

QIBA Profile:

<Title of the Profile> (<Acronym>)

Stage: A. Initial Draft

|  |
| --- |
| **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. |

**Table of Contents**

[Change Log: 4](#_Toc488845204)

[Open Issues: 5](#_Toc488845205)

[Closed Issues: 5](#_Toc488845206)

[1. Executive Summary 6](#_Toc488845207)

[2. Clinical Context and Claims 7](#_Toc488845208)

[2.1 Clinical Interpretation 7](#_Toc488845209)

[2.2 Discussion 8](#_Toc488845210)

[3. Profile Activities 10](#_Toc488845211)

[3.0. Site Conformance 12](#_Toc488845212)

[3.0.1 Discussion 12](#_Toc488845213)

[3.0.2 Specification 12](#_Toc488845214)

[3.1. Staff Qualification 12](#_Toc488845215)

[3.1.1 Discussion 12](#_Toc488845216)

[3.1.2 Specification 13](#_Toc488845217)

[3.2. Product Validation 13](#_Toc488845218)

[3.2.1 Discussion 13](#_Toc488845219)

[3.2.2 Specification 13](#_Toc488845220)

[3.3. Pre-delivery 15](#_Toc488845221)

[3.3.1 Discussion 15](#_Toc488845222)

[3.3.2 Specification 15](#_Toc488845223)

[3.4. Installation 15](#_Toc488845224)

[3.4.1 Discussion 15](#_Toc488845225)

[3.4.2 Specification 15](#_Toc488845226)

[3.5. Periodic QA 15](#_Toc488845227)

[3.5.1 Discussion 16](#_Toc488845228)

[3.5.2 Specification 16](#_Toc488845229)

[3.6. Protocol Design 16](#_Toc488845230)

[3.6.1 Discussion 16](#_Toc488845231)

[3.6.2 Specification 16](#_Toc488845232)

[3.7. Subject Selection 17](#_Toc488845233)

[3.7.1 Discussion 17](#_Toc488845234)

[3.7.2 Specification 17](#_Toc488845235)

[3.8. Subject Handling 17](#_Toc488845236)

[3.8.1 Discussion 17](#_Toc488845237)

[3.8.2 Specification 17](#_Toc488845238)

[3.9. Image Data Acquisition 17](#_Toc488845239)

[3.9.1 Discussion 17](#_Toc488845240)

[3.9.2 Specification 18](#_Toc488845241)

[3.10. Image Data Reconstruction 18](#_Toc488845242)

[3.10.1 Discussion 18](#_Toc488845243)

[3.10.2 Specification 18](#_Toc488845244)

[3.11. Image QA 18](#_Toc488845245)

[3.11.1 Discussion 18](#_Toc488845246)

[3.11.2 Specification 19](#_Toc488845247)

[3.12. Image Distribution 19](#_Toc488845248)

[3.12.1 Discussion 19](#_Toc488845249)

[3.12.2 Specification 19](#_Toc488845250)

[3.13. Image Analysis 19](#_Toc488845251)

[3.13.1 Discussion 20](#_Toc488845252)

[3.13.2 Specification 20](#_Toc488845253)

[3.14. Image Interpretation 20](#_Toc488845254)

[3.14.1 Discussion 20](#_Toc488845255)

[3.14.2 Specification 20](#_Toc488845256)

[4. Assessment Procedures 21](#_Toc488845257)

[4.1. Assessment Procedure: Voxel Noise 21](#_Toc488845258)

[4.2. Assessment Procedure: <Parameter Y> 21](#_Toc488845259)

[4.3. Assessment Procedure: PET Calibration Factor 22](#_Toc488845260)

[5. Conformance 22](#_Toc488845261)

[References 23](#_Toc488845262)

[Appendices 24](#_Toc488845263)

[Appendix A: Acknowledgements and Attributions 24](#_Toc488845264)

[Appendix B: Background Information 24](#_Toc488845265)

[Appendix C: Conventions and Definitions 24](#_Toc488845266)

[Appendix D: Model-specific Instructions and Parameters 25](#_Toc488845267)

[Appendix E: Conformance Checklists 26](#_Toc488845268)

[**Instructions** 26](#_Toc488845269)

[**Site Checklist** 27](#_Toc488845270)

[**Acquisition Device and Reconstruction Software Checklist** 28](#_Toc488845271)

[**Image Analysis Tool Checklist** 29](#_Toc488845272)

[**Radiologist Checklist** 32](#_Toc488845273)

[**Physicist Checklist** 35](#_Toc488845274)

[**Technologist Checklist** 36](#_Toc488845275)

