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
1	SB	M	291	3.1.2.3	refraining from reading is not necessary for WB oncology imaging	remove this	Keep wording as is., due to concern of increased activity of neck musculature during reading.
2	SB	M	294	3.1.2.3	what is the justification for preventing patients voiding for 30mins after injection?		Added text to indicate justification for specification
3	SB	H	297 & 305	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	Revised text to address this concern.
4	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	Added text to include this content
5	esp	M-H	315+	3.1.2.3	Does height need to be measured post baseline?		Revised to require weight measure at all time points; height measure

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							required at baseline
6	LP &SB	H	365 & 646	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	Revised text to require same scanner for quantitative trials
7	SB	M	377	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	Revised to"not intended as a clinically diagnostic CT"
8	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	Accepted and done
9	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	The suggestion is felt not to be disallowed by the current wording. NO change made.
10	esp	M-H	433	3.2.1.1	Intra document consistency issue	Text indicates +/- 15 minutes as acceptable while tabular text indicates +/- 10 minutes	Revised by deleting allowance of +/- 15 mins in informative text
11	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…	**PHYSICS/QA-check with SW as to capability, then address**
12	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	**GROUP**
13	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	Draft text provided by Dr. Kinahan
14	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	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	The specification as written is felt to balance ideal and practical considerations for worldwide utility. Going beyond the

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					decay corrections). The "bias" from the expected value is then monitored via the "Accuracy" parameter, which is set to 2.5%.	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%	"minimum" requirement set out in the Profile is also acceptable. No change to text.
15	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	Decision to keep text as is. Does not account for short term fluctuations and direct comparison to F18 standard is not possible in all countries.
16	LP	M	660	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	
17	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	**GROUP**
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.
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
20	LP	M	843	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		No; we've found that epoxy densities vary too much.

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21	LP	H	843 & 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	**PHYSICS/QA** With DICOM
22	esp	L-M	847-850	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	
23	LP	L	858	4.2	incorrect DICOM tag	change "acquisition time" to "series time"	No, Reference field name is correct, DICOM tag is in error (changed to 0008 0032). ADDED new comment to improve explanation in text.
24	TC	M-H	857-860		Provide clearer explanation of the terms used and DICOM cross-reference.	Raised on TC call of 08Mar – PK/DC fup.	**DICOM**
25	LP	M	892	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	**PHYSICS/QA**
26	LP	H	892	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)		**PHYSICS/QA**
27	LP	M	892	4.2	SUV should be displayed on the scanner workstation to 2d.p		Wording revised to indicate minimum SUV statistic display of 2 d.p. for analysis station; note this is not display requirement of Acq. Device. currently
28	LP	M	892	4.2	Decay correction methodology: Wish to have a DICOM field to indicate if data is derived or		**DICOM**

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					original. Series date/time should not be altered on derived series		
29	LP	M	892	4.2	Bed position Temporal Differences: Should include time per bed (0018, 1242) ActualFrameDuration. Desirable to include slice overlap		**DICOM**
30	Vendor	M	892	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.	**PHYSICS/QA**
31	Vendor	M	892	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.	**DICOM**
32	Vendor	M	892	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...	
33	Vendor	M	892	4.2	Documentation of Exam Specification: Does this specification apply to both PET and CT?	Make modalities clear in this description.	
34	LP	M	901	4.3	Should have DICOM field to indicate if TOF and resolution recovery are on or off		**DICOM**
35	LP	M	901	4.3	Reconstruction parameters: Should be in DICOM header (0054, 1103) ReconstructionMethod and (0018, 1210) convolutionKernel. Desirable to have iterations and subsets		**DICOM**
36	LP	L	924	4.4.1	ROI output stats: SUV is unitless	delete g/ml	No. While SUV is unitless, when use formula, do get units. Additional explanatory text inserted into Section 3.4.3
37	esp	M	925+	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."	
38	Vendor	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.	**DICOM**
39	esp	M-H	1073	App. A	Need to insert list of members	TBD by chairpersons / RSNA staff	List of TC

