Duke University

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.

Site Conformity indicates whether you have performed the requirement and confirmed conformance.

Site Opinion allows you to indicate how the requirement relates to your current, preferred practice. If a requirement is not feasible or not worth it to achieve the Profile Claim, please explain to help us understand 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

Parameter	Site Conformity	Requirement	Site Opinion
Site Conformance			
Acquisition Devices	☐ Yes ☐ No	Shall confirm all participating acquisition devices conform to this Profile.	☐ Routinely performed ☐ Feasible, will do to conform ☐ Feasible, but not going to do it ☐ Not feasible (explain why)
Reconstruction Software	☐ Yes ☐ No	Shall confirm all participating reconstruction software conforms to this Profile.	☐ Routinely performed ☐ Feasible, will do to conform ☐ Feasible, but not going to do it ☐ Not feasible (explain why)
Image Analysis Tools	☐ Yes ☐ No	Shall confirm all participating image analysis tools conform to this Profile.	☐ Routinely performed ☐ Feasible, will do to conform ☐ Feasible, but not going to do it ☐ Not feasible (explain why)
Radiologists	☐ Yes ☐ No	Shall confirm all participating radiologists conform to this Profile.	☐ Routinely performed ☐ Feasible, will do to conform ☐ Feasible, but not going to do it ☐ Not feasible (explain why)
Physicists	☐ Yes ☐ No	Shall confirm all participating physicists conform to this Profile.	☐ Routinely performed ☐ Feasible, will do to conform ☐ Feasible, but not going to do it ☐ Not feasible (explain why)
Technologists	☐ Yes ☐ No	Shall confirm all participating technologists conform to this Profile.	☐ Routinely performed ☐ Feasible, will do to conform ☐ Feasible, but not going to do it ☐ Not feasible (explain why)

ACQUISITION DEVICE AND RECONSTRUCTION SOFTWARE CHECKLIST

Parameter	Site Conformity	Requirement	Site Opinion
Product Validation (section 3.1)			
Acquisition Protocol	□ Yes □ No	Shall be capable of storing protocols and performing scans with all the parameters set as specified in section 3.4.2 "Protocol Design Specification".	□ Routinely performed □ Feasible, will do to conform □ Feasible, but not going to do it □ Not feasible (explain why)
	□ Yes □ No	Shall prepare a protocol conformant with section 3.4.2 "Protocol Design Specification" and validate that protocol as described in section 3.4.2.	□ Routinely performed □ Feasible, will do to conform □ Feasible, but not going to do it □ Not feasible (explain why)
	□ Yes □ No	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 performed □ Feasible, will do to conform □ Feasible, but not going to do it □ Not feasible (explain why)
	□ Yes □ No	Shall validate that the protocol achieves: • a standard deviation that is < 60HU. See 4.2. Assessment Procedure: Voxel Noise	□ Routinely performed □ Feasible, will do to conform □ Feasible, but not going to do it □ Not feasible (explain why)
Image Header	□ Yes □ No	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 performed □ Feasible, will do to conform □ Feasible, but not going to do it □ Not feasible (explain why) Not all reconstruction settings are saved in header
Image Header	□ Yes □ No	Shall record actual timing and triggers in the image header by including the Contrast/Bolus Agent Sequence (0018,0012).	□ Routinely performed □ Feasible, will do to conform □ Feasible, but not going to do it □ Not feasible (explain why) N/A. Do not do contrast enhance chest exams.
Image Header	□ Yes □ No	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 performed □ Feasible, will do to conform □ Feasible, but not going to do it □ Not feasible (explain why) Cannot find in header
Reconstruction Protocol	□ Yes □ No	Shall be capable of performing reconstructions and producing images with all the parameters set as specified in 3.4.2 "Protocol Design Specification".	□ Routinely performed □ Feasible, will do to conform □ Feasible, but not going to do it □ Not feasible (explain why)
Image Header	□ Yes	Shall record in the DICOM image header the actual	□ Routinely performed

