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 v1.04

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
18	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?	Will allow **deluxe** Jasczak; note that this does not allow for hot object resolution assessment at this time. – (PK) wording for hot object
19	RW/ esp	M-H	784	3.6.5.3	PERCIST criteria uses SUL metric for minimum threshold determination; suggest revise multiplier for SUV when SD is not included in equation and add disclaimer.	Suggest using 1.9 x SUL or SUV liver when 2 x SD is not included. That said, about 5-10 % of cases may be un-evaluable at the 1.9 x liver as they are not hot enough… . Maybe it could be stated that "less FDG avid lesions than the evaluable threshold of 1.9 x liver may still be studied, but caution is in order, as their low initial FDG uptake may make changes in SUV less informative."	Draft change made; for review internally – lines 793-795 (RW)
27	LP	M	892	4.2	SUV should be displayed on the scanner		Wording revised

Leave Blank	Your Initials	Priority L M H	Line # (Please indicate either Line # or Section #)	Section #	Issue	Proposal	Leave Blank
					workstation to 2d.p		(in Section 4.4) to indicate SUV statistic display to accuracy of at least 2 decimal places for analysis station; Text added to indicate that sometimes Acquisition Device may behave as workstation.
47	PH	M	811-822		Is an appropriate body (ACRIN or ACR) certificate pre-requisite for QIBA compliance? If it is, then are all QIBA requirements in the profile additional requirements?	You should state clearly whether it is or not and define which requirements of ACRIN or/and ACR, etc. will be applied.	group
49	PH	M	856-892		For the text in line 856 to 862, why do you want decay requirements in this section?	Put this information in the following table.	Check Gap on informative versus normative
58	PH	H	p. 39 L892-893	4.2 table	PET and CT voxel size: Are all of these different combinations necessary? Are these guidelines? - that has a different feel.	Vendors can create protocols which meet these requirements.	Unclear as to issue here. . . check with LS.
62	PH	M	p.42, L917	table	Table: if this is specifically for dynamic studies, state so (multi-bed decay is applied already, as stated in p.41)	Clarification.	To insert wording to indicate that this is NOT for dynamic.
63	PH	M	L919		Suggest making it clear that 2D is meant to refer to the original input slice, not any other slab.	Suggest making it clear that 2D is meant to refer to the original input slice, not any other slab.	Check other sections to see if this is already covered – that ROIs can only be used on unprocessed images or add to informative text (4.4 or 4.5 check)
64	PH	M	p.44		"tracking tumor info across scans" table line 2. Need a great deal of specs - same ROI, but tumor changed, 2D vs 3D, registration impact …. .	In general, the gray text throughout the document requires more clear definition of compliance.	Group – p 45 – ROI saving/retrieve" row - ?clarification of query needed?

Leave Blank	Your Initials	Priority L M H	Line # (Please indicate either Line # or Section #)	Section #	Issue	Proposal	Leave Blank
65	PH	L	p.45, L946,		"all sw version numbers": consider if the software does not create new dicom object. Specifically "record all the software version numbers in the DICOM header' is vague. Please consider to change it to the recommended sentence	In the future, new DICOM attributes will be provided, and then the software version for acquisition, reconstruction and display shall be all stored in the DICOM attributes without over-stepping each other as in the case of today. Specifically, a new DICOM object is created when a new processing is done with respective software version information stored.	Group – p. 47. "SW Version tracking" row
67	PH	M	p.67		Appendix G: For Philips data, Regarding the robust version, the BQML unit data also has a private attribute to allow one to get the suv directly (instead of going thru all other steps). – Everyone can access Philips private attributes defined in the DICOM conformance statement. Consider put this into codes.		Physics / DICOM – this is already in Appendix G.2 (PK)
69	JDP	M	350	3.1.3.1.3	This table includes an estimate of the amount of infiltration, in terms of minor, moderate and severe. The DICOM Supplement 159, Radiopharmaceutical Administration Radiation Dose Report, includes characterization of the amount of extravasation in terms of activity (in MBq), as well as recording symptoms of the extravasation. It would be nice if these two were harmonized.	Determine if these are truly recording the same thing (extravasation versus infiltration). If so, it would be nice of the two were harmonized.	group
72	JDP	M	666	3.6.3.1.4	This section discusses synchronizing clocks on the various systems involved. There is already a standard way to express this using the IHE Consistent Time Profile.	Consider requiring support for the IHE Consistent Time Profile rather than specify a (possibly) different set of requirements on the scanner.	Added strawman text for 'future' requirement – for group review
80	JDP	M	892	4.2	Scanning Workflow: What is the purpose of the future requirement for storing and receiving pre-defined protocols? If you allow proprietary formats then you have lost the ability for re-use in multi-center situations since each site may have different vendor equipment. Also, it is a stretch to expect a scanner to read an image (or a whole series) and reverse engineer the acquisition protocol that created it.	Suggest dropping these future requirements.	Group discussion needed.
83	JDP	M	892	4.2	Documentation of Exam Specification: Why the requirement to record number of bed	Drop the requirement for recording number of bed positions in DICOM images.	Group discussion needed.

Leave Blank	Your Initials	Priority L M H	Line # (Please indicate either Line # or Section #)	Section #	Issue	Proposal	Leave Blank
					positions. The DICOM Standard specifically avoids any mention of bed positions since this is a highly implementation specific notion. Each image includes information about its position, orientation, acquisition and reconstruction parameters. What else would be gained by recording bed positions? In addition, for acquisitions done while the bed is in motion, the idea of bed positions is meaningless.		
88	JJS	H	323-4	3.1.3.1.1	USP is expired standard. FDG must now be produced under 21 CFR 212 Current Good Manufacturing Practice for PET Drugs	"The FDG radiopharmaceutical must be produced under 21 CFR 212 Current Good Manufacturing Practice for PET Drugs…"	PC: The FDG must be produced under Current Good Manufacturing Practice as specified by the FDA, EMEA or other appropriate regulatory agency. Regulations such as 21 CFR 212 or USP <823> Radiopharmaceuticals for Positron Emission Tomography (PET) must be followed. Consult with PK, PC and RB for add'l revisions.

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!