QIBA Profile:
<Title of the Profile> (<Acronym>)

Stage: A. Initial Draft

Comment [OK1]: GUIDANCE:
Later will change to:
B. Version for Public Comment when approved for Public Comment
C. Public Comment Resolution Draft while comments are resolved
D. Publicly Reviewed Version when approved for re-publication
E. Technically Confirmed Profile when approved by cmte
F. Clinically Confirmed Profile when approved by cmte

Notation in this Template		
Template Element	**Appears as**	**Instructions**
Boilerplate text	Plain black text	Don't change. Should appear in all profiles.
Example text	Plain grey text	Provides an example of content and wording appropriate to that location. Rewrite it to your needs and change the text color back to Automatic (which will make it black).
Placeholder	<text in angle brackets>	Replace text and <> with your text. Use Find/Replace for ones that appear frequently.
Guidance	Comment with "GUIDANCE" at the top.	Delete it when you've followed it and don't need it anymore.

Comment [OK2]: GUIDANCE:
Guidance looks like this.
p.s. you can delete this whole notation table when you don't need it anymore.

Table of Contents

Comment [OK3]: GUIDANCE:
Please do not change the Level 1 headings or numbering.
Also, do not make gratuitous changes to fonts, sizes, formatting, numbering etc.

"Safe Pasting" (i.e. always paste Text Only) will avoid cluttering the document with random paragraph styles and anomalous formatting.

Line Numbers are very helpful during group reviews ("There's a word missing in line 169.") but you can turn them off (under Page Layout) if you find them distracting.

Change Log:

Comment [OK4]: GUIDANCE:
The Change Log section is typically removed when the Profile is Technically Confirmed, at which point changes are managed with the Change Proposal process.

This table is a best-effort of the authors to summarize significant changes to the Profile.

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Date	Sections Affected	Summary of Change
2015.10.10	All	Major cleanup based on comments resolved in the Process Cmte. Also had to remove a few hundred extraneous paragraph styles.
2015.10.21	All	Approved by Process Cmte
2015.11.04	2 (Claims) 3 (Requirements)	Incorporating the more refined form of the claim language and referenced a separate claim template. Added Voxel Noise requirement to show example of the linkage between the requirement and the assessment procedure.

Open Issues:

The following issues are provided here to capture associated discussion, to focus the attention of reviewers on topics needing feedback, and to track them so they are ultimately resolved. In particular, comments on these issues are highly encouraged during the Public Comment stage.

Q. A.
Q. A.

Comment [OK5]: GUIDANCE:
The Open Issues and Closed Issues sections are typically removed when the Profile is Technically Confirmed. If a Biomarker Committee finds these sections obstructive or unnecessary, they may be moved to the bottom of the document or omitted completely.

Comment [OK6]: GUIDANCE:
Capture issues that are unresolved or obstructing progress. The idea is to allow forward progress even though some issues may still be under consideration.
After the Q. State the issue as a concise question
After the A. State a tentative answer or leave it blank.
Put additional discussion and details in separate paragraphs as needed.
Add a new table row for each issue.

Closed Issues:

The following issues have been considered closed by the biomarker committee. They are provided here to forestall discussion of issues that have already been raised and resolved, and to provide a record of the rationale behind the resolution.

Q. Is this template open to further revisions? A. Yes. This is an iterative process by nature. Submit issues and new suggestions/ideas to the QIBA Process Cmte.
Q. A.

Comment [OK7]: GUIDANCE:
Copy-Paste issued down here when they are closed.
Try for a concise answer beside the A, e.g. Yes.
Put necessary rationale or details below.

1. Executive Summary

The goal of a QIBA Profile is to help achieve a useful level of performance for a given biomarker.

The **Claim** (Section 2) describes the biomarker performance.
The **Activities** (Section 3) contribute to generating the biomarker. Requirements are placed on the **Actors** that participate in those activities as necessary to achieve the Claim.
Assessment Procedures (Section 4) for evaluating specific requirements are defined as needed.

