QIBA Profile Conformance

Self - Attestation Document

QIBA Profile title	FDG-PET/CT as an imaging biomarker measuring response to cancer therapy
QIBA Profile version	November 18, 2016
Company/Institution doing self-attestation	
Company/Institution responsible person	
Date Self-Attestation was submitted to QIBA	
Date Self-Attestation was reviewed by QIBA	
Date Conformance was registered by QIBA	

Some checklist items reference a required Assessment Procedure which may be found in the Profile Document.

Some checklist items have clarifications, rationale, or guidance in the corresponding Discussion section in the Profile Document.

To obtain a copy of the Profile Document, visit http://qibawiki.rsna.org/index.php/Profiles

If a QIBA Conformance Statement is already available for an actor (e.g. your acquisition device), a site may choose to provide a copy of that statement rather than confirming each of the requirements in that Actors checklist yourself.

Vendors publishing a QIBA Conformance Statement shall provide a set of "Model-specific Parameters" (as shown in Annex A) describing how their product was configured to achieve conformance. Vendors shall also provide access or describe the characteristics of the test set used for conformance testing.

QIBA Conformance Statements

QIBA Conformance Statements are documents prepared and published by vendors or sites to describe the intended conformance of their products, staff or institution to one or more QIBA Profiles.

Conformance requirements are defined in the QIBA Profile document for each Actor in the Profile. For some requirements, the Profile document also defines assessment procedures.

This conformance statement contains all relevant checklists for all relevant actors for site or product conformance. Supporting material is available on the QIBA wiki conformance section for the respective profile. Checklists in this conformance statement document need to be filled out.

Users can use Conformance Statements to determine whether their staff and products can be expected to deliver the biomarker performance described in the Profile Claim. Achieving the performance claim depends on all Actors described in the Profile being present at the site and conforming to the requirements.

A QIBA Conformance Statement is not intended to promote or advertise aspects of a product or site not directly related to its implementation of QIBA capabilities.

IMPORTANT NOTE: Vendors and sites are solely responsible for the accuracy and validity of their QIBA Conformance Statements. QIBA and its sponsoring organizations have not evaluated or approved any QIBA Conformance Statement or any related product, site or staff, and QIBA and its sponsoring organizations shall have no liability or responsibility to any party for any claims or damages, whether direct, indirect, incidental or consequential, including but not limited to business interruption and loss of revenue, arising from any use of, or reliance upon, any QIBA Conformance Statement.

QIBA Conformance Statement for a Product

QIBA Conformance Statement			
Vendor	**Product Name**	**Version**	**Date**
This product conforms to all specifications required for the QIBA Profiles and Actors listed below:			
Profiles Implemented	**Actors Implemented**	**Notes**	
FDG-PET/CT as an Imaging Biomarker Measuring Response to Cancer Therapy (2016)	Acquisition Device		
	Reconstruction Software		
Links to Additional Information			
General information on QIBA: qibawiki.rsna.org			

F.3 Format of a QIBA Conformance Statement for a Site

Each Conformance Statement shall follow the format shown in the following table.

The submitter may add a cover page and information required by their documentation policies.

QIBA Conformance Statement		
Site Name	**Responsible Person**	**Date**
This site conforms to all specifications required for the QIBA Profiles and Actors listed below:		
Profiles Implemented	**Actors Implemented**	**Notes**
FDG-PET/CT as an Imaging Biomarker Measuring Response to Cancer Therapy (2016)	Imaging Site	
Links to Additional Information		
General information on QIBA: qibawiki.rsna.org		

Annex A: Conformance Notes

QIBA FDG PET/CT Imaging Site

The following checklist may be used to ascertain a PET imaging site's qualification for quantitative imaging according to the QIBA FDG PET/CT Profile.

#	***Site and Personnel Qualifications***	***Status***
1.	The site is accredited (ACR, IAC, TJC, etc.) or has Qualified status for clinical trials (ECOG-ACRIN, SNMMI-CTN, EARL, CROs, etc.)	__ yes __no
2.	The site has the support of technologists, physicists, and physicians experienced in the use of FDG-PET/CT, and meeting the qualifications described below.	__ yes __no
3.	Technologists: PET studies are performed by technologists whose certification is equivalent to the recommendations published by the representatives from the Society of Nuclear Medicine Technologists Section (SNMTS) or the American Society of Radiologic Technologists (ASRT) and should also meet all local, regional, and national regulatory requirements for the administration of ionizing radiation to patients.	__ yes __no
4.	Physicists: The medical physicist is certified in Medical Nuclear Physics or Radiological Physics by the American Board of Radiology (ABR); in Nuclear Medicine Physics by the American Board of Science in Nuclear Medicine (ABSNM); in Nuclear Medicine Physics by the Canadian College of Physicists in Medicine; or equivalent certification in other countries; or have 3 years of PET experience. Regardless of certification, the physicist should have specific experience in PET and its quantitative use.	__ yes __no
5.	Physicians overseeing and interpreting PET/CT scans are qualified by the ABR (Diagnostic and/or Nuclear Radiology) or American Board of Nuclear Medicine (ABNM) or equivalent within the United States or an equivalent entity appropriate for the geographic location in which the imaging study(ies) will be performed and/or interpreted.	__ yes __no
	Imaging Procedures	
6.	Patient height and weight are entered into scanner during PET/CT acquisition.	__ yes __no
7.	Blood glucose is measured for each patient within 2 hours preceding FDG administration. Measured value and measurement time are documented.	__ yes __no
8.	If and when glucose threshold is exceeded, the reason shall be documented.	__ yes __no
9.	For each patient, the pre-injection FDG activity is measured and injected and residual activity is measured. Initial and residual measurement times and injection time are entered into the console.	__ yes __no
10.	FDG is administered through a 24-gauge or larger indwelling catheter placed anatomically remote to any sites of suspected pathology, preferably in an antecubital vein. Intravenous ports should not be used, unless no other venous access is available. In the case of manual administration, a three-way valve system should be attached to the intravenous cannula so as to allow at least a 10cc normal (0.9% NaCl) saline flush following FDG injection. For automated injection devices alternate flushing mechanisms are allowed.	__ yes __no

