere are measured on the slice of the sphere centers.

For uniformity evaluation, twelve circular ROIs with a 37-mm diameter are placed over the background on the slice of the sphere centers and on the slices ± 1 and ± 2 cm off the sphere centers, making a total of 60 ROIs as described above. The SD_{Δ SUVmean} is calculated as follows:

$$SD_{\Delta SUVmean} = \sqrt{\frac{1}{n-1} \sum_{i=1}^{n} (\Delta SUV_{mean,i})^2}$$
(15)

$$\Delta SUV_{mean} = \left(\frac{SUV_{mean}}{SUV_{TOT}} - 1\right) \tag{16}$$

where SUV_{mean} is the mean activity of each 37-mm ROI, n=60, and SUV_{TOT} is the average of the 60 SUV_{mean} .

The NEC_{phantom}, N_{10mm}, Q_{H,10mm}/N_{10mm}, and CV_{background} are calculated on the PET images of the planned clinical acquisition duration (The scan duration may be changed and determined by this phantom experiment). On the other hand, the SUV_{B,ave}, RC_{10mm}, SUV_{max} of each hot sphere, and SD_{Δ SUVmean} are calculated on the PET images of 30-minute acquisition.

The requested phantom test criteria are described below:

- (i) Noise equivalent count is $NEC_{phantom} > 10.8M$ counts (Optional).
- (ii) Percent background variability is $N_{10mm} < 5.6\%$ (Optional).
- (iii) Percent contrast to background variability ratio is $Q_{H,10mm}/N_{10mm} > 2.8$ (Optional).
- (iv) Noise level is $CV_{background} < 10\%$.
- (v) Accuracy of SUV in the uniform area satisfies $SUV_{B,ave}$ being within 1.00±0.05.
- (vi) Recovery coefficient for the 10-mm sphere is $RC_{10mm} > 0.38$.
- (vii) Harmonization of SUV_{max} satisfies the specified range below (Table 3).
- (viii) Uniformity satisfies $SD_{\Delta SUVmean} \le 0.0250$, which corresponds to 95% of the SUV_{mean} being distributed within 1.00 ± 0.05 assuming normal distribution.

Sphere size (mm)	Upper limit	Lower limit
37	4.17	3.82
28	4.21	3.56
22	4.09	3.25
17	3.71	2.58
13	3.04	1.52
10	2.00	1.19

Table 3: Specified range of SUV_{max} for harmonization.

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History

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1–1	2013.12	First edition

2–1 2017.1 Add whole-body FDG–PET for oncology