Parameter	Site Conformity	Requirement	Site Opinion
	□ No 	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.	□ Feasible, will do to conform □ Feasible, but not going to do it □ Not feasible (explain why)

IMAGE ANALYSIS TOOL CHECKLIST

Parameter	Site Conformity	Requirement	Site Opinion
Product Validation (section 3.1)			
Multiple Tumors	☐ Yes ☐ No	Shall allow multiple tumors to be measured.	☐ Routinely performed ☐ Feasible, will do to conform ☐ Feasible, but not going to do it ☐ Not feasible (explain why)
Multiple Tumors	☐ Yes ☐ No	Shall either correlate each measured tumor across time points or support the radiologist to unambiguously correlate them.	☐ Routinely performed ☐ Feasible, will do to conform ☐ Feasible, but not going to do it ☐ Not feasible (explain why)
Reading Paradigm	☐ Yes ☐ No	Shall be able to present the reader with both timepoints side-by-side for comparison when processing the second timepoint.	☐ Routinely performed ☐ Feasible, will do to conform ☐ Feasible, but not going to do it ☐ Not feasible (explain why)
Reading Paradigm	☐ Yes ☐ No	Shall re-process the first time point if it was processed by a different Image Analysis Tool or Radiologist.	☐ Routinely performed ☐ Feasible, will do to conform ☐ Feasible, but not going to do it ☐ Not feasible (explain why)
Tumor Volume Computation	☐ Yes ☐ No	Shall be validated to compute tumor volume with accuracy within 3 % of the true volume.	☐ Routinely performed ☐ Feasible, will do to conform ☐ Feasible, but not going to do it ☐ Not feasible (explain why)
Tumor Volume Computation	☐ Yes ☐ No	See section 4.3 Assessment Procedure: Tumor Volume Computation.	☐ Routinely performed ☐ Feasible, will do to conform ☐ Feasible, but not going to do it ☐ Not feasible (explain why)
Tumor Volume Change Repeatability	☐ Yes ☐ No	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 performed ☐ Feasible, will do to conform ☐ Feasible, but not going to do it ☐ Not feasible (explain why)
Tumor Volume Bias & Linearity	☐ Yes ☐ No	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 ($\hat{\beta}_1$) between 0.98 and 1.02	☐ Routinely performed ☐ Feasible, will do to conform ☐ Feasible, but not going to do it ☐ Not feasible (explain why) This can be done. Please provide tools to perform calculations and

<table>
<tr><th>Parameter</th><th>Site Conformity</th><th>Requirement</th><th>Site Opinion</th></tr>
<tr><td></td><td></td><td>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.</td><td>reporting standards</td></tr>
<tr><td>Confidence Interval of Result</td><td>□ Yes
□ No</td><td>Shall calculate and make available to the operator the 95% confidence interval for tumor volume change based on the equation:
$(Y_2 - Y_1) \pm 1.96 \times \sqrt{(Y_1 \times wCV_1)^2 + (Y_2 \times wCV_2)^2}$
Where
Y_1 and Y_2 is the volume measured at timepoint 1 and 2,
wCV_1 and wCV_2 is the within-nodule coefficient of variation for Y_1 and Y_2 as taken from the following table,
D_1 and D_2 is the longest in-plane diameter of the volume at timepoint 1 and 2:
<table><tr><th>D_1, D_2</th><th>10-34mm</th><th>35-49mm</th><th>50-100mm</th></tr><tr><td>wCV_1, wCV_2</td><td>0.141</td><td>0.103</td><td>0.085</td></tr></table></td><td>It can be done. An excel spreadsheet with formula would be useful. Tools for the calculation would need to be provided along with a standard reporting system.