This QIBA Profile (<Title of the Profile>) addresses tumor volume change which is often used as a biomarker of disease progression or response to treatment. It places requirements on Acquisition Devices, Technologists, Radiologists, Reconstruction Software and Image Analysis Tools involved in Subject Handling, Image Data Acquisition, Image Data Reconstruction, Image QA and Image Analysis.

Comment [OK8]: GUIDANCE:
Name the biomarker and state its primary application

The requirements are focused on achieving sufficient accuracy and avoiding unnecessary variability of the tumor volume measurements.

The clinical performance target is to achieve a 95% confidence interval for the tumor volume change with precision of-25% to +30%.

This document is intended to help clinicians basing decisions on this biomarker, imaging staff generating this biomarker, vendor staff developing related products, purchasers of such products and investigators designing trials with imaging endpoints.

Note that this document only states requirements to achieve the claim, not “requirements on standard of care.” Conformance to this Profile is secondary to properly caring for the patient.

QIBA Profiles addressing other imaging biomarkers using CT, MRI, PET and Ultrasound can be found at qibawiki.rsna.org.

2. Clinical Context and Claims

Clinical Context

Quantifying the volumes of tumors and measuring tumor longitudinal changes within subjects; i.e. evaluating growth or regression with image processing of CT scans acquired at different time points.

Conformance to this Profile by all relevant staff and equipment supports the following claim(s):

Claim 1: A measured increase in mass volume of 30% or more indicates that a true increase has occurred with 95% confidence.

Claim 2: For a measured change in mass volume of *X*, a 95% confidence interval for the true change is [*X*-25%, *X*+30%].

This claim holds when:

- **the tumor is measurable at both timepoints (i.e., tumor margins are sufficiently conspicuous and geometrically simple enough to be recognized on all images in both scans; the tumor is unattached to other structures of equal density)**
- **the tumor longest in-plane diameter is between 10 mm (volume 0.5 cm^3) and 100 mm (volume 524 cm^3) at both timepoints**

Claim 3: For a measured volume of *X*, a 95% confidence interval for the true volume is *X* ± 15%.

Discussion

These claims are based on estimates of the within-nodule coefficient of variation (wCV) for nodules in this size range. In the claim statement the CI is expressed as Y ± 1.96 × Y × wCV. The claim assumes that the wCV is constant for nodules in the specified size range and that there is negligible bias in the measurements (i.e. bias < 5%). For estimating the critical % change, the % Repeatability Coefficient (%RC) is used: 2.77 × wCV × 100.

The -25% and +30% boundaries can be thought of as “error bars” or “noise” around the measurement of volume change. If you measure change within this range, you cannot be certain that there has really been a change. However, if a tumor changes size beyond these limits, you can be 95% confident there has been a true change in the size of the tumor, and the perceived change is not just measurement variability. Note that this does not address the biological significance of the change, just the likelihood that the measured change is real.

Clinical interpretation with respect to the magnitude of true change:
The magnitude of the true change is defined by the measured change and the error bars (+-83%). If you measure the volume to be 200mm^3 at baseline and 380mm^3 at follow-up, then the measured change is a 90% increase in volume (i.e., 100x(380-200)/200). The 95% confidence interval for the true change is a 7% to 173% increase in volume. The asymmetric range in Claim 1 (-25% to +30%) is due to the way change is conventionally expressed (as a percentage of the first measurement rather than, say, a

Comment [OK9]: GUIDANCE:
Describe one or more clinical practice utilities or clinical trial endpoints this Profile could serve. E.g.
- Determining eligibility of subjects in a clinical trial.
- Triaging eligible subjects into cohorts based on stage or severity of disease.
- Assessing response to treatment.
- Establishing the presence of progression of disease.
- Monitoring for adverse events.
- Establishing a database for the development, optimization, and validation of imaging biomarkers.

Comment [OK10]: GUIDANCE:
State the claim(s).
Claim formulation is a lot more nuanced that it may seem.

Refer to the QIBA Claim Template for important additional guidance on how to formulate your claims and the text that will go here in the Claim lines, the "claim holds" lines and the associated Discussion below.

Comment [OK11]: GUIDANCE:
This is an example of a pair of "longitudinal claims", e.g. where the biomarker is a difference between two measurements taken at different time points.

