Public Comment Form for QIBA Documents

Notes:

1. **Initials** identify the commenter to facilitate clarification of the issue and/or communication of the resolution.
2. **Priority**
   - **L**: Low. Typo or other minor correction that an editor can manage; requires no group discussion.
   - **M**: Medium issue or clarification. Requires discussion, but should not lead to long debate.
   - **H**: High. Important issue where there is a major issue to be resolved; requires discussion/debate.
3. **Line #** shows exactly where in the original document the issue occurs, and is necessary for sorting.
4. **Section #** shows in which section the issue occurs (e.g., 4.1.2)
5. **Issue**: Describe your issue; include enough to indicate what you see as a problem.
6. **Proposal**: Propose a resolution to your issue, e.g., suggested new wording or description of a way to address the issue; leave blank if no resolution can be provided.

Document Filename: QIBA FDG-PET/CT as an Imaging Biomarker Measuring Response to Cancer Therapy v1.02

Public Comment Review Period: 17Jan2013 – 15Feb2013

Leave Blank	Your Initials	Priority L M H	Line # (Please indicate either Line # or Section #)	Section #	Issue	Proposal	Leave Blank
	esp	L	68	1	Missing word – 'to'	Intended 'to' account	DONE
	LP	L	68	1.	missing "to" in sentence	change to: "categories are intended **to** account…"	DONE
	esp	L	104 & other	1	Uniform initial capitalization of Profile	Change profile to initial cap 'Profile'	DONE (to check full text)
	esp	L	126	2	Punctuation	Remove period '.' after tumors and before [	DONE
	esp	L	166	2	Define term	PSF – Point Spread Function	
	esp	L	167	2	Define term	TOF – Time of Flight	
	esp	L	176	3	Grammar	Change first word 'the' to 'of'	DONE
	LP	L	175-176	3.	missing "of" in sentence	change to: "SUVx refers to one **of** the several…"	DONE
	esp	L	176	3	Punctuation/Grammar	Remove comma and insert 'or' between SUVmax and SUVpeak	DONE
	esp	M	193	3	Clarification of mathematical formula	Insert brackets [ ] around entire fraction and add 'x 100' in order to get percentage	
	esp	L	208	3.1.1	Term change	Change 'patients' to 'subjects'	DONE
	esp	L	253	3.1.2	Incorrect intra-document reference	Change to Section '3.2.1' instead of '2.1'	DONE
	SB	M	291	3.1.2.3	refraining from reading is not necessary for WB oncology imaging	remove this	

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	SB	M	293	3.1.2.3	what is the justification for preventing patients voiding for 30mins after injection?		
	SB	H	296 & 304	3.1.2.3	strongly disagree. Catheterization often leads to pockets of concentrated urine. Bladder washouts increase dose to staff. Invasive and unnecessary	remove this	
	SB	M	309	3.1.2.3	ideally sedation should be given for the scan duration and not the uptake period	include this comment in the text	
	esp	M-H	314+	3.1.2.3	Does height need to be measured post baseline?		
	esp	L	316 - 317	3.1.2.3	Formatting	Change bracket type in outer parenthesis to [ ] style rather than ( ) style.	DONE
	esp	L	322	3.1.3.1	Define term	USP = United States Pharmacopeia	
	LP	L	326	3.1.3.1.2	duplication of "administered"	change to: "The 18F-FDG activity administered…"	DONE
	esp	L	349-350	3.1.3.1.3	Mis-spelling	Spelling correction 'images' located in the tabular section between lines 349 and 350	DONE
	LP	L	Table	3.1.3.1.3	spelling mistake under specification in Table on page 14 - images	change iamges to images	DONE
	esp	L	352	3.1.3.2	Formatting and reference change to be consistent with remainder of document	Insert 'Protocol' to read . . UPICT FDG-PET Protocol (Section 3.2) and delete descriptor of that Protocol Section contained in "quotes".	DONE
	LP &SB	H	364 & 645	3.2 & 3.6.3	we disagree that subsequent scans can be done on a different scanner as it is not possible to demonstrate equivalence	scans should be rescheduled if possible or the patient excluded from the study	
	esp	L	369	3.2	Consistency	Remove 'Reference' from inside parenthesis	DONE
	SB	M	376	3.2	Don't like this phase, the scan is still 'diagnostic' just not full-dose high resolution.	Suggest omitting this phase or state "fully diagnostic" CT scan	
	SB	M	381	3.2	Strategy 2a preferred as it avoids any impact of contrast on quantitation unless a time interval is specified between contrast and PET	include note that this is the preferred strategy	
	SB	H	397	3.2	it may not be practical to only employ one imaging strategy in a clinical trial depending on local protocols and facilities. e.g. in some of our trials we require CE-CT, but this can be done as part of the PET study or as a separate CT study	clarify that strategy 2a and 2b should not both be used within a clinical trial, but strategy 1 plus a separate CE-CT can be used with strategy 2a to allow sites that do not have the facility to perform CE-CT in the PET centre	
	esp	M-H	432	3.2.1.1	Intra document consistency issue	Text indicates +/- 15 minutes as acceptable while tabular text indicates +/- 10 minutes	
	esp	L	451	3.2.1.2	Duplication of text	Remove 'Respiratory Motion' intro phrase	DONE
	esp	L	460-462 & other	3.2.1.2	Punctuation	Add a period "." After each phrase for multiple line items in tabular format in this Section	DONE (to check full text)