Tera : +0.12 and CI=[-0.41,0.65]
Philips : -0.15 and CI=[-0.77,0.47]
Syngo : +0.09 and CI=[-0.60,0.78]
All consistent with no change.</td></tr>
<tr><td>Result Recording</td><td>□ Yes
□ No</td><td>Shall record percentage volume change relative to baseline for each tumor.</td><td>□ Routinely performed
□ Feasible, will do to conform
□ Feasible, but not going to do it
□ Not feasible (explain why)</td></tr>
<tr><td>Result Recording</td><td>□ Yes
□ No</td><td>Shall record the confidence interval of result for each change measurement.</td><td>□ Routinely performed
□ Feasible, will do to conform
□ Feasible, but not going to do it
□ Not feasible (explain why)</td></tr>
<tr><td>Result Recording</td><td>□ Yes
□ No</td><td>Shall record the image analysis tool version.</td><td>□ Routinely performed
□ Feasible, will do to conform
□ Feasible, but not going to do it
□ Not feasible (explain why)</td></tr>
</table>

See Appendix A

Volume and longest in-plane diameter measures on a solitary pulmonary nodule with small mediastinal attachment. Images at both timepoints meet the QIBA profile requirements. See image attached.

Timepoint 1			Timepoint 2		
TeraRecon	**Philips**	**Syngo.vya**	**TeraRecon**	**Philips**	**Syngo.vya**
1.29 cm^3	**1.67 cm^3**	**1.73 cm^3**	**1.41 cm^3**	**1.52 cm^3**	**1.82 cm^3**
15.7 mm	**16.6 mm**	**16.6 mm**	**16.0 mm**	**16.1 mm**	**17.4 mm**

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

Overall Repeatability Coefficient $\widehat{RC}_p$	**Allowable Overall %Bias** (RMSE Target: 7.1%)	**Allowable Shape 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 ultimate responsibility to the radiologist. Some technical specifications are system dependent and may require special attention from a physicist. All protocols should be validated by the physicist.

Parameter	Site Conformity	Specification		Site Opinion
Staff Qualification (section 3.2)				
Tumor Volume Change Repeatability	□ Yes □ No	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 performed □ Feasible, will do to conform □ Feasible, but not going to do it □ Not feasible (explain why)
Protocol Design (section 3.4.2)				
Acquisition Protocol	□ Yes □ No	Shall prepare a protocol to meet the specifications in section 3.4-protocol design.		□ Routinely performed □ Feasible, will do to conform □ Feasible, but not going to do it □ Not feasible (explain why)
Acquisition Protocol	□ Yes □ No	Shall ensure technologists have been trained on the requirements of this profile.		□ Routinely performed □ Feasible, will do to conform □ Feasible, but not going to do it □ Not feasible (explain why)
Total Collimation Width	□ Yes □ No	Shall set to Greater than or equal to 16mm.	Total Collimation Width (0018,9307)	□ Routinely performed □ Feasible, will do to conform □ Feasible, but not going to do it □ Not feasible (explain why)
IEC Pitch	□ Yes □ No	Shall set to Less than 1.5.	Spiral Pitch Factor (0018,9311)	□ Routinely performed □ Feasible, will do to conform □ Feasible, but not going to do it □ Not feasible (explain why)
Nominal Tomographic Section Thickness (T)	□ Yes □ No	Shall set to Less than or equal to 1.5mm.	Single Collimation Width (0018,9306)	□ Routinely performed □ Feasible, will do to conform □ Feasible, but not going to do it □ Not feasible (explain why)

