Commenter	Section	Line #	Priority	Issue	Proposal	Committee Discussion	Resolution (w Rationale if rejected)	Status	
IMPORTANT: Use ***File->Make a copy...*** to copy this template into a new file for your comments and edit the name (upper left) to rename it.							1	TBD	To be decided
See http://qibawiki.rsna.org/index.php/Public_Comment_Process for more guidance on the comment resolution process							8	OK	No action requested
							0	Discuss	Need to decide resolution
							1	TODO	Resolution decided
							26	Done	Profile update completed
		Use PDF lines, they're stable		Describe your issue. Don't write a book, but do include enough to indicate what you see as a problem.	Suggest new wording or describe a way to address the issue. The committee may simply accept your suggested text. Even if they don't, it gives a good sense of what you're looking for. Leaving this blank means you can't imagine how to resolve the issue	<Cmte Notes as needed.> <Optionally, use the Owner column to divide up the work and assign rows to a committee member who will lead discussion and resolution>	Describe how the comment was/will be resolved. May be simply accepted & changed as proposed, may be accepted & resolved differently, or may be rejected with a rationale for why.	TBD	
Patrick Bolan	2	165-215	M-H	The repeatability claims do not specify the size of lesion or ROI. In general smaller ROIs will have larger wCVs. The literature cited to support the claims used specific lesion sizes.	Add to the applicability criteria (lines 189-195) a size range for each of the three target tissues, taken from the literature cited for each.	Provide min/max or range of lesion size from cited literature, or provide CoV across different ranges of lesion size Address in discussion section, size of ROI/VOI should be as large as possible. Otherwise, use DRO to generate estimate In Discussion, make point to report this type of information in future test-retest papers. Leave as is, literature does not always support a size range for lesions. Discussion suggestion is a good one, we should include a mention of that for future papers.	Added text lines 216-218 regarding need for ROI size and shape specification.	Done	
Geoffrey D. Clarke	2-clincal context	205	H	SNR has no units	remove the units s/mm2 in line #205	accept proposed resolution	removed units	Done	
Geoffrey D. Clarke	2-clincal context	130, 219	M	Subsection labeling confusing	Label subsection Clinical Context 2.1 and Clinical Interpretation 2.2 (lines #130 and #219)	check other profiles and template. If as proposed, change, otherwise leave as-is.	Created subsection 2.1. Labeled Claims as subsection 2.2, and clinical interpretation as subsection 2.3	Done	
Geoffrey D. Clarke	3.11	452	L	improve clarity	A range of specific values for "Low SNR" in the paragraph starting at line #452 may be helpful	Value cannot be easily specified based on literature; Appendix has values derived from DRO, line 1106: "To satisfy site qualification requirements (3.2.2) and avoid introduction of bias due to low SNR conditions, 1106 an MRI system should have SNR > 50+-5 for the b=0 image in an ROI of 1 cm diameter (80-100 pixels)."	Added "(<5)" to reflect what's in the DRO section, as well as a generally good SNR for b=0.	Done	
Geoffrey D. Clarke	3.11	452	M	improve clarity	Specific instructions on method for SNR measurements may be helpful, i.e. reference to Appendix E	Accept proposed resolution (App. E contains reference to NEMA methods)	Made in-line reference to Appendix E.2, and added reference to appropriate NEMA guidance	Done	
Geoffrey D. Clarke	3.11.1	497-498	M	improve clarity	In Figure 2, values for SNR for (a) and (b) would be instructive AND/OR reporting the average ADC in a common ROI	Values not readily assessible from images. Images obtained with parallel imaging, which yields non-uniform noise in background. "Low SNR" descriptor is this sense is qualitative (begs question of needing a different descriptor for quantitative vs visually-assessed qualitative "low SNR").	None taken. Future revisions of the profile may consider incorporating similar images for which SNR is available via methods described in Appendix E.2	Done	
Geoffrey D. Clarke	3.11.1	504	M	improve clarity	In Figure 3, values for SNR AND/OR average ADC in common ROI would be instructive	See Reply for 5; ADC not needed.	None taken, same future consideration as comment 5	Done	
Geoffrey D. Clarke	3.11.1	504	H	Arrows missing	In Figure 3, add the colored arrows referenced in the figure description	Add arrows per proposed solution	Arrows added.	Done	
Geoffrey D. Clarke	3.11.1	507	L	improve clarity	In Figure 4, use colored arrows	Adopt proposal.	yellow arrows.	Done	
Geoffrey D. Clarke	3.11.1	522	L	improve clarity	In Figure 6, use colored arrows	Adopt proposal.	yellow arrows	Done	
Geoffrey D. Clarke	3.11.1	531, 541	L	improve clarity	In Figures 8 & 9, use colored arrows	Adopt proposal.	yellow arrows	Done	