Comment [OK12]: GUIDANCE:
Clinically relevant limitations on the claim may be stated here. Do not re-iterate profile requirements here. That is already covered by the sentence preceding Claim 1.

Comment [OK13]: GUIDANCE:
This is an example of a "cross-sectional claim", e.g. one where the biomarker is a measurement taken at a single time point.

Comment [OK14]: GUIDANCE:
If useful, this section allows further explanation to clinicians how the claim should be interpreted/applied in clinical practice.

Comment [OK15]: GUIDANCE:
This example sentence is only relevant to longitudinal claims.

Comment [OK16]: GUIDANCE:
It is likely useful to explain to a clinician what a reasonable clinical interpretation of the biomarker measurement would be, given the performance claim.

percentage of the smaller measurement) and how measurements are performed.

Clinical interpretation with respect to progression or response:

TBA

The lower bound on the tumor longest in-plane diameter is set to limit the variability introduced when approaching the resolution of the dataset, e.g. partial volume. The upper bound is set to limit the variability introduced by more complex tumor morphology and organ involvement, and also to keep performance assessment procedures manageable.

While Claim 1 has been informed by an extensive review of the literature and expert consensus that has not yet been fully substantiated by studies that strictly conform to the specifications given here. The expectation is that during field test, data on the actual field performance will be collected and any appropriate changes made to the claim or the details of the Profile. At that point, this caveat may be removed or re-stated.

Comment [OK17]: GUIDANCE:
If you need a Claim Disclaimer, feel free to use/modify this text.

The performance values in Claim 1 reflect the likely impact of variations permitted by this Profile. The Profile permits different compliant actors (acquisition device, radiologist, image analysis tool, etc.) at the two timepoints (i.e. it is not required that the same scanner or image analysis tool be used for both exams of a patient). If one or more of the actors are the same, the implementation is still compliant with this Profile and it is expected that the measurement performance will be improved. To give a sense of the possible improvement, the following table presents expected precision for alternate scenarios, however except for the leftmost, these precision values are **not** Claims of this Profile.

Comment [OK18]: GUIDANCE:
Profile users can expect to achieve at least the performance in the claim for any set of actors that meet the profile requirements.
If the actors manage to exceed the profile requirements, users may achieve performance better than the claim.

The CT Cmte found the following text and table a useful way to provide informative material about such performance scenarios.

Table 1: Expected Precision for Alternate Scenarios (Informative)

Different Acquisition Device				Same Acquisition Device			
Different Radiologist		Same Radiologist		Different Radiologist		Same Radiologist	
Different Analysis Tool	Same Analysis Tool	Different Analysis Tool	Same Analysis Tool	Different Analysis Tool	Same Analysis Tool	Different Analysis Tool	Same Analysis Tool
47%	46%	33%	32%	38%	36%	13%	11%

Notes:
1. Precision is expressed here as the total deviation index.
2. A measured change in tumor volume that exceeds the relevant precision value in the table indicates 95% confidence in the presence of a true change.
3. A 95% confidence interval for the magnitude of the true change is given by: ± the relevant precision value.

3. Profile Activities

The Profile is documented in terms of "Actors" performing "Activities". Equipment, software, staff or sites may claim conformance to this Profile as one or more of the "Actors" in the following table.

Conformant Actors shall support the listed Activities by conforming to all requirements in the referenced Section.

Table 1: Actors and Required Activities

Actor	Activity	Section
Acquisition Device	Pre-delivery	3.1.
	Subject Handling	3.5.
	Image Data Acquisition	3.6.
Technologist	Subject Handling	3.5.
	Image Data Acquisition	3.6.
	Image Data Reconstruction	3.7.
Radiologist	Subject Handling	3.5.
	Image QA	3.8.
	Image Analysis	3.10.
Reconstruction Software	Image Data Reconstruction	3.7.
Image Analysis Tool	Image Analysis	3.10.

Comment [OK19]: GUIDANCE:
Modify the actor and activity names and change the text to black.