Parameter	Site Conformity	Specification		Site Opinion
Scan Duration for Thorax	□ Yes □ No	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 performed □ Feasible, will do to conform □ Feasible, but not going to do it □ Not feasible (explain why)
Reconstruction Protocol	□ Yes □ No	Shall prepare a protocol to meet the specifications in this table.		□ Routinely performed □ Feasible, will do to conform □ Feasible, but not going to do it □ Not feasible (explain why)
Reconstruction Protocol	□ Yes □ No	Shall ensure technologists have been trained on the requirements of this profile.		□ Routinely performed □ Feasible, will do to conform □ Feasible, but not going to do it □ Not feasible (explain why)
Reconstructed Image Thickness	□ Yes □ No	Shall set to between 1.0mm and 2.5mm (inclusive).	Slice Thickness (0018,0050)	□ Routinely performed □ Feasible, will do to conform □ Feasible, but not going to do it □ Not feasible (explain why) 0.625 mm ST is standard at our institution
Reconstructed Image Interval	□ Yes □ No	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 performed □ Feasible, will do to conform □ Feasible, but not going to do it □ Not feasible (explain why)
Subject Handling (section 3.5)				
Contrast Protocol	□ Yes □ No	Shall prescribe a contrast protocol that achieves enhancement consistent with baseline.		□ Routinely performed □ Feasible, will do to conform □ Feasible, but not going to do it □ Not feasible (explain why) N/A typically we do not use contrast in standard chest exams
Use of intravenous contrast	□ Yes □ No	Shall determine whether the selected contrast protocol, if any, will achieve sufficient tumor conspicuity.		□ Routinely performed □ Feasible, will do to conform □ Feasible, but not going to do it □ Not feasible (explain why) N/A typically we do not use contrast in standard chest exams
Use of oral contrast	□ Yes □ No	Shall determine whether the selected contrast protocol, if any, will achieve sufficient tumor conspicuity.		□ Routinely performed □ Feasible, will do to conform □ Feasible, but not going to do it □ Not feasible (explain why) N/A typically we do not use contrast in standard chest exams

Parameter	Site Conformity	Specification	Site Opinion
Image QA (section 3.8)			
Patient Motion Artifacts	☐ Yes ☐ No	Shall confirm the images containing the tumor are free from artifact due to patient motion.	☐ Routinely performed ☐ Feasible, will do to conform ☐ Feasible, but not going to do it ☐ Not feasible (explain why)
Dense Object Artifacts	☐ Yes ☐ No	Shall confirm the images containing the tumor are free from artifact due to dense objects, materials or anatomic positioning.	☐ Routinely performed ☐ Feasible, will do to conform ☐ Feasible, but not going to do it ☐ Not feasible (explain why)
Clinical Conditions	☐ Yes ☐ No	Shall confirm that there are no clinical conditions affecting the measurability of the tumor.	☐ Routinely performed ☐ Feasible, will do to conform ☐ Feasible, but not going to do it ☐ Not feasible (explain why)
Tumor Size	☐ Yes ☐ No	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.)	☐ Routinely performed ☐ Feasible, will do to conform ☐ Feasible, but not going to do it ☐ Not feasible (explain why) Please indicate why it is limited to this size range.
Tumor Margin Conspicuity	☐ Yes ☐ No	Shall confirm the tumor margins are sufficiently conspicuous and unattached to other structures of equal density to distinguish the volume of the tumor.	☐ Routinely performed ☐ Feasible, will do to conform ☐ Feasible, but not going to do it ☐ Not feasible (explain why)
Contrast Enhancement	☐ Yes ☐ No	Shall confirm that the phase of enhancement and degree of enhancement of appropriate reference structures (vascular or tissue) are consistent with baseline.	☐ Routinely performed ☐ Feasible, will do to conform ☐ Feasible, but not going to do it ☐ Not feasible (explain why)
Tumor Measurability	☐ Yes ☐ No	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 performed ☐ Feasible, will do to conform ☐ Feasible, but not going to do it ☐ Not feasible (explain why)
Consistency with Baseline	☐ Yes ☐ No	Shall confirm that the tumor is similar in both timepoints in terms of all the above parameters.	☐ Routinely performed ☐ Feasible, will do to conform ☐ Feasible, but not going to do it ☐ Not feasible (explain why) Protocol consistency can be confirmed. Consistent use of a single imaging system cannot be guaranteed especially in the case of referrals from other

Parameter	Site Conformity	Specification	Site Opinion
			institutions.
Image Analysis (section 3.9)			
Reading Paradigm	□ Yes □ No	Shall re-process the first time point if it was processed by a different Image Analysis Tool or Radiologist.	□ Routinely performed □ Feasible, will do to conform □ Feasible, but not going to do it □ Not feasible (explain why)
Result Verification	□ Yes □ No	Shall review & approve margin contours produced by the tool.	□ Routinely performed □ Feasible, will do to conform □ Feasible, but not going to do it □ Not feasible (explain why) This is not typically done at this institution. However, this may be requested in special cases.