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							members to be provided by RSNA staff for insertion
40	PM	H	1169	Appendix C	SUV is dimensionless, there should be a density term in the definition of SUV		technically g/ml is correct. The density term is included in the equation and text added to clarify
41	esp	M-H	1205-1212	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	
42	Vendor	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?	
43	Vendor	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.	Unclear as to the question?
44	Vendor	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).	WIP
45	EAE	H	908	4.4	Explicit report of calculated minutes between injection and initiation of imaging, rather than requiring user to make the calculations from data. Background: Most instruments actually do this, and may flag problems such as excessive variation compared with a baseline study. User calculations are time consuming and highly subject to error.	"Shall display, or include link to display, the number of minutes between injection and intiation of imaging"	Already included Section 4.4 Normative item 'metadata' –display workstation – does this also need to be added to Section 4.2?
46	EAE	H	1108	appendix	Additional relevant literature citation is available: Variance of SUVs for FDG-PET/CT is greater in clinical practice than under ideal study settings. Kumar V, Nath K, Berman CG, Kim J,		Added to references in Appendix B

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					Tanvetyanon T, Chiappori AA, Gatenby RA, Gillies RJ, **Eikman** EA. Clin Nucl Med. 2013 Mar;38(3):175-82. doi: 10.1097/RLU.0b013e318279ffdf. PMID 23354032 [PubMed - in process]		
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
48	PH	H	710 and 892-893 table		Be consistent or clearer on the definition of SUV pass-requirements. For example, in the table on line 710, SUV of 1.0 with range of 0.9 to 1.0 is called (an ACRIN requirement). However, in line 892, SUV range of 0.98 to 1.02 is stated. The definition of the two numbers is not clear. We believe this is a QIBA specific requirement. However, this criterion will potentially eliminate a lot of PET systems.	Consider relaxing the 0.98 – 1.02 requirement since it may not have a big impact on the final quantitation since other errors are much bigger.	Group – first reference (0.9 – 1.10) is to QC on site; latter (0.98 – 1.02) refers to scanner specif when leaving factory.
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.	
50	PH	H	p. 37		On page 37, shall be able to record the administrated radioactivity, in both MBq and mCi. Question - can you store one number in two different units?	On page 37, shall be able to record the administrated radioactivity, in either MBq or mCi	Physics – p 39 – "Administered Radiotracer radioactivity" row
51	PH	M	p. 37+ table		General comments, in the future boxes, when a new DICOM is mentioned, it should be more specific; otherwise, it is difficult for vendors to plan for it. Even if the attributes are not approved yet, it should have a name.	Be more specific.	Group/DICOM
52	PH	M	p. 36 892	table	What is the purpose of acquiring 60 min or more?	Clarification	Physics/QA –p.38 "PET Scanner calibration" row
53	PH	M		4.4	Table after line 916: Reference time for decay correction - check Series Time field. Clarification and rationale is needed.	Clarification and rationale is needed.	DICOM – p.44 "Reference Time for decay correction" row
54	PH	H	p. 43 L925-	4.4.1 table	Voxel Inclusion Policy: Conformity at this level is unlikely given the number of vendors and the	A better approach is to use a standard data set (digital reference object) and check for	Physics/QA –p. 44 line 956

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			926		variation in the way in which an ROI is drawn.	consistent results.	
55	PH	H	p. 45 L940-940	4.4.3 table	Can this replace the Voxel inclusion policy above and remove the issues we had with that requirement?	Replace the Voxel inclusion policy above and remove the issues we had with that requirement.	Physics/QA – p. 47 line 971
56	PH	M	p. 45 L940-940	4.4.3 table	Alignment accuracy - define 'perfectly aligned' tolerance. (Should it be +/- 2mm as it is in 4.2 PET-CT alignment?)	Define alignment accuracy – provide a value.	Physics/QA – p. 47 "Alignment Accuracy" row
57	PH	M	p. 39 L892-893	4.2 table	There should be alignment between this QIBA requirement and NEMA PET-CT alignment task force for these alignment requirements.	Align with NEMA PET-CT alignment task force.	Physics/QA – p. 40 "PET-CT Alignment" row
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.	Group / physics – p 41 – "PET and CT Voxel size" rows
59	PH	H		4.3	Recon methodology - This seems open ended. Same comment for with and without scatter and attenuation.	Rather than turn on and off, vendors can create optimized protocols. It would be preferred to have a protocol that addresses this and has been optimized carefully elsewhere (such as the Harmonization Project).	Physics
60	PH	H		4.3	Vendors may get 'standardization fatigue'. What is really being asked for?	Clarification. Request specific protocols.	Removed requirement for with and without TOF and scatter Done – pending
61	PH	H	p.41 L901-902	4.3 table	Voxel size - not consistent with previous voxel requirement in 4.2. This looks like a request for a recon knob? Is that really what is needed?	Clarification. Request specific protocols.	Physics
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.	Physics
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?
65	PH	L	p.45,		"all sw version numbers": consider if the	In the future, new DICOM attributes will be	Group – p. 47.