Comment [OK20]: GUIDANCE:
Inside each Activity section is a subsection for Specification which contains the requirements table. If it is necessary to explain the rationale or meaning of any of the parameters or requirements, that goes in the subsection for Discussion.

This keeps the requirements concise and allows implementers to jump straight to the meat, but still allows for relevant background. Keep the discussion brief though.

To help readers, at the beginning of a discussion paragraph (if possible as the first words) name the associated parameter and bold it, and sequence the discussion paragraphs in the same order as the specification table.

The requirements in this Profile do not codify a Standard of Care; they only provide guidance intended to achieve the stated Claim. Failing to conform to a "shall" in this Profile is a protocol deviation. Although deviations invalidate the Profile Claim, such deviations may be reasonable and unavoidable and the radiologist or supervising physician is expected to do so when required by the best interest of the patient or research subject. How study sponsors and others decide to handle deviations for their own purposes is entirely up to them.

The sequencing of the Activities specified in this Profile are shown in Figure 1:

<activity sequence diagram>

Figure 1: <Title of the Profile> - Activity Sequence

Comment [OK21]: GUIDANCE:
Consider providing a diagram showing the how the activities are sequenced to produce the biomarker.

3.1. Pre-delivery

This activity describes calibrations, phantom imaging, performance assessments or validations prior to delivery of equipment to a site (e.g. performed at the factory) that are necessary to reliably meet the Profile Claim.

3.1.1 DISCUSSION

3.1.2 SPECIFICATION

Parameter	Actor	Requirement

3.2. Installation

This activity describes calibrations, phantom imaging, performance assessments or validations following installation of equipment at the site that are necessary to reliably meet the Profile Claim.

3.2.1 DISCUSSION

3.2.2 SPECIFICATION

Parameter	Actor	Requirement

3.3. Periodic QA

This activity describes calibrations, phantom imaging, performance assessments or validations performed periodically at the site, but not directly associated with a specific subject, that are necessary to reliably meet the Profile Claim.

3.3.1 DISCUSSION

3.3.2 SPECIFICATION

Parameter	Actor	Requirement

Comment [OK22]: GUIDANCE:
Various activity sections have been included to give a sense of where certain details might go and what the activities might be called. Over time QIBA may include more example text in each.

It is hoped this will facilitate some convergence in style, content and naming between profiles which will reduce learning curves of adopters and allow biomarker committees to ~~steal~~ benefit from each other's Profile work.

Feel free to delete sections that are not relevant for your biomarker or to populate them with null text such as "This activity is not a source of significant variance for this biomarker" or "No specific pre-delivery activities are required by this Profile".

The null text approach may be useful during early phases of Profile development because it keeps people thinking about it and you may change your mind later.

You can also merge multiple activities into a single activity if it is unreasonable that they would be performed on different equipment or by different people for a given subject.

Keeping the activities in roughly chronological order is probably easiest to understand.

Comment [OK23]: GUIDANCE:
Inside each Activity section is a subsection for Specification which contains the checklist table of requirements. If it is necessary to explain the rationale or meaning of any of the parameters or requirements or how a requirement impacts the claim, that goes in the subsection for Discussion.

This keeps the requirements concise and allows implementers to jump straight to the meat, but still allows for relevant background. Keep the discussion brief though.

To help readers, at the beginning of a discussion paragraph (if possible as the first words) name the associated parameter and bold it, and sequence the discussion paragraphs in the same order as the specification table.

Remember: Normative material ("shall") goes in the Specification. Informative material goes in the ...

Comment [OK24]: GUIDANCE:
Some assessment procedures use a database of control patient data instead of a phantom. Others might scan a "normal control" person rather than a phantom (e.g. there is no phantom for fMRI BOLD). Reconstruction or processing algorithms might be assessed with a virtual phantom to have known ground truth.

Comment [OK25]: GUIDANCE:
The actor indicates who is responsible for the specification being met. They might not actually do some of the things personally, but they are responsible for making sure that it is being done and being done correctly.
Also, sites may choose to contract certain third parties to perform the role of certain actors, or they may have in-house staff fill those roles.