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.

Protocol design should be done collaboratively between the physicist and the radiologist with ultimate responsibility to the radiologist. Some technical specifications are system dependent and may require special attention from a physicist. All protocols should be validated by the physicist.

Parameter	Site Conformity	Requirement	Site Opinion
Periodic QA (section 3.3)			
QC	□ Yes □ No	Shall perform relevant quality control procedures as recommended by the manufacturer. Shall record the date/time of QC procedures for auditing.	□ Routinely performed □ Feasible, will do to conform □ Feasible, but not going to do it □ Not feasible (explain why)
Protocol Design (section 3.4.2)			
In-plane Spatial Resolution	□ Yes □ No	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 performed □ Feasible, will do to conform □ Feasible, but not going to do it □ Not feasible (explain why)
Voxel Noise	□ Yes □ No	Shall validate that the protocol achieves: • a standard deviation that is < 60HU. See section 4.2. Assessment Procedure: Voxel Noise	□ Routinely performed □ Feasible, will do to conform □ Feasible, but not going to do it □ Not feasible (explain why)

See Appendix B

ACR phantom was scanned on the GE 750 HD scanner using the prescribed protocols. The following results were obtained:

In-plane spatial resolution: **f50 -> 0.45 mm^{-1}**

Voxel noise: **standard deviation -> 35 HU**

TECHNOLOGIST CHECKLIST

Parameter	Site Conformity	Specification	Site Opinion
Subject Handling (section 3.5)			
Use of intravenous contrast	□ Yes □ No	Shall use the prescribed intravenous contrast parameters.	□ Routinely performed □ Feasible, will do to conform □ Feasible, but not going to do it □ Not feasible (explain why) N/A for chest
Use of intravenous contrast	□ Yes □ No	Shall document the total volume of contrast administered, the concentration, the injection rate, and whether a saline flush was used.	□ Routinely performed □ Feasible, will do to conform □ Feasible, but not going to do it □ Not feasible (explain why) N/A for chest
Use of oral contrast	□ Yes □ No	Shall use the prescribed oral contrast parameters.	□ Routinely performed □ Feasible, will do to conform □ Feasible, but not going to do it □ Not feasible (explain why) N/A for chest
Use of oral contrast	□ Yes □ No	Shall document the total volume of contrast administered and the type of contrast.	□ Routinely performed □ Feasible, will do to conform □ Feasible, but not going to do it □ Not feasible (explain why) N/A for chest
Subject Positioning	□ Yes □ No	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 performed □ Feasible, will do to conform □ Feasible, but not going to do it □ Not feasible (explain why)
Artifact Sources	□ Yes □ No	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 performed □ Feasible, will do to conform □ Feasible, but not going to do it □ Not feasible (explain why) We use the breast shield, but we found that it does not cause artifacts
Table Height & Centering	□ Yes □ No	Shall adjust the table height for the mid-axillary plane to pass through the isocenter.	□ Routinely performed □ Feasible, will do to conform □ Feasible, but not going to do it □ Not feasible (explain why)
Table Height & Centering	□ Yes □ No	Shall position the patient such that the “sagittal laser line” lies along the sternum (e.g. from the suprasternal notch to the	□ Routinely performed □ Feasible, will do to conform □ Feasible, but not going to do it