# Change Log:

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

|  |  |  |
| --- | --- | --- |
| **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.  |
| 2015.12.16 |  | Minor changes to remove reference to "qualitative" measurements, fix reference to guidance and clean some formatting. |
| 2016.01.06 | 1, 3.8.1 | Rewording to avoid the term "accuracy". |
| 2017.05.12 | 1, 2, 3, 5, AppE | Explain profile stages.Update Claim examples to match guidance.Add Clinical Interpretation subsection to separate that topic from general discussion of the claims.Add Discriminatory text example.Add Section 3 activity requirement subsections with examples for Site Conformance, Staff Qualification, Product Validation, Protocol Design (some of these are to disentangle activities that happen at different times, i.e. product validation, protocol design and patient image acquisition, that were previously entangled Add Conformance section 5. Add Checklist appendix with requirements regrouped by actor. |

# 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. |

# 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. |

# 1. Executive Summary

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

Profile development is an evolutionary, phased process; this Profile is in the <Consensus> stage. The performance claims represent expert consensus and will be empirically demonstrated at a subsequent stage. Users of this Profile are encouraged to refer to the following site to understand the document’s context: http://qibawiki.rsna.org/index.php/QIBA\_Profile\_Stages.

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.
**Conformance** (Section 5) regroups Section 3 requirements by Actor to conveniently check Conformance.

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.

The requirements are focused on achieving known (ideally negligible) bias 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 true increase in tumor volume has occurred with 95% confidence if the measured increase is 30% or more.

Claim 2: A 95% confidence interval for the true change in tumor volume is [*X*-25%, *X*+30%], where X is the measured change.

**This claim holds when:**

* **the tumor longest in-plane diameter is between 10 mm (volume 0.5 cm3) and 100 mm (volume 524 cm3) at both timepoints**

Claim 3: A 95% confidence interval for the true tumor volume is *X* ± 15%, where X is the measured volume.

## 2.1 Clinical Interpretation

QIBA Claims describe the technical performance of quantitative measurements. The clinical significance and interpretation of those measurements is left to the clinician. Some considerations are presented in the following text.

Clinical interpretation with respect to neurodegenerative cause of symptoms:
QIBA Profiles do not make claims of the clinical performance of a profiled measurement, such as clinically distinguishing groups of subjects (those with vs. without a particular disease, or those at different stages of disease) based on specific values (i.e., cut-points) of the measured biomarker. However, a study [reference] of profile-conformant measurements has reached the following conclusion.

When assessing patients during initial presentation of Parkinsonian symptoms, SBR measured in the posterior putamen that is either (a) 50% or less than the value in aged-matched controls, or (b) 80% or less than the value in the whole striatum, might be considered diagnostic for a neurodegenerative cause of the symptoms with a sensitivity of at least 85% and specificity of at least 80% [reference].

## 2.2 ****Discussion****

The 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 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.

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.

 **Table 1: Expected Precision for Alternate Scenarios (Informative)**

|  |  |
| --- | --- |
| DifferentAcquisition Device | SameAcquisition Device |
| DifferentRadiologist | SameRadiologist | DifferentRadiologist | SameRadiologist |
| 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 | Product Validation | 3.2. |
| Pre-delivery | 3.3. |
| Periodic QA | 3.5. |
| Technologist | Subject Handling | 3.8. |
| Image Data Acquisition | 3.9. |
| Image Data Reconstruction | 3.10. |
| Radiologist | Staff Qualification | 3.1. |
| Image QA | 3.11. |
| Physicist | Staff Qualification | 3.1. |
| Periodic QA | 3.5. |
| Reconstruction Software | Product Validation | 3.2. |
| Image Analysis Tool | Product Validation | 3.2. |
| Image Analysis | 3.10. |
| Site | Site Conformance | 3.0. |

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

## 3.0. Site Conformance

This activity involves establishing the overall conformance of an imaging site to this Profile. It includes criteria to confirm the conformance of each of the participating Actors at the site.

### 3.0.1 Discussion

A site conforms to the Profile if each relevant actor conforms to each requirement assigned in the Activities of the Profile. Activities represent steps in the chain of preparing for and generating biomarker values (e.g. product validation, system calibration, patient preparation, image acquisition, image analysis, etc.).

Since a site may assess conformance actor by actor, a checklist document is available in Appendix E which extracts, for convenient reference, all the requirements in this Profile and regroups the requirements by Actor.

Sites may be able to obtain a QIBA Conformance Statement for some actors (e.g. Acquisition Devices) attesting to their conformance to this Profile, rather than the site having to confirm conformance themselves.

### 3.0.2 Specification

| **Parameter** | **Actor** | **Specification** |
| --- | --- | --- |
| Acquisition Devices | Site | Shall confirm all participating acquisition devices conform to this Profile. |
| Reconstruction Software | Site | Shall confirm all participating reconstruction software conforms to this Profile. |
| Image Analysis Tools | Site | Shall confirm all participating image analysis tools conform to this Profile. |
| Radiologists | Site | Shall confirm all participating radiologists conform to this Profile. |
| Physicists | Site | Shall confirm all participating physicists conform to this Profile. |
| Technologists | Site | Shall confirm all participating technologists conform to this Profile. |

## 3.1. Staff Qualification

This activity involves evaluating the human Actors (Radiologist, Physicist, and Technologist) prior to their participation in the Profile. It includes training, qualification or performance assessments that are necessary to reliably meet the Profile Claim.