Nandita deSouza	All		M	Is it valid to include b=0 as the low value? There is too much variability around this	b=25-50 as the low b value	Clarify in discussion, potentially address with T/I/A parameter values non-zero b also likely requires more averaging due to diffusion gradient directionality Some scanners don't produce a true zero b-value	Added text to 3.6.1.	Done	
Dena Flamini	3.6.2.1	371-Table	L	This is just one example of Tables throughout the body of the document. I feel that that the tables break the flow of thought. Listing all tables only in the Appendix also makes editing/updating quite simple.	Remove all parameter tables from the body of the document and only provide reference to them. Full tables should only be located in the appendix.	Good point. Could potentially keep full tables in Checklists/Appendices, shrink tables in main body of text. Also potentially addressable with more explicit instructions to visit the checklists prior to reading the full document. This is a question for Process that may be addressed in future Profile templates.	None presently. Issue has been brought up with the Process Committee, and may be revisited in the future.	OK	
Jim Gimpel	Appendix A	1007	L	Error in line numbering: goes from 1007 to 894		Address line numbering error in Word.	addressed line-numbering by forcing continuous numbering at two-column acknowledgements section in Appendix A, then suppressing numbering for the second column.	Done	
Jim Gimpel	Appendix D	964	L	Aquisition Matrix for Achieva / 5.1.7 reads 128 x 126	Should this instead read 128 x 128?	Not a typo! Might indicate that matrix size ± 2 or 3 is acceptable	dagger footnote for matrix size in first spec table	Done	
Jim Gimpel	3.8.1	400	M	When using terms like "antispasmodic agent", it may be helpful to parenthetically cite examples of familiar labels.	"antispasmodic agents (e.g. glucagon, hyoscine, etc.)"	Approach is to keep general as possible with regards to non-DWI-specific material More of a technical guideline than best practice guidelines.	no changes made	Done	
Jim Gimpel	Appendix B	907, 909b	L	Font colors inconsistent		Fix font colors	fixed	Done	
Jim Gimpel	3.2.2	319	M	While preservation of parameters such as b-value and diffusion direction is required and consultation of the vendors' DICOM conformance statements is wisely advised throughout, it's worth further emphasizing the need to ensure that any tags (often private tags) that contain this information are not de-identified by PACS solutions prior to image submission.	Over-anonymization is a very common occurrence in the multicenter setting, particularly with sites imposing risk-averse anonymization policies prior to image submission. Suggest language to further emphasize that de-identification (specifically) does not remove necessary tags.	If private tags are used related to DWI, they should not be scrubbed. Add language to explicitly point this out as an advisement. Some private tags are identified on a vendor basis elesewhere in the Profile (cite specific location, likely Appendix D).	created new requirement	Done	

Commenter	Section	Line #	Priority	Issue	Proposal	Committee Discussion	Resolution (w Rationale if rejected)	Status
Jim Gimpel	3.5	334-341	H	Periodic QA section reads a little vague and the profile is noticeably silent on recommendations regarding the frequency of Periodic QA. While this may be understandable given that the tolerance for variance may depend on DWI's role in a given study endpoint, citations outlining the risks associated with lapses in periodic QA could be beneficial (particularly to industry) and may indeed be expected of this profile.	At a minimum, perhaps the panel should acknowledge that there exists a lack of sufficient data to define such a schedule.	Can be study-specific, should be performed after hw/sw upgrade (already in profile)	added additional text to 3.5.1	Done
Jim Gimpel	3	243-249	L	Paragraphs 3 and 4 are redundant		Keep 4th paragraph; delete 3rd.	deleted 3rd paragraph	Done
Jim Gimpel	3.13.2	641	M	ROI geometry – presumably for linear reproducibility between timepoints; but I'm not clear on the preferences between these methods and how they get one closer to reproducibility - why is the ideal method better than target and target better than acceptable?; In all cases, will there not be inherent variance in patient positioning and landmarking between studies?	Perhaps the ideal method could actually go so far as to incorporate image registration/fusion of timepoints when place ROIs.	This specification is about preserving ROI placement for retrospective analysis. Screenshot is informative, but does not contain easily accessible ROI geometries; binary masks are better, but DICOM segment objects are best.	no changes made	Done
Jim Gimpel	3.12.1	563, 578	M	There is a 'should' vs. 'shall' conflict on retention of directional DWI imaging between these two lines		line 563 shall be changed to "shall"	changed to "shall"	Done