Parameter	Site Conformity	Specification		Site Opinion
		xiphoid process).		□ Not feasible (explain why)
Breath hold	☑ Yes □ No	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 performed □ Feasible, will do to conform □ Feasible, but not going to do it □ Not feasible (explain why)
Breath hold	□ Yes ☑ No	Shall ensure that for each tumor the breath hold state is consistent with baseline.		□ Routinely performed □ Feasible, will do to conform □ Feasible, but not going to do it ☑ Not feasible (explain why) Not sure there is a consistent way to ensure/verify this
Image Header	□ Yes ☑ No	Shall record factors that adversely influence subject positioning or limit their ability to cooperate (e.g., breath hold, remaining motionless, agitation in subjects with decreased levels of consciousness, subjects with chronic pain syndromes, etc.).		□ Routinely performed ☑ Feasible, will do to conform □ Feasible, but not going to do it □ Not feasible (explain why)
Contrast-based Acquisition Timing	□ Yes ☑ No	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 performed □ Feasible, will do to conform ☑ Feasible, but not going to do it □ Not feasible (explain why) N/A
Contrast-based Acquisition Timing	□ Yes ☑ No	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 performed □ Feasible, will do to conform ☑ Feasible, but not going to do it □ Not feasible (explain why) N/A
Image Data Acquisition (section 3.6)				
Acquisition Protocol	□ Yes ☑ No	Shall select a protocol that has been previously prepared and validated for this purpose (See section 3.4.2 "Protocol Design Specification").		□ Routinely performed ☑ Feasible, will do to conform □ Feasible, but not going to do it □ Not feasible (explain why)
Acquisition Protocol	□ Yes ☑ No	Shall report if any parameters are modified beyond the specifications in section 3.4.2 "Protocol Design Specification".		□ Routinely performed ☑ Feasible, will do to conform □ Feasible, but not going to do it □ Not feasible (explain why)
Scan Plane (Image Orientation)	☑ Yes □ No	Shall set Consistent with baseline.	Gantry/Detector Tilt (0018,1120)	☑ Routinely performed □ Feasible, will do to conform □ Feasible, but not going to do it □ Not feasible (explain why)
Tube Potential (kVp)	☑ Yes □ No	Shall set Consistent with baseline (i.e. the same kVp setting if available, otherwise as similar as possible).	KVP (0018,0060)	☑ Routinely performed □ Feasible, will do to conform □ Feasible, but not going to do it

Parameter	Site Conformity	Specification		Site Opinion
				□ Not feasible (explain why)
Scanogram	□ Yes □ No	Shall confirm on the scanogram the absence of artifact sources that could affect the planned volume acquisitions.		□ Routinely performed □ Feasible, will do to conform □ Feasible, but not going to do it □ Not feasible (explain why)
Scan Duration for Thorax	□ Yes □ No	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 performed □ Feasible, will do to conform □ Feasible, but not going to do it □ Not feasible (explain why)
Anatomic Coverage	□ Yes □ No	Shall ensure the tumors to be measured and additional required anatomic regions are fully covered.	Anatomic Region Sequence (0008,2218)	□ Routinely performed □ Feasible, will do to conform □ Feasible, but not going to do it □ Not feasible (explain why)
Anatomic Coverage	□ Yes □ No	Shall, if multiple breath-holds are required, obtain image sets with sufficient overlap to avoid gaps within the required anatomic region(s), and shall ensure that each tumor lies wholly within a single breath-hold.	Anatomic Region Sequence (0008,2218)	□ Routinely performed □ Feasible, will do to conform □ Feasible, but not going to do it □ Not feasible (explain why)
Image Header	□ Yes □ No	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 performed □ Feasible, will do to conform □ Feasible, but not going to do it □ Not feasible (explain why)
Acquisition Field of View (FOV)	□ Yes □ No	Shall set Consistent with baseline.	Data Collection Diameter (0018,0090)	□ Routinely performed □ Feasible, will do to conform □ Feasible, but not going to do it □ Not feasible (explain why)
Image Data Reconstruction (section 3.7)				
Reconstruction Protocol	□ Yes □ No	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 performed □ Feasible, will do to conform □ Feasible, but not going to do it □ Not feasible (explain why)
In-plane Spatial Resolution	□ Yes □ No	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^{-1} of the f50 value recorded for the baseline scan protocol. See section 3.4.2 for further details.		□ Routinely performed □ Feasible, will do to conform □ Feasible, but not going to do it □ Not feasible (explain why) The technical expectations can only be met if done in consultation with a physicist