### 3.1.1 Discussion

These requirements, as with any QIBA Profile requirements, are focused on achieving the Profile Claim. Evaluating the medical or professional qualifications of participating actors is beyond the scope of this profile.

### 3.1.2 Specification

| **Parameter** | **Actor** | **Specification** |
| --- | --- | --- |
| Tumor VolumeChange Repeatability | Radiologist | Shall, if operator interaction is required by the Image Analysis Tool to perform measurements, be validated to achieve tumor volume change repeatability with:* an overall repeatability coefficient of less than or equal to 16%.
* a small subgroup repeatability coefficient of less than 21%
* a large subgroup repeatability coefficient of less than 21%

See section 4.4. Assessment Procedure: Tumor Volume Change Repeatability. |
| Qualification | Physicist | Shall be a Qualified Medical Physicist (QMP) as defined by AAPM. |

## 3.2. Product Validation

This activity involves evaluating the product Actors (Acquisition Device, Reconstruction Software, and Image Analysis Tool) prior to their use in the Profile (e.g. at the factory). It includes validations and performance assessments that are necessary to reliably meet the Profile Claim.

### 3.2.1 Discussion

Performance measurements of specific protocols are not addressed here. Those are included in section 3.6.2.

**Segmentation** may be performed automatically by a software algorithm, manually by a human observer, or semi-automatically by an algorithm with human guidance/intervention, for example to identify a starting seed point, stroke, or region, or to edit boundaries.

### 3.2.2 Specification

| **Parameter** | **Actor** | **Requirement** |
| --- | --- | --- |
| Acquisition Protocol | Acquisition Device | Shall be capable of storing protocols and performing scans with all the parameters set as specified in section 3.6.2 "Protocol Design Specification". |
| Acquisition Device | Shall prepare a protocol conformant with section 3.6.2 "Protocol Design Specification" and validate that protocol as described in section 3.6.2. |
| Image Header | Acquisition Device | Shall record in the DICOM image header the actual values for the tags listed in the DICOM Tag column in sections 3.6.2 "Protocol Design Specification". |
| Image Header | Acquisition Device | Shall record actual timing and triggers in the image header by including the Contrast/Bolus Agent Sequence (0018,0012). |
| Image Header | Acquisition Device | Shall support recording in the image header (Image Comments (0020,4000) or Patient Comments (0010,4000)) information entered by the Technologist about the acquisition.  |
| Reconstruction Protocol | Reconstruction Software | Shall be capable of performing reconstructions and producing images with all the parameters set as specified in section 3.6.2 "Protocol Design Specification". |
| Image Header | Reconstruction Software | Shall record in the DICOM image header the actual values for the tags listed in the DICOM Tag column in section 3.6.2 "Protocol Design Specification" as well as the model-specific Reconstruction Software parameters utilized to achieve conformance. |
| Multiple Tumors | Image Analysis Tool | Shall allow multiple tumors to be measured.Shall either correlate each measured tumor across time points or support the radiologist to unambiguously correlate them. |
| Reading Paradigm | Image Analysis Tool | Shall be able to present the reader with both timepoints side-by-side for comparison when processing the second timepoint.Shall re-process the first time point if it was processed by a different Image Analysis Tool or Radiologist. |
| Tumor Volume Computation | Image Analysis Tool | Shall be validated to compute tumor volume with accuracy within 3% of the true volume.See section 4.3 Assessment Procedure: Tumor Volume Computation. |
| Tumor VolumeChange Repeatability | Image Analysis Tool | Shall be validated to achieve tumor volume change repeatability with: * an overall repeatability coefficient of less than or equal to 16%.
* a small subgroup repeatability coefficient of less than 21%
* a large subgroup repeatability coefficient of less than 21%

See section 4.4. Assessment Procedure: Tumor Volume Change Repeatability.  |
| Confidence Interval of Result | Image Analysis Tool | Shall calculate and make available to the operator the 95% confidence interval for tumor volume change based on the equation:Where  *Y1* and *Y2* is the volume measurement at timepoint 1 and 2, *wCV1* and *wCV2* is the within-nodule coefficient of variation for *Y1*  and *Y2* as taken from the following table, *D1* and *D2* is the longest in-plane diameter of the volume at  timepoint 1 and 2:

|  |  |  |  |
| --- | --- | --- | --- |
|  ***D1*, *D2*** | **10-34mm** | **35-49mm** | **50-100mm** |
| ***wCV1*,*wCV2*** | 0.141 | 0.103 | 0.085 |

 |
| Result Recording | Image Analysis Tool | Shall record percentage volume change relative to baseline for each tumor. Shall record the confidence interval of result for each change measurement.Shall record the image analysis tool version.  |

## 3.3. 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.

### 3.3.1 Discussion

### 3.3.2 Specification

| **Parameter** | **Actor** | **Requirement** |
| --- | --- | --- |
|  | Acquisition Device |  |
|  |  |
|  |  |  |

## 3.4. 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.

### 3.4.1 Discussion

### 3.4.2 Specification

| **Parameter** | **Actor** | **Requirement** |
| --- | --- | --- |
|  |  |  |
|  |  |
|  |  |  |

## 3.5. 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.

### 3.5.1 Discussion

### 3.5.2 Specification

| **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. |
|  |  |  |
| Time sync | Physicist | Shall confirm on a weekly basis that all device clocks are synchronized to within +- 1 minute. |

## 3.6. Protocol Design

This activity involves designing acquisition and reconstruction protocols for use in the Profile. It includes constraints on protocol acquisition and reconstruction parameters that are necessary to reliably meet the Profile Claim.