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	LP	L	484	3.2.1.4	typo	change address to “addresses”	DONE
	LP	M	524	3.3.1	PET voxel size – not all current scanners can do 3-4mm voxels without reducing the FOV. The GE DST without Dimension console upgrade can only recon to 128x128 matrix = 4.7mm voxels.	change 3-4mm to being IDEAL and make target <5mm. UNLESS the idea is to exclude older generation scanners from clinical trials…	
	SB	M	Table	3.3.2	it says quantitative analysis should only be performed on unprocessed images – what about studies where the PET and CT need registered i.e. patient movement?	Clarify if these images should be excluded from analysis	
	LP	M	552	3.3.3	no mention of storage of RAW data – this has proved invaluable in cases where recons have not been done correctly. Not difficult to store on modern systems	provide recommendations or say the clinical protocol should indicate if raw data should be stored locally	
	NPL (JK)	H	657 (Table)	3.6.3.1.1	the objective of the constancy test is to check for instrumental drift, and thus the deviation or bias from a traceable activity is irrelevant. Indeed, one does not even need to know the activity accurately. All one needs to measure is the ionisation current. What is important is that the reading is constant over time (after appropriate decay corrections). The “bias” from the expected value is then monitored via the “Accuracy” parameter, which is set to 2.5%.	the constancy limits should be MUCH tighter than 2.5%, or even better that the limits are decided form a statistical analysis of historical measurements, via a control (or Shewart) chart, with appropriately defined action limits and control limits etc. For the chambers we use at NPL, the standard deviation is more like 0.1%, going back over decades. My guess is that for clinical instruments the limits would be more like 0.5%	
	LP	H	657 (Table)	3.6.3.1.1	for the accuracy test in the UK, sites do an annual F-18 intercomparison with the primary standard at NPL so the calibrator factor is traceable	An annual F-18 intercomparison with NIST/NPL should be allowed in place of monthly measurements with a traceable source	
	LP	M	661	3.6.3.1.2	is it necessary to have calibration of stadiometers to this level if not using height to adjust SUV	suggest if not using for SUV, calibration at installation is sufficient	
	LP	L	697	3.6.4	should include kBq/ml	change to “0.1 to 0.2uCi/ml (3.7-7.4kBq/ml)”	
	LP	M	710	3.6.4	the phantom tests are not easy to follow	include a summary table with all the test names, frequency and a reference to the section with the description	
	LP	H	710	3.6.4	in the UK no-one owns the ACR phantom	could the Jasczak phantom which is widely available be used as an alternative for the resolution measurements?	
	esp	L	722	3.6.4.1	Grammar	Change ‘provide’ to ‘provided’	DONE
	LP	L	722	3.6.4.1	d missing on “provide”	change to “provided”	DONE

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	esp	L	727	3.6.4.1	Possible misused word	'Uniformly' to 'uniformity'	
	esp	L	745	3.6.4.4	Grammar	Change 'stacks DICOM of images' to 'stacks of DICOM images' or "of stacked DICOM images"	DONE
	LP	L	745	3.6.4.4	re word sentence "of stacks DICOM of images"	change to "of stacked DICOM images"	DONE
	esp	L	787	3.6.5.3	Typo	'portahepatis' should be 'porta hepatis'	DONE
	SB	M	791	3.6.5.3	add "avoiding the wall of the aorta or areas of calcification"	to read "tracking the long axis of the aorta avoiding the wall of the aorta or areas of calcification."	
	esp	L-M	808	3.6.6	Grammar – sentence structure unclear intent	. . what statistics to evaluate and how these performance metrics should be used in the analysis.	DONE
	LP	M	813	4	include UK NCRI qualification	add UK-NCRI	
	LP	M	842	4.1	CT scanner calibration – if sites are already scanning a uniform Ge-68 cylinder daily to check the PET calibration could the CT be checked using this phantom (HU will obviously be different, but uniformity and output can be checked) and the water equivalent weekly		
	LP	H	842 & 891	4.1 & 4.2	PET calibration should be checked daily with a phantom and ideally tracked in the DICOM header	daily scan of Ge-68 cylinder should be performed	
	esp	L-M	846-849	4.2	Informative text is not located with the correlative content in tabular format	Consider relocating informative text regarding SW versioning to Section 4.5	
	LP	L	857	4.2	incorrect DICOM tag	change "acquisition time" to "series time"	
	esp	L	886	4.2	typo	Insert hyphen to make 'meta-data'	DONE
	esp	L	891-893	4.2	Multiple minor typo's including incorrect or lack of period in tabular section Specification		DONE
	LP	M	891	4.2	PET Scanner calibration: This test is not clear, it has the same name as the routine Qc tests in the previous table, there is no frequency or activity specified for the PET calibration. Is this referring to cross-calibration? If not, what is the justification for using a 60 min + acquisition for PET scanner calibration?	Clarification of what this test is for	
	LP	H	891	4.2	PET Scanner calibration: on GE and Siemens systems there are likely to be jumps bigger than this if the manufacturers protocol is followed. (GE quarterly cross-calibration and after source Ge-68 cylinder change on Siemens)		