Parameter	Site Conformity	Specification		Site Opinion
Voxel Noise	□ Yes □ No	Shall either • select the same protocol as used for the baseline scan, or • select a protocol with a recorded standard deviation within 5HU of the standard deviation recorded for the baseline scan protocol. See section 3.4.2 for further details.		□ Routinely performed □ Feasible, will do to conform □ Feasible, but not going to do it □ Not feasible (explain why) The technical expectations can only be met if done in consultation with a physicist
Reconstructed Image Thickness	□ Yes □ No	Shall set to between 1.0mm and 2.5mm (inclusive) and consistent (i.e. within 0.5mm) with baseline.		□ Routinely performed □ Feasible, will do to conform □ Feasible, but not going to do it □ Not feasible (explain why) Why not less than 1mm? 0.625 mm ST is standard at our institution.
Reconstructed Image Interval	□ Yes □ No	Shall set to less than or equal to the Reconstructed Image Thickness (i.e. no gap, may have overlap) and consistent with baseline.		□ Routinely performed □ Feasible, will do to conform □ Feasible, but not going to do it □ Not feasible (explain why)
Reconstruction Characteristics	□ Yes □ No	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 performed □ Feasible, will do to conform □ Feasible, but not going to do it □ Not feasible (explain why)
Reconstruction Field of View	□ Yes □ No	Shall ensure the Field of View spans at least the full extent of the thoracic and abdominal cavity, but not substantially greater than that, and is consistent with baseline.	Reconstruction Field of View (0018,9317)	□ Routinely performed □ Feasible, will do to conform □ Feasible, but not going to do it □ Not feasible (explain why)

4.1. Assessment Procedure: In-plane Spatial Resolution

This procedure can be used by a manufacturer or an imaging site to assess the In-plane Spatial Resolution of reconstructed images. Resolution is assessed in terms of the f50 value (in mm^{-1}) of the modulation transfer function (MTF). Loosely speaking, the MTF represents the blur of an infinitely small feature of interest, f50 represents the spatial frequency at which the contrast of the feature has decreased by 50%, and the inverse of the f50 value represents the size of a feature that would be degraded 50%. So for an f50 value of 0.4 mm^{-1}, features that are 2.5mm (or smaller) would have their contrast degraded by 50% (or more).

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 scan a spatial resolution phantom, such as the ACR CT Accreditation Program (CTAP) Phantom's module 1, which has a series of HU-value cylindrical inserts including one with soft-tissue equivalence. The acquisition protocol and reconstruction parameters shall conform to this Profile (See Section 3.4.2, 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. I.e., the noise level during resolution assessment should correspond to that measured during noise assessment.

The phantom shall be positioned with the center of the phantom at isocenter and properly aligned along the z-axis as described in the ACR CTAP documentation about alignment of the beads.

When the scan is performed, the assessor shall generate an MTF curve, measured as an average of the MTF in the x-y plane along the edge of a target soft-tissue equivalent insert using AAPM TG233 methodology as implemented in manufacturer analysis software, AAPM TG233 software or equivalent.
The assessor shall then determine and record the f50 value, defined as the spatial frequency (in mm^{-1} units) corresponding to 0.5 MTF on the MTF curve.

The procedure described above is provided as a reference method. This reference method and the method used by the scanner manufacturer for FDA submission of MTF values are accepted methods for this assessment procedure. Note that for iterative reconstruction, the manufacturer may have specific test methodologies appropriate for the given algorithm.

Sites may submit to QIBA a proposed alternative method and evidence that the results produced by the proposed method are equivalent to this reference method or to the manufacturer 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 may be applied if the reconstruction method is conventional filtered backprojection or iterative reconstruction.

4.2. Assessment Procedure: Voxel Noise

This procedure can be used by a manufacturer 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 be compliant with this Profile (See Section 3.4.2, 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 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 or manufacturer methodology. 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 intended to be a simple phantom measurement that sets a reasonable floor on the noise which is considered sufficient to avoid degrading segmentation performance. The procedure may be used for both conventional filtered backprojection and iterative reconstruction methods. It is noted that when characterizing reconstruction methods, voxel noise is a limited representation of image noise when noise texture is varied.