### 3.6.1 Discussion

The Profile considers Protocol Design to take place at the imaging site, however, sites may choose to make use of protocols developed elsewhere.

The approach of the specifications here is to focus as much as possible on the characteristics of the resulting dataset, rather than one particular technique for achieving those characteristics. This is intended to allow as much flexibility as possible for product innovation and reasonable adjustments for patient size (such as increasing acquisition mAs and reconstruction DFOV for larger patients), while reaching the performance targets. Again, the technique parameter sets in the Conformance Statements for Acquisition Devices and Reconstruction Software may be helpful for those looking for more guidance.

The purpose of the minimum scan duration requirement is to permit acquisition of an anatomic region in a single breath-hold, thereby preventing respiratory motion artifacts or anatomic gaps between breath-holds. This requirement is applicable to scanning of the chest and upper abdomen, the regions subject to these artifacts, and is not required for imaging of the head, neck, pelvis, spine, or extremities.

Pitch is chosen so as to allow completion of the scan in a single breath hold.

### 3.6.2 Specification

| **Parameter** | **Actor** | **Requirement** | **DICOM Tag** |
| --- | --- | --- | --- |
|  |  |  |  |
|  |  |  |
|  |  |  |  |

## 3.7. 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.

### 3.7.1 Discussion

### 3.7.2 Specification

| **Parameter** | **Actor** | **Requirement** |
| --- | --- | --- |
|  |  |  |
|  |  |
|  |  |  |

## 3.8. Subject Handling

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

### 3.8.1 Discussion

### 3.8.2 Specification

| **Parameter** | **Actor** | **Requirement** |
| --- | --- | --- |
|  | Technologist |  |
|  |  |
|  |  |  |

## 3.9. 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.

### 3.9.1 Discussion

### 3.9.2 Specification

| **Parameter** | **Actor** | **Requirement** | **DICOM Tag** |
| --- | --- | --- | --- |
| Acquisition Protocol | Technologist | Shall select a protocol that has been previously prepared and validated for this purpose (See section 3.6.2 "Protocol Design Specification").Shall report if any parameters are modified beyond the specifications in section 3.6.2 "Protocol Design Specification". |  |
| Scan Plane (Image Orientation) | Technologist | Shall set Consistent with baseline. | Gantry/Detector Tilt (0018,1120) |
| Scanogram | Technologist | Shall confirm on the scanogram the absence of artifact sources that could affect the planned volume acquisitions.  |  |
|  |  |  |  |

## 3.10. 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.

### 3.10.1 Discussion

### 3.10.2 Specification

| **Parameter** | **Actor** | **Requirement** |
| --- | --- | --- |
|  |  |  |
| Reconstruction Protocol | Technologist | Shall select a protocol that has been previously prepared and validated for this purpose (See section 3.6.2 "Protocol Design Specification").Shall report if any parameters are modified beyond those specifications. |

## 3.11. Image QA

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

### 3.11.1 Discussion

**Tumor Size** can affect the bias and precision 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 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.

### 3.11.2 Specification

| **Parameter** | **Actor** | **Requirement** |
| --- | --- | --- |
| Patient Motion Artifacts | Radiologist | Shall confirm the images containing the tumor are free from artifact due to patient motion. |
| Dense Object Artifacts | Radiologist | Shall confirm the images containing the tumor are free from artifact due to dense objects, materials or anatomic positioning.  |
| 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 cm3 and 524 cm3.) |
| 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. |

## 3.12. Image Distribution

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

### 3.12.1 Discussion

### 3.12.2 Specification

| **Parameter** | **Actor** | **Requirement** |
| --- | --- | --- |
|  |  |  |
|  |  |
|  |  |  |

## 3.13. Image Analysis

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

### 3.13.1 Discussion

### 3.13.2 Specification

| **Parameter** | **Actor** | **Requirement** |
| --- | --- | --- |
| Tumor VolumeChange Repeatability | Image Analysis Tool | Shall be validated to achieve tumor volume change repeatability with: * an overall repeatability coefficient of less than or equal to 16%.
* a small subgroup repeatability coefficient of less than 21%
* a large subgroup repeatability coefficient of less than 21%

See 4.4. Assessment Procedure: Tumor Volume Change Repeatability.  |
|  |  |
|  |  |  |

## 3.14. 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.

### 3.14.1 Discussion

### 3.14.2 Specification

| **Parameter** | **Actor** | **Requirement** |
| --- | --- | --- |
|  |  |  |
|  |  |
|  |  |  |

# 4. Assessment Procedures

Most of the requirements described in Section 3 can be assessed for conformance by direct observation, however some of the performance-oriented requirements are assessed using a procedure. When a specific assessment procedure is required or to provide clarity, those procedures are defined in subsections here in Section 4 and the subsection is referenced from the corresponding requirement in Section 3.