11.	For follow-up scans, patients are imaged with the same workflow (i.e. patient handling, imaging acquisition, image processing, and image analysis) as for baseline scans.	__ yes __no
12.	The FDG uptake time (from injection to scan) is 60 minutes, with an acceptable range of 55-75 minutes. When repeating a scan on the same subject, uptake time for the 2nd scan is within 10 minutes of that for the first scan.	__ yes __no
13.	If the patient is observed to take a deep breath during the CT scan it is documented and a repeat CT study is considered.	__ yes __no
14.	When a patient is rescanned, the same scan direction is used.	__ yes __no
15.	Reconstructed PET images, with and without attenuation correction, and CT images are archived at the imaging site.	__ yes __no
	QA/QC	
16.	The site performs all PET/CT scanner QA/QC procedures recommended by the manufacturer and at the recommended frequency (e.g., daily, weekly, quarterly) and assures that the output values are acceptable.	__ yes __no
17.	Daily QA procedures are performed prior to any subject scan.	__ yes __no
18.	A water or water-equivalent phantom is scanned and evaluated daily and acceptable output is ensured.	__ yes __no
19.	Dose calibrator constancy is evaluated daily on the F-18 setting. Day-to-day differences no greater than 2.5% are allowed. Cs-137, Co-57, or simulated F-18 may be used.	__ yes __no
20.	The dose calibrator accuracy is evaluated monthly with measured values differing no more than 2.5% from the actual source value. Cs-137, Co-57, or simulated F-18 may be used.	__ yes __no
21.	Dose calibrator linearity is assessed at least annually over a range of 37-1110 MBq, with deviation of no more than 2.5% over the entire range.	__ yes __no
22.	Scales for patient weight measurement are evaluated annually or after any repair by qualified personnel, with error no more than 2.5% from expected values using a NIST-traceable or equivalent standard.	__ yes __no
23.	The glucose measuring device is measured and tested according to a CLIA-approved, CLIA-cleared, or equivalent (if outside the United State) procedure.	__ yes __no
24.	The PET/CT scanner computer and all clocks in the imaging facility used to record activity/injection measurements are synchronized to standard time reference within +/-1 minute. Synchronization of all clocks used in the conduct of the FDG-PET/CT study is checked weekly and after power outages or civil changes for Daylight Savings (North America) or Summer Time (Europe).	__ yes __no
25.	Quantitative Calibration Accuracy: PET scanner quantitative accuracy relative to the dose calibrator is verified quarterly and after scanner upgrades, maintenance or repairs, new setups and modifications to the dose calibrator via a uniform phantom scan of activity measured in the dose calibrator, achieving a large central ROI mean SUV value of 1.0 (acceptable range 0.9-1.1).	__ yes __no

26.	Axial Uniformity: Using a uniform cylinder phantom or equivalent shall obtain a slice-to-slice variability of less than 10% for the slices within the central 80% of the axial FOV.	__ yes __no
27.	PET Resolution: Cold rods (as in the Jaszczak or ACR PET phantoms) of diameter 9.5 mm or smaller must be visible. A hot cylinder (as in the ACR PET phantom) of 12 mm or smaller must be visible OR the 13 mm sphere of the NEMA image quality phantom must be visible.	__ yes __no
28.	PET noise: In a uniform phantom of 0.1 to 0.2 µCi/ml F-18 concentration the coefficient of variation of voxel values within a rectangular or circular region of at least 3 cm (side or diameter) must be no greater than 15% for all slices within the central 80% of the axial FOV.	__ yes __no
	Specific Personnel Responsibilities	
29.	A technologist or physicist assesses uniformity (within-plane and across slices) and compares with previous results. Quarterly and following software upgrades.	__ yes __no
30.	A technologist or physicist shall perform the Quantitative Calibration Accuracy test. Quarterly and following software upgrades or changes to the dose calibrator	__ yes __no
31.	A physicist shall perform and document performance of a quantitative assessment (using a phantom with differing size defined targets such as the ACR or NEMA IQ phantoms processed with routine image reconstruction protocols) for lesion resolution. Annually.	__ yes __no
32.	A physicist Shall perform a quantitative assessment of image noise in phantom images to be of consistent and acceptable quality. Annually.	__ yes __no