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			L946,		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	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.	"SW Version tracking" row
66	PH	M	p.64, L1430		Negative SUVbw (-0.11)? Also p.63, pet image after line 1404.	Clarification on the meaning/reason for an SUV < 0.	p. 63 line 1466;
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
68	PH	M	General		Since the purpose is to promote comparability and consistency, it might be a good idea to show with concrete examples (perspective study, retrospective study, or animal imaging) that the goal is indeed achieved (or can be achieved).	Show examples that the goal has been achieved.	group
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
70	JDP	H	470	3.2.1.3	This table includes a requirement to record the scanning direction in the "appropriate DICOM field". There is no DICOM attribute that describes the direction of motion during the scanning process. The Patient Orientation attributes characterize the relationship of the patient to the gantry, but that does not determine which direction the table moves during the scan.	This needs to be an optional item for future implementation.	DICOM
71	JDP	M	481	3.2.1.4	Bed overlap is not currently adjustable by an	Please clarify that the current requirement is	Deleted bed

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					operator on all PET/CT systems.	that the acquisition mode will be selected such that it will work for any scanner model, and not that the bed overlap is expected to be adjustable on the scanner or recorded in DICOM information.	overlap requirement
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 text for 'future' requirement
73	JDP	M	892	4.2	Table: What DICOM attributes would be used to record the PET calibration tracking, and what information is needed? Are Date of Last Calibration (1800,1200) and Time of Last Calibration (0018,1201) sufficient? Also, I do not agree that a DICOM Image header is the proper place to record an entire history of calibrations of the acquisition device. The same comment would also apply to the CT calibration tracking information.	Need to find another means of reporting the calibration history, outside of the images.	DICOM
74	JDP	M	892	4.2	For Radionuclide calibrator calibration tracking, is DICOM attribute Dose Calibration Factor (0054,1322) sufficient? If not, what information is needed? Is the intent to record a history of calibration factors, as the name implies? This would not be available to the scanner and should not be added to images. The calibrator is a separate device from the scanner.	Need to find another means of reporting the calibration history, outside of the images.	DICOM
75	JDP	M	892	4.2	There is currently no DICOM attribute in the PET IOD for recording glucose level.	Glucose level is currently included in the proposed Radiopharmaceutical Administration Radiation Dose Report (Supplement159).	DICOM
76	JDP	H	892	4.2	Discussion of Administered Radionuclide. Do not require the modality to accept the radionuclide from DICOM Modality Worklist. There are several reasons. First, there is no standard way for the Worklist Server to receive radionuclide information from the real source. Second, this information is secondary to the procedure codes and can be deduced from that. Third, this is not current common practice.	Future implementations should accept this information from the Dose Report.	DICOM