Parameter	Actor	Requirement
PET Calibration Factor	Physicist	Shall assess the current PET Calibration Factor at least quarterly. See 4.3 Assessment Procedure: PET Calibration Factor. Shall record the date/time of the calibration for auditing.
	Acquisition Device	Shall be capable of performing the PET Calibration Factor assessment. Shall record the most recent PET Calibration Factor for use in subsequent activities.
Qualification	Physicist	Shall be a Qualified Medical Physicist (QMP) as defined by AAPM.
Time sync	Physicist	Shall confirm on a weekly basis that all device clocks are synchronized to within +- 1 minute.

Comment [OK25]: GUIDANCE:
The actor indicates who is responsible for the specification being met. They might not actually do some of the things personally, but they are responsible for making sure that it is being done and being done correctly.
Also, sites may choose to contract certain third parties to perform the role of certain actors, or they may have in-house staff fill those roles.

Comment [OK26]: GUIDANCE:
As with all profile requirements, add qualification requirements only if they are necessary to achieve the claim

3.4. Subject Selection

This activity describes criteria and procedures related to the selection of appropriate imaging subjects that are necessary to reliably meet the Profile Claim.

3.4.1 DISCUSSION

3.4.2 SPECIFICATION

Parameter	Actor	Requirement

3.5. Subject Handling

This activity describes details of handling imaging subjects that are necessary to reliably meet the Profile Claim.

Comment [OK27]: GUIDANCE:
This may include:
- Timing Relative To Index Intervention Activity
- Timing Relative To Confounding Activities
- Contrast Preparation And Administration
- Subject Positioning
- Instructions to Subject During Acquisition
- Timing/Triggers

Alternatively, some of these topics may be elevated to activities in their own right.

This can include relative timings between scans or details related to the interaction of contrast media or tracers from a prior scan with the following scan. On the other hand, issues related to running two sequences/series would generally be handled inside the acquisition activity rather than here.

3.4.1 DISCUSSION

3.4.2 SPECIFICATION

Parameter	Actor	Requirement

3.6. Image Data Acquisition

This activity describes details of the data acquisition process that are necessary to reliably meet the Profile Claim. It may also include calibrations, performance assessments or validations during acquisition (such as laying the subject on a calibrator or placing a pocket phantom next to the subject) that are necessary to reliably meet the Profile Claim.

3.6.1 DISCUSSION

3.6.2 SPECIFICATION

Parameter	Actor	Requirement	DICOM Tag

3.7. Image Data Reconstruction

This activity describes criteria and procedures related to producing images from the acquired data that are necessary to reliably meet the Profile Claim.

3.7.1 DISCUSSION

3.7.2 SPECIFICATION

Parameter	Actor	Requirement

3.8. Image QA

This activity describes criteria and evaluations of the images that are necessary to reliably meet the Profile Claim.

3.8.1 DISCUSSION

Tumor Size can affect the accuracy of measurements. Both theoretical considerations and the groundwork projects done by QIBA indicate that for tumors that are small, errors in measurement represent a greater percentage of the measured size. For tumors that are smaller than the limits defined in this profile, please see the profile produced by the QIBA Small Nodule group for more information on imaging recommendations and performance claims. For tumors that are extremely large, the limitations

Comment [OK28]: GUIDANCE:
Acquisition is more inherently about how the data is acquired, but try to come up with device-neutral requirements. For example, specify a required table speed rather than a model-specific table mode.

Consider variance contributed by differences in technology used, differences in model design, or differences between devices of the same model, and whether such factors and variances can be measured and compensated for.

Again, avoid specifying details not expected to affect the performance claim.

Some profiles might have more than one acquisition activities. E.g. a combined PET/CT Image Data Acquisition activity could be split into a PET Image Data Acquisition activity and a CT Image Data Acquisition activity if needed to focus on them individually and/or to allow them to be performed on a non-hybrid scanner.

Consult the Metrology group on how device variation impacts longitudinal claims vs cross-sectional claims.
Requiring that longitudinal measurements be taken on the same device can reduce such impacts, but may also drastically reduce the practical usability of the profile in clinical practice.