## 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 mm2 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>

…

The assessor shall download the test files from the CT Volumetry Profile Conformance Testing section of the QIDW Data Inventory of the Quantitative Imaging Data Warehouse (QIDW http://qidw.rsna.org/) by selecting the RIDER Lung CT Data.

Note: To access the QIDW, the assessor will be required to register for a (free) user account.

## 4.3. Assessment Procedure: PET Calibration Factor

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.

The assessor shall scan a phantom of uniform …

# 5. Conformance

To conform to this Profile, participating staff and equipment (“Actors”) shall support each activity assigned to them in Table 1 in Section 3.

To support an activity, the actor shall conform to the requirements (indicated by “shall language”) listed in the Specifications table of the activity. Each activity has a dedicated subsection in Section 3. For convenience, the Specification table requirements have been duplicated and regrouped by actor in the form of a checklist in Appendix E.

Some requirements reference a specific assessment procedure in section 4 that shall be used to assess conformance to that requirement.

If a QIBA Conformance Statement is already available for an actor (e.g. your analysis software), you may choose to provide a copy of that statement rather than confirming each of the requirements in that Actors checklist yourself.

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.

# References

# Appendices

## Appendix A: Acknowledgements and Attributions

## Appendix B: Background Information

## Appendix C: Conventions and Definitions

## Appendix D: Model-specific Instructions and Parameters

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 MedicalCT LightsV3.14 | *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 MedicalCT WSV3.14 |

|  |  |
| --- | --- |
| Reconstructed Slice Width, mm | 1.25 |
| Reconstruction Interval | 1.0mm |
| Display FOV, mm | 350 |
| Recon kernel | STD |

 |

## Appendix E: Conformance Checklists



**QIBA Checklist:**

**CT Tumor Volume Change for Advanced Disease (CTV-AD)**

**Instructions**

This Checklist is organized by "Actor" for convenience. If a QIBA Conformance Statement is already available for an actor (e.g. your analysis software), you may choose to provide a copy of that statement rather than confirming each of the requirements in that Actors checklist yourself.

Within an Actor Checklist the requirements are grouped by the corresponding Activity in the QIBA Profile document. If you are unsure about the meaning or intent of a requirement, additional details may be available in the Discussion section of the corresponding Activity in the Profile.

Conforms (Y/N) indicates whether you have performed the requirement and confirmed conformance. When responding **N**, please explain why.

Site Opinion is included during the Technical Confirmation process to allow you to indicate how the requirement relates to your current, preferred practice. When responding **Not Feasible** or **Feasible, will not do** (i.e. not worth it to achieve the Profile Claim), please explain why.

Since several of the requirements mandate the use of specific assessment procedures, those are also included at the end to minimize the need of referring to the Profile document.

Feedback on all aspects of the Profile and associated processes is welcomed.

**Site checklist Page 2**

**Acquisition Device checklist Page 3**

**Image Analysis Tool checklist Page 4**

**Radiologist checklist Page 6**

**Physicist checklist Page 9**

**Technologist checklist Page 10**

**Site Checklist**

Name of Site Checked:

| **Parameter** | **Conforms (Y/N)** | **Requirement** | **Site Opinion** |
| --- | --- | --- | --- |
| **Site Conformance (section 3.0)** |
| Acquisition Devices |  | Shall confirm all participating acquisition devices conform to this Profile. | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Reconstruction Software |  | Shall confirm all participating reconstruction software conforms to this Profile. | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Image Analysis Tools |  | Shall confirm all participating image analysis tools conform to this Profile. | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Radiologists |   | Shall confirm all participating radiologists conform to this Profile. | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Physicists |  | Shall confirm all participating physicists conform to this Profile. | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Technologists |  | Shall confirm all participating technologists conform to this Profile. | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |

**Acquisition Device and Reconstruction Software Checklist**

Acquisition Device(s) Checked - Make/Model/Version:

| **Parameter** | **Conforms (Y/N)** | **Requirement** | **Site Opinion** |
| --- | --- | --- | --- |
| **Product Validation (section 3.2)** |
| Acquisition Protocol |  | Shall be capable of making validated protocols (designed and validated by the manufacturer and/or by the site) available to the technologist at scan time. | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
|  | Shall prepare a protocol conformant with section 3.4.2 "Protocol Design Specification". | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
|  | Shall validate that the protocol achieves an f50 value that is between 0.3 mm-1 and 0.75 mm-1.See section 4.1. Assessment Procedure: In-plane Spatial Resolution | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
|  | Shall validate that the protocol achieves: * a standard deviation that is < 60HU.