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					Lastly, the upcoming Radiopharmaceutical Administration Radiation Dose Report (Supplement 159 to the DICOM Standard) will provide a means for the dose creating and/or administration system to supply this information along with other dose information to the scanner.		
77	JDP	L	892	4.2	Administered Radiotracer. The name of DICOM tag (0054,0300) is Radionuclide Code Sequence, not Radiotracer Code Sequence.		DICOM
78	JDP	M	892	4.2	Administered Radiotracer radioactivity: The residual activity is not currently part of the PET IOD. The NM IOD includes the residual activity but not the date/time of the measurement. The activity that is recorded in PET DICOM images is already supposed to account for any residual. Why is this detail useful?	The requirement for direct transfer of activity information to the scanner would be addressed by the Radiopharmaceutical Administration Radiation Dose Report (DICOM Supplement 159).	DICOM
79	JDP	H	892	4.2	Decay Correction Methodology: Series Time (0008,0031) is not the same as acquisition time. There is a specific set of attributes for recording the acquisition time; Acquisition Date (0008,0022) and Acquisition Time (0008,0032), which are part of the existing PET IOD. Series Time is not intended for capturing an acquisition time and you should not force scanners to use it that way. The DICOM Standard is clear that for PET (see PS3.3, section C.8.9.1.1.2), "The Series Date (0008,0021) and Series Time (0008,0031) are not tied to any real-world event (e.g. acquisition start, radiopharmaceutical administration) and their real-world meaning are implementation dependent." Further, since the PET IOD already includes acquisition start time, the radiopharmaceutical start time, and the activity at the time of administration, there is no need to use Series Time for any calculations.	Revise the requirement so that decay correction is required to be done such that decay correction is done to a single reference time (this is already required by the DICOM standard), which can be acquisition time. This will be consistent with the requirement that Decay Correction (0054,1102) is "START". There should be no mention of Series Time here.	DICOM
80	JDP	M	892	4.2	Scanning Workflow: What is the purpose of the future requirement for	Suggest dropping these future requirements.	

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					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.		
81	JDP	H	892	4.2	PET Radiation Dose: This requirement would require that a scanner generate the Radiopharmaceutical Administration Radiation Dose Report. This is not correct. Supplement 159 (the definition of the Radiopharmaceutical Administration Radiation Dose Report) states that the scanner is a consumer of this report, not a generator of the report.	Revise this and related requirements such that the dose administration or calibration systems create the dose report, and that the scanner consumes this report to obtain information needed for the PET images.	
82	JDP	M	892	4.2	Scanning Direction: There is no place to record the scanning direction in the current DICOM PET IOD. This would require a change to the DICOM Standard.		DICOM
83	JDP	M	892	4.2	Documentation of Exam Specification: Why the requirement to record number of bed 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.	Drop the requirement for recording number of bed positions in DICOM images.	DICOM / group
84	JDP	M	892	4.2	Bed Position Temporal Differences: DICOM already supports recording this information (i.e. image durations) as part of each image. So there is no Standard change required. However, there is no concept of bed positions in DICOM.	Remove the reference to bed positions. The requirement could be, "Shall be able to provide and document non uniform scan times for different images dependent upon areas of clinical concern."	DICOM – p.42 "Bed Position Temporal Differences" row
85	JDP	H	914	4.4	As mentioned above, this is a misuse of Series Time, and is not necessary. There is no DICOM	Delete lines 914 through 917 (including the table).	DICOM – p 44 "Reference time

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					requirement that Series Time occur before acquisition time. In fact, since each reconstruction creates a new Series, it is likely that a Series Time would fall after the acquisition times. Series Time is not needed for decay correction.		for decay correction"
86	JDP	M	946	4.5	DICOM currently records software versions, and hardware model names (but not version numbers). Scanners may not use hardware versions.	Clarify requirements such that appropriate system identification is captured, but realize that it may not be done as a hardware version number.	DICOM
87	LS	M		General	A case report form/worksheet with elements for each issue detailed would be essential.		the group is addressing this in two ways 1) through develop a common data format for a site to document the PET covariates (with ideal situation where this is an electronic data capture from DICOM tags) and 2) consideration of a 'checklist' which would 'map' the 'actual level of performance' for each subject for each of the normative text 'rows'.
	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…"	
	JJS	H		3.1.3.1.2	Nowhere in this section (or document, near as I can tell) do we require the user to administer the quantity of FDG defined by the protocol	In Table?: "The technologist shall…inject the quantity of FDG as prescribed in the protocol, within the range defined in the protocol"	
	JJS	M		3.3.2&3.3.3	3.3.2 Table has data archive entry. 3.3.3 has data archive entry. These are not the same, but shouldn't they be in same table?	Move table entry from 3.3.2 to 3.3.3	

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!