Jim Gimpel	3.12.1	578	M	We have experience push-back on site archival of additional series such as these due to concerns over storage requirements (whether real or perceived).	Can the profile expand on the value of retaining directional DWI to more soundly justify this requirement? (for example, might this be used to tease out motion or eddys that are unique to one or more direction?)	line 564 should expand upon value of this information. Proposed rationales are good; might additionally consider assessment of gradient non-linearity along a given direction (for known ADC, i.e., in a phantom).	removed this requirement from the specification table and checklists	Done
Jim Gimpel	Appendix F	1155	M	Checklists: Does the document explain the purpose of Appendix F: Checklists? Is this a tool for study sponsor use in assessing site capability and is there thought given on a scoring strategy (especially since "will not do" and "not feasible" are options) or is that beyond the scope of the profile?	Elaborate on purpose of or use case for checklists	Good comment. Profile is written in accordance with a standard template. The issue of checklists and text to direct readers to them quickly shall be brought up in the Process Committee.	"will not do" and "not feasible" are important options for vetting of the Profile to achieve technical confirmation. No changes have been made, but the purpose of the checklists and their position and referencing within the Profile have been brought up for further review to the Process Committee.	OK
Dan Krainak	2	162	L	breast not included	include "breast" for consistency with the rest of the document.	Include breast in clinical context for consistency.	included breast	Done
Dan Krainak	3.6	362-364, 371-388	L	Are k-space undersampling techniques (such as compressed sensing) permissible within the profile?	Include in lines 363-364 if k-space undersampling acquisitions are outside the scope of the profile. Alternatively, update the profile to acknowledge inclusion.	No test-retest studies using undersampled techniques, make mention in lines 363-364 of this status.	added mention of k-space undersampling. Will add references accordingly	TODO
Dan Krainak	Overall	non-specific	M	Very informative document		Thank you!	no changes made	OK
Dan Krainak	Overall	non-specific	M	Question unclear - is this about assessing the sites about to achieve the claim in people? Or more about patient positioning, conforming to acquiring and analyzing data in the same way across time.	If this is about assessing repeatability of the measurement within individuals across time, is there a mechanism to consistently select a non-diseased ROI expected to be physiologically consistent across time such that an independent assessment of ADC in this region (not the tumor which might change) across multiple sessions could be assessed to determine if the values were maintained within the claim. I'm sure you'll have many other ideas; just a thought.	All reproducibility claims derive from patient data presented in peer-reviewed literature. Comparison to non-pathologic regions is very close to discrimination, which is a topic beyond the scope of this profile effort.	no changes made	OK
Dan Krainak	Individual Comment	non-specific	H	Disclaimer: Note these are my personal feedback, not FDA comments.		Understood, and thank you!	no changes made	OK
Eric E. Sigmund	3.6.2.4	386	M	Lipid suppression is only listed as required, with no recommendation or priority on fat saturation methods	Ideal/target: combined spectral and relaxation-based fat suppression (e.g. SPAIR); Acceptable:Relaxation-based (STIR) or spectral-based (Fat-sat) alone if SPAIR not available	Accept recommendation. Provide additional discussion on why prior to table.	rewrote requirement for lipid suppression based on proposal	Done
Eric E. Sigmund	3.6.2.4	386	M	Phase encode orientations A-P and L-R ranked equally acceptable; A-P phase encoding preserves anatomic symmetry for axial breast fields of view	Ideal/target : A-P phase encode; Acceptable: L-R phase encode	Accept recommendation. If possible, provide justification in discussion.	generated additional paragraph is 3.6.1 referring to this issue.	Done
Ona Wu	Overall			Increase the qualifications descriptions for actors		We feel that the qualifications are outside the scope of the document		OK
Ona Wu	Overall			perhaps clarify common actors so that a "specific actor" holds responsibility		We feel that the qualifications are outside the scope of the document		OK
Canon Medical Systems	Appendix D		H	No Canon Medical Systems phantom protocol	Include Canon Medical Systems phantom protocol	Include protocol	Included protocol	Done
Mark Rosen	3.6, 3.11		L	it looks like the low SNR in Fig 3C is due to high liver iron. I did not see mention of iron as a QC issue in validity of liver ADC evaluation. Arguably this affects the liver and not a liver lesion. Perhaps a topic for future revisions?		Will not address in present version of the profile, but something to consider in the future		OK