See 4.2. Assessment Procedure: Voxel Noise | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Image Header |  | Shall record in the DICOM image header the actual values for the tags listed in the DICOM Tag column in sections 3.4.2 "Protocol Design Specification". | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Image Header |  | Shall support recording in the image header (Image Comments (0020,4000) or Patient Comments (0010,4000)) information entered by the Technologist about the acquisition.  | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Reconstruction Protocol |  | Shall be capable of performing reconstructions and producing images with all the parameters set as specified in 3.4.2 "Protocol Design Specification". | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Image Header |  | Shall record in the DICOM image header the actual values for the tags listed in the DICOM Tag column in section 3.4.2 "Protocol Design Specification" as well as the model-specific Reconstruction Software parameters utilized to achieve compliance. | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |

**Image Analysis Tool Checklist**

Image Analysis Tool(s) Checked - Make/Model/Version:

| **Parameter** | **Conforms (Y/N)** | **Requirement** | **Site Opinion** |
| --- | --- | --- | --- |
| **Product Validation (section 3.2)** |
| Multiple Tumors |  | Shall allow multiple tumors to be measured. | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Multiple Tumors |  | Shall either correlate each measured tumor across time points or support the radiologist to unambiguously correlate them. | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Reading Paradigm |  | Shall be able to present the reader with both timepoints side-by-side for comparison when processing the second timepoint. | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Reading Paradigm |  | Shall be able to re-process the first time point (e.g. if it was processed by a different Image Analysis Tool or Radiologist). | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Tumor Volume Computation |  | Shall be validated to compute tumor volume with accuracy within 3 % of the true volume. See section 4.3 Assessment Procedure: Tumor Volume Computation. | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Tumor VolumeChange Repeatability |  | Shall be validated to achieve tumor volume change repeatability with: * an overall repeatability coefficient of less than or equal to 16%.
* a small subgroup repeatability coefficient of less than 21%
* a large subgroup repeatability coefficient of less than 21%

See section 4.4. Assessment Procedure: Tumor Volume Change Repeatability.  | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Tumor Volume Bias& Linearity |  | Shall be validated to achieve:* an overall tumor volume %bias of less than the Allowable Overall %Bias
* a tumor volume %bias for each shape subgroup (spherical, ovoid, lobulated) of less than the Allowable Shape Subgroup %Bias
* slope ( between 0.98 and 1.02

The Allowable Overall %Bias and the Allowable Shape Subgroup %Bias are taken from Table 3.1.2-2 based on the overall repeatability coefficient achieved by the Image Analysis Tool using the assessment procedure in section 4.4. See section 4.5 Assessment Procedure: Tumor Volume Bias and Linearity. | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Confidence Interval of Result |  | Shall calculate and make available to the operator the 95% confidence interval for tumor volume change based on the equation:Where  *Y1* and *Y2* is the volume measured at timepoint 1 and 2, *wCV1* and *wCV2* is the within-nodule coefficient of  variation for *Y1* and *Y2* as taken from the following table, *D1* and *D2* is the longest in-plane diameter of the volume  at timepoint 1 and 2:

|  |  |  |  |
| --- | --- | --- | --- |
|  ***D1*, *D2*** | **10-34mm** | **35-49mm** | **50-100mm** |
| ***wCV1*,*wCV2*** | 0.141 | 0.103 | 0.085 |

 | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Result Recording |  | Shall record percentage volume change relative to baseline for each tumor.  | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Result Recording |  | Shall record the confidence interval of result for each change measurement.  | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Result Recording |  | Shall record the image analysis tool version.  | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |

**Table 3.1.2-2:
Allowable Tumor Volume %Bias based on Repeatability Coefficient**

|  |  |  |
| --- | --- | --- |
| **OverallRepeatability Coefficient p** | **AllowableOverall %Bias**(RMSE Target: 7.1%)  | **AllowableShape Subgroup %Bias**(RMSE Target: 7.8%) |
| 5% | <6.7% | <7.4% |
| 6% | <6.5% | <7.3% |
| 7% | <6.3% | <7.1% |
| 8% | <6.1% | <6.8% |
| 9% | <5.8% | <6.6% |
| 10% | <5.5% | <6.3% |
| 11% | <5.1% | <5.9% |
| 12% | <4.6% | <5.6% |
| 13% | <4.1% | <5.1% |
| 14% | <3.4% | <4.6% |
| 15% | <2.6% | <4.0% |
| 16% | <1.1% | <3.2% |
| 17% | n/a (failed repeatability) | n/a (failed repeatability) |

**Radiologist Checklist**

**Note:** The Radiologist is responsible for the protocol parameters, although they may choose to use a protocol provided by the vendor of the acquisition device. The Radiologist is also responsible for ensuring that the protocol has been validated, although the Physicist actor is responsible for performing the validation. Protocol design should be done collaboratively between the physicist and the radiologist with the ultimate responsibility to the radiologist. Some parameters are system dependent and may require special attention from a physicist.