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	LP	M	891	4.2	SUV should be displayed on the scanner workstation to 2d.p		
	LP	M	891	4.2	Decay correction methodology: Wish to have a DICOM field to indicate if data is derived or original. Series date/time should not be altered on derived series		
	LP	M	891	4.2	Bed position Temporal Differences: Should include time per bed (0018, 1242) ActualFrameDuration. Desirable to include slice overlap		
	AS	M	891	4.2	PET-CT Alignment: are mobile PET/CT scanners expected to be covered in this profile, and expected to be within +/- 2mm alignment?	Mobile PET-CT scanners often can not be as well aligned as stationary ones – may want to consider a looser specification.	
	AS	M	891	4.2	PET Radiation Dose: Does a DICOM Radiopharmaceutical Administration Radiation Dose Structured Report actually exist?	If it does, give clear reference to the specification.	
	AS	M	891	4.2	PET Voxel Size: Is range truly 3-4 mm in x- and y-directions, or is this meant to be BETTER THAN 3 to 4 mm. In other words, would a reconstruction pixel size of 2.5 mm work?	Shall be able to reconstruct PET voxels with a size of 4 mm or better in all three dimensions...	
	AS	M	891	4.2	Documentation of Exam Specification: Does this specification apply to both PET and CT?	Make modalities clear in this description.	
	LP	M	900	4.3	Should have DICOM field to indicate if TOF and resolution recovery are on or off		
	LP	M	900	4.3	Reconstruction parameters: Should be in DICOM header (0054, 1103) ReconstructionMethod and (0018, 1210) convolutionKernel. Desirable to have iterations and subsets		
	esp	L	908	4.4	Spelling	Insert second ‘t’ in concentration	DONE
	esp	L	911	4.4	Missing word	Insert ‘a’ . . . as ‘a’ separate file	DONE
	esp	L	915	4.4	Missing format / punctuation	Insert close parenthesis as end of sentence.	DONE
	LP	L	924	4.4.1	ROI output stats: SUV is unitless	delete g/ml	
	esp	M	924+	4.4.1	ROI Output Statistics row: modify a specification to allow user flexibility without minimizing manufacturer requirement	Insert ‘have the capability’ so that it reads . . “Shall <u>have the capability</u> to output results with at least two decimal places.”	
	AS	M		4.4.3	DICOM Compliance: not clear what “transferable” means. Can this be made more clear?	Perhaps list equipment that image data will be transferred to: PACS, HIS, RIS, etc.	

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	esp	L	951 & other	Referen	Missing period at end of reference	Add period '.' at end of reference	DONE (to check full text)
	esp	M-H	1072	App. A	Need to insert list of members	TBD by chairpersons / RSNA staff	
	esp	L	1081	App. B	Punctuation	Add comma after expected. . . As expected,	DONE
	esp	L	1096	App. B	Typo ?	Abbreviation of within coefficient of variation should be wCOV based on earlier reference to COV as abbreviation	
	esp	L	1145	App. C	Punctuation	Add period '.' at end of sentence	DONE
	esp	L	1155	App. C	Typo	Change initial word, 'no' to 'on'	DONE
	esp	L	1156	App. C	Missing word	. . . .used 'to' refer to	DONE
	PM	H	1168	Appendix C	SUV is dimensionless, there should be a density term in the definition of SUV		
	esp	M-H	1204-1211	App. C	The document indicates that guidelines for response criteria threshold by SUV change is beyond scope, then indicates these threshold in this Section which is inconsistent	Either insert disclaimer language in this Section or delete these specific threshold statements for PMR, CMR, PMD, SMD	
	esp	L	1215	App. C	QA acronym is not defined	QA - Quality Assurance is a proactive. . .	DONE
	esp	L	1218	App. C	QC acronym is not defined	QC - Quality Control describes specific tests. . .	DONE
	AS	M		Various	Vendors will need standards in order to implement specifications in gray boxes. Examples are interfacing to blood glucose, weight, etc. measurement machines, and those that require DICOM fields that don't exist, yet.	Progress on standards adoption as it relates to this QIBA profile will need to be dynamic and tracked. Perhaps put a link on the website where this Profile will be stored?	
	AS	M	1451-2	Apdx F Regarding DRO	Better description of how exactly partial volume effects are incorporated into the phantom to make it easier for external groups to self-validate.	Provide more details such that internal institution tests can be developed and run.	
	AS	M	1451-2	Apdx F Regarding DRO	Not enough detail in Fig. 2's Table.	Useful if table extended with acceptable ranges for all values (the columns in the table).	

Add lines as needed.

Please leave the first and last columns blank. The committee will use the first column to number comments and the last column to record resolution.

Thank you for your comments!