Comment [OK29]: GUIDANCE:
The DICOM Tag column correlates the specification with an associated DICOM Tag. The requirement here can mandate that the actor include and populate the tag to be conformant.
The Image QA Activity could include a specification to do (automated or manual) confirmation of conformance by checking these tags.

If the column is not useful, it can be removed.

Comment [OK30]: GUIDANCE:
Try to focus Reconstruction requirements on the characteristics of the data that comes out of the Reconstruction (i.e. the results) rather than on the procedure for producing those results.

Constraining the procedure can unnecessarily impede innovative methods or technologies that would meet or exceed the needed performance.

on measurement are based less on imaging physics and more on anatomy. Such tumors are likely to cross anatomical boundaries and abut structures that make consistent segmentation difficult.

Tumor Margin Conspicuity refers to the clarity with which the boundary of the tumor can be discerned from the surroundings. Conspicuity can directly impact the ability to segment the tumor to properly determine its volume. Conspicuity problems can derive from poor contrast enhancement, from the inherent texture, homogeneity or structure of the tumor, or from attachment of the tumor to other structures.

3.8.2 SPECIFICATION

Parameter	Actor	Requirement
Tumor Size	Radiologist	Shall confirm (now or during measurement) that tumor longest in-plane diameter is between 10 mm and 100 mm. (For a spherical tumor this would roughly correspond to a volume between 0.5 cm^3 and 524 cm^3.)
Tumor Margin Conspicuity	Radiologist	Shall confirm the tumor margins are sufficiently conspicuous and unattached to other structures of equal density to distinguish the volume of the tumor.

3.9. Image Distribution

This activity describes criteria and procedures related to distributing images that are necessary to reliably meet the Profile Claim.

Comment [OK31]: GUIDANCE:
In many profiles there will be no specific requirements on image distribution, or they will be folded into the Reconstruction activity since many modalities have Auto-send features.

3.9.1 DISCUSSION

3.9.2 SPECIFICATION

Parameter	Actor	Requirement

3.10. Image Analysis

This activity describes criteria and procedures related to producing measurements from the images that are necessary to reliably meet the Profile Claim.

Comment [OK32]: GUIDANCE:
Note that in principle some measurements could be qualitative rather than quantitative.

3.10.1 DISCUSSION

3.10.2 SPECIFICATION

Parameter	Actor	Requirement

3.11. Image Interpretation

This activity describes criteria and procedures related to clinically interpreting the measurements and images that are necessary to reliably meet the Profile Claim.

Comment [OK33]: GUIDANCE: Interpretation is a human activity and may involve considering/combining multiple inputs.

3.11.1 DISCUSSION

3.11.2 SPECIFICATION

Parameter	Actor	Requirement

4. Assessment Procedures

To conform to this Profile, participating staff and equipment ("Actors") shall support each activity assigned to them in Table 1.

To support an activity, the actor shall conform to the requirements (indicated by "shall language") listed in the specifications table of the activity subsection in Section 3.

Although most of the requirements described in Section 3 can be assessed for conformance by direct observation, some of the performance-oriented requirements cannot, in which case the requirement will reference an assessment procedure in a subsection here in Section 4.

Formal claims of conformance by the organization responsible for an Actor shall be in the form of a published QIBA Conformance Statement. Vendors publishing a QIBA Conformance Statement shall provide a set of "Model-specific Parameters" (as shown in Appendix D) 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.

4.1. Assessment Procedure: Voxel Noise

This procedure can be used by a vendor or an imaging site to assess the voxel noise of reconstructed images. Voxel noise is assessed in terms of the standard deviation of pixel values when imaging a material with uniform density.

The assessor shall first warm up the scanner's x-ray tube and perform calibration scans (often called air-calibration scans) according to scanner manufacturer recommendations. The assessor shall then scan a phantom of uniform density, such as the ACR CT Accreditation Program (CTAP) Phantom's module 3, which is a 20 cm diameter cylinder of water equivalent material. The phantom shall be placed at the isocenter of the scanner. The acquisition protocol and reconstruction parameters shall conform to this Profile (See Section 3.6.2 and 3.7.2). The same protocol and parameters shall be used when performing the assessments in 4.1 and 4.2.