Radiologist(s) Checked:

| **Parameter** | **Conforms (Y/N)** | **Specification** | **Site Opinion** |
| --- | --- | --- | --- |
| **Staff Qualification (section 3.1)** |
| Tumor VolumeChange Repeatability |  | Shall, if operator interaction is required by the Image Analysis Tool to perform measurements, be validated to achieve tumor volume change repeatability with:* an overall repeatability coefficient of less than or equal to 16%.
* a small subgroup repeatability coefficient of less than 21%
* a large subgroup repeatability coefficient of less than 21%

See 4.4. Assessment Procedure: Tumor Volume Change Repeatability. | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| **Protocol Design (section 3.6.2)** |
| Acquisition Protocol |  | Shall prepare a protocol to meet the specifications in section 3.4-protocol design. |  | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Acquisition Protocol |  | Shall ensure technologists have been trained on the requirements of this profile. |  | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Total Collimation Width |  | Shall set to Greater than or equal to 16mm. | Total Collimation Width(0018,9307) | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| IEC Pitch |  | Shall set to Less than 1.5. | Spiral Pitch Factor(0018,9311) | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Nominal Tomographic Section Thickness (T) |  | Shall set to Less than or equal to 1.5mm. | Single Collimation Width(0018,9306) | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Scan Duration for Thorax |  | Shall achieve a table speed of at least 4cm per second, if table motion is necessary to cover the required anatomy. | Table Speed(0018,9309) | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Reconstruction Protocol |  | Shall prepare a protocol to meet the specifications in this table. |  | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Reconstruction Protocol |  | Shall ensure technologists have been trained on the requirements of this profile. |  | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Reconstructed Image Thickness |  | Shall set to between 0.5mm and 2.5mm (inclusive). | Slice Thickness (0018,0050) | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Reconstructed Image Interval |  | Shall set to less than or equal to the Reconstructed Image Thickness (i.e. no gap, may have overlap). | Spacing Between Slices (0018,0088) | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| **Subject Handling (section 3.8)** |
| Contrast Protocol |  | Shall prescribe a contrast protocol (which may be No Contrast) that achieves enhancement consistent with baseline. | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Use of intravenous contrast |  | Shall determine whether the selected contrast protocol, if any, will achieve sufficient tumor conspicuity. | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Use of oral contrast |  | Shall determine whether the selected contrast protocol, if any, will achieve sufficient tumor conspicuity. | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| **Image QA (section 3.8)** |
| Patient Motion Artifacts |  | Shall confirm the images containing the tumor are free from artifact due to patient motion. | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Dense Object Artifacts |  | Shall confirm the images containing the tumor are free from artifact due to dense objects, materials or anatomic positioning.  | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Clinical Conditions |  | Shall confirm that there are no clinical conditions affecting the measurability of the tumor.  | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Tumor Size |  | 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 cm3 and 524 cm3.) | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Tumor Margin Conspicuity |  | Shall confirm the tumor margins are sufficiently conspicuous and unattached to other structures of equal density to distinguish the volume of the tumor. | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Contrast Enhancement |  | Shall confirm that the phase of enhancement, if any, and degree of enhancement of appropriate reference structures (vascular or tissue) are consistent with baseline.  | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Tumor Measurability |  | Shall disqualify any tumor they feel might reasonably degrade the consistency and accuracy of the measurement.Conversely, if artifacts or attachments are present but the radiologist is confident and prepared to edit the contour to eliminate the impact, then the tumor need not be judged non-conformant to the Profile. | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Consistency with Baseline |  | Shall confirm that the tumor is similar in both timepoints in terms of all the above parameters. | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| **Image Analysis (section 3.9)** |
| Reading Paradigm |  | Shall re-process the first time point if it was processed by a different Image Analysis Tool or Radiologist. | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| ResultVerification |  | Shall review & approve margin contours produced by the tool. | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |

**Physicist Checklist**

**Note:** The role of the Physicist actor may be played by an in-house medical physicist, a physics consultant or other staff (such as vendor service or specialists) qualified to perform the validations described.

Physicist(s) Checked:

| **Parameter** | **Conforms (Y/N)** | **Requirement** | **Site Opinion** |
| --- | --- | --- | --- |
| **Periodic QA (section 3.5)** |
| QC |  | Shall perform relevant quality control procedures as recommended by the manufacturer.Shall record the date/time of QC procedures for auditing. | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| **Protocol Design (section 3.6.2)** |
| In-plane Spatial Resolution |  | Shall validate that the protocol achieves an f50 value that is between 0.3 mm-1 and 0.75 mm-1.See section 4.1. Assessment Procedure: In-plane Spatial Resolution | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Voxel Noise  |  | Shall validate that the protocol achieves: * a standard deviation that is < 60HU.

See section 4.2. Assessment Procedure: Voxel Noise | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |

**Technologist Checklist**

Technologist(s) Checked:

| **Parameter** | **Conforms (Y/N)** | **Specification** | **Site Opinion** |
| --- | --- | --- | --- |
| **Subject Handling (section 3.8)** |
| Use of intravenous contrast |  | Shall use the prescribed intravenous contrast parameters. | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Use of intravenous contrast |  | Shall document the total volume of contrast administered, the concentration, the injection rate, and whether a saline flush was used.  | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Use of oral contrast |  | Shall use the prescribed oral contrast parameters. | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Use of oral contrast |  | Shall document the total volume of contrast administered and the type of contrast.  | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Subject Positioning |  | Shall position the subject consistent with baseline. If baseline positioning is unknown, position the subject Supine if possible, with devices such as positioning wedges placed as described in section 3.5.1. | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Artifact Sources |  | Shall remove or position potential sources of artifacts (specifically including breast shields, metal-containing clothing, EKG leads and other metal equipment) such that they will not degrade the reconstructed CT volumes. | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Table Height & Centering |  | Shall adjust the table height for the mid-axillary plane to pass through the isocenter.  | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Table Height & Centering |  | Shall position the patient such that the “sagittal laser line” lies along the sternum (e.g. from the suprasternal notch to the xiphoid process). | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Breath hold |  | Shall instruct the subject in proper breath-hold and start image acquisition shortly after full inspiration, taking into account the lag time between full inspiration and diaphragmatic relaxation.  | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Breath hold |  | Shall ensure that for each tumor the breath hold state is consistent with baseline. | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Contrast-based Acquisition Timing |  | Shall ensure that the time-interval between the administration of intravenous contrast (or the detection of bolus arrival) and the start of the image acquisition is consistent with baseline (i.e. obtained in the same phase; arterial, venous, or delayed). | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Contrast-based Acquisition Timing |  | Shall ensure that the time-interval between the administration of oral contrast and the start of the image acquisition is consistent with baseline. (Note that the tolerances for oral timing are larger than for intravenous). | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| **Image Data Acquisition (section 3.6)** |  |
| Acquisition Protocol |  | Shall select a protocol that has been previously prepared and validated for this purpose (See section 3.4.2 "Protocol Design Specification"). |  | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Acquisition Protocol |  | Shall report if any parameters are modified beyond the specifications in section 3.4.2 "Protocol Design Specification". |  | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Scan Plane (Image Orientation) |  | Shall set Consistent with baseline. | Gantry/Detector Tilt (0018,1120) | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Tube Potential (kVp) |  | Shall set Consistent with baseline (i.e. the same kVp setting if available, otherwise as similar as possible). | KVP (0018,0060) | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Scanogram |  | Shall confirm on the scanogram the absence of artifact sources that could affect the planned volume acquisitions.  |  | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Scan Duration for Thorax |  | Shall achieve a table speed of at least 4cm per second, if table motion is necessary to cover the required anatomy. | Table Speed(0018,9309) | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Image Header |  | Shall enter on the console any factors that adversely influenced subject positioning or limited their ability to cooperate (e.g., breath hold, remaining motionless, agitation in subjects with decreased levels of consciousness, subjects with chronic pain syndromes, etc.).  | Image Comments (0020,4000) or Patient Comments (0010,4000 | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Acquisition Field of View (FOV) |  | Shall set Consistent with baseline. | Data Collection Diameter (0018,0090) | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| **Image Data Reconstruction (section 3.7)** |  |
| Reconstruction Protocol |  | Shall select a protocol that has been previously prepared and validated for this purpose (See section 3.4.2 "Protocol Design Specification").Shall report if any parameters are modified beyond those specifications. |  | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| In-plane Spatial Resolution |  | Shall either* select the same protocol as used for the baseline scan, or
* select a protocol with a recorded f50 value within 0.2 mm-1of the f50 value recorded for the baseline scan protocol.

See section 3.4.2 for further details. |  | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Voxel Noise  |  | Shall either* select the same protocol as used for the baseline scan, or
* select a protocol with a recorded standard deviation within 5HUof the standard deviation recorded for the baseline scan protocol.

 See section 3.4.2 for further details. |  | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Reconstructed Image Thickness |  | Shall set to between 0.5mm and 2.5mm (inclusive) if not set in the protocol. |  | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Reconstructed Image Interval |  | Shall set to less than or equal to the Reconstructed Image Thickness (i.e. no gap, may have overlap) and consistent with baseline. |  | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| Reconstruction Characteristics |  | Shall set the reconstruction kernel and parameters consistent with baseline (i.e. the same kernel and parameters if available, otherwise the kernel most closely matching the kernel response of the baseline).  | Convolution Kernel Group (0018,9316), Convolution Kernel (0018,1210) | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |
| ReconstructionField of View |  | Shall ensure the Field of View spans at least the full extent of the thoracic and abdominal cavity, but not substantially greater than that. | Reconstruction Field of View (0018,9317)  | □ Routinely do already□ Feasible, will do□ Feasible, will not do□ Not feasible |