When the scan is performed, the assessor shall select a single representative slice from the uniformity portion of the phantom. An approximately circular region of interest (ROI) of at least 400 mm^2 shall be placed near the center of the phantom.

The assessor shall record the values reported for the ROI mean and standard deviation.

The procedure described above is provided as a reference method. Sites or vendors may submit to QIBA a proposed alternative method (such as using the water phantom portion of a manufacturer's QA phantom) and evidence that the results produced by the proposed method are equivalent to this reference method. Upon review and approval by QIBA, the alternative method will also become an accepted assessment procedure in this Profile.

The test procedure described here is based on the use of conventional filtered backprojection reconstruction methods; extreme care must be taken when iterative reconstruction methods are used as their use may invalidate some of the assumptions inherent in this method.

4.2. Assessment Procedure: <Parameter Y>

Comment [OK34]: GUIDANCE:
Describe how the actor is required to go about assessing it's performance with respect to Parameter Y.

Note that the requirement in Section 3 names the metric and defines the passing score. Section 4 just defines the procedure for generating the metric value. The same assessment procedure might be used to assess the performance of the software and the operator, or they might be separate procedures.

A site might find these procedures useful to track their performance improvement, although that goes beyond the scope of the profile.

Consider consulting the work of the QIBA Metrology group (or recruit the group members themselves) when drafting these sections.

Try to keep the text strictly to the performance of the procedure. Additional informative/educational material can be put in an Appendix and referenced if necessary.

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4.3. Assessment Procedure: PET Calibration Factor

Comment [OK35]: This section is incomplete and likely littered with errors. Feel free to improve it.

This procedure can be used by a vendor, physicist or an imaging site to assess the PET Calibration Factor of an acquisition device. PET Calibration Factor is assessed in terms of compensating value that needs to be applied to get the image voxel values produced by the acquisition device to match the known activity in kBq/mL of scanned phantom. The units of the PET Calibration factor are kBq/mL divided by the arbitrary units used by the acquisition device to record image voxel values.

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The assessor shall scan a phantom of uniform …

350

References

Comment [OK36]: GUIDANCE:
Use standard manuscript format

355

Appendices

Appendix A: Acknowledgements and Attributions

Appendix B: Background Information

Appendix C: Conventions and Definitions

Appendix D: Model-specific Instructions and Parameters

Comment [OK37]: GUIDANCE:
This appendix is non-normative.
Include it in your profile if you feel it would be useful.
We're still working out how we want to use it.

For acquisition modalities, reconstruction software and software analysis tools, profile conformance requires meeting the activity specifications above in Sections 2, 3 and 4.

This Appendix provides, as an informative tool, some specific acquisition parameters, reconstruction parameters and analysis software parameters that are expected to be compatible with meeting the profile requirements. Just using these parameters without meeting the requirements specified in the profile is not sufficient to achieve conformance. Conversely, it is possible to use different compatible parameters and still achieve conformance.

Sites using models listed here are encouraged to consider using these parameters for both simplicity and consistency. Sites using models not listed here may be able to devise their own settings that result in data meeting the requirements.

IMPORTANT: The presence of a product model/version in these tables does not imply it has demonstrated conformance with the QIBA Profile. Refer to the QIBA Conformance Statement for the product.

Table D.1 Model-specific Parameters for Acquisition Devices

Acquisition Device	Settings Compatible with Conformance	
Acme Medical CT Lights V3.14	*Submitted by: Gotham University Hospital*	
	kVp	120
	Number of Data Channels (N)	64
	Width of Each Data Channel (T, in mm)	0.625
	Gantry Rotation Time in seconds	1.0
	mA	120
	Pitch	0.984
	Scan FoV	Large Body (500mm)

Table D.2 Model-specific Parameters for Reconstruction Software

Reconstruction Software	Settings Compatible with Conformance	
Acme Medical CT WS V3.14	Reconstructed Slice Width, mm	1.25
	Reconstruction Interval	1.0mm
	Display FOV, mm	350
	Recon kernel	STD