4.3. Assessment Procedure: Tumor Volume Computation

This procedure can be used by a manufacturer or an imaging site to assess whether an Image Analysis Tool computes the volume of a single tumor correctly. Accuracy is assessed in terms of the percentage error when segmenting and calculating the volume of a tumor with known truth.

The assessor shall obtain the test files in DICOM format from the QIDW. They can be found by searching for the CT volumetry digital reference object (DRO) DICOM image set. The test files represent a digital test object with z-axis resolution of 1.5mm. A test nodule with -10 HU radio-density is placed within a flat -1000 HU region of the phantom to make the segmentation intentionally easy since the test is not intended to stress the segmentation tool but to instead evaluate any bias in the volume computation after the lesion is segmented.

The assessor shall use the Image Analysis Tool to segment and calculate the volume of the single tumor present in the test images.

The assessor shall record the percentage difference between the reported volume and the true value. The true value is provided in the description of the test files on QIDW.

4.4. Assessment Procedure: Tumor Volume Change Repeatability

This procedure can be used by a manufacturer or an imaging site to assess the repeatability with which the volume of a single tumor is measured. Repeatability is assessed in terms of the repeatability coefficient when segmenting and calculating the volume of a tumor with known truth. The procedure assesses an Image Analysis Tool and a Radiologist operating the tool as a paired system.

The assessment procedure has the following steps:

- Obtain a designated test image set (see 4.4.1).
- Determine the volume change for designated tumors (see 4.4.2).
- Calculate statistical metrics of performance (see 4.4.3).

Note that tumor detection is not evaluated by this procedure since the locations of the target lesions are provided.

4.4.1 OBTAIN TEST IMAGE SET

The test image set consists of multiple target tumors in the lung in multiple subjects which is representative of the stated scope of the Profile.

The assessor shall obtain the test files in DICOM format from the CT Volumetry Profile Conformance section of the Quantitative Imaging Data Warehouse (QIDW http://qidw.rsna.org/) by selecting the test subset of the RIDER Lung CT Dataset.

The test files represent 31 cases, with two time points per case, each with one target tumor to segment. The target tumor is identified in terms of its x/y/z coordinates in the dataset. The list of target tumors and coordinates are provided in a .csv file associated with each study in the Dataset download package. Note that for some of the cases the two time points are in different series in the same study and for some of the cases the two time points are in different studies.

Future editions of the Profile may address a larger number of body parts (e.g., metastases in the mediastinum, liver, adrenal glands, neck, retroperitoneum, pelvis, etc.) by including such tumors in the test data, and may test boundary condition performance by including test data that is marginally conformant (e.g. maximum permitted slice thickness, maximum permitted noise, etc.) to confirm conformant performance is still achieved.

The target tumors have been selected to be measureable (as defined in the Profile) and have a range of volumes, shapes and types to be representative of the scope of the Profile.

The test image set has been acquired according to the requirements of this Profile (e.g. patient handling, acquisition protocol, reconstruction).

If the algorithm has been developed using the specified test files, that shall be reported by the assessor. It is undesirable to test using training data, but until more datasets are available it may be unavoidable.

4.4.2 DETERMINE VOLUME CHANGE

The assessor shall segment each target tumor at each timepoint as described in the Image Analysis Activity (See 3.9). The assessor is permitted to edit the tumor segmentation or seed point if that is part of the normal operation of the tool. If segmentation edits are performed, results shall be reported both with and without editing.

When evaluating an Image Analysis Tool, a single reader shall be used for this entire assessment procedure. When evaluating a Radiologist, a single tool shall be used for this entire assessment procedure.

The assessor shall calculate the volume (Y) of each target tumor at time point 1 (denoted Y_{i1}) and at time point 2 (Y_{i2}) where *i* denotes the *i*-th target tumor.

The assessor shall calculate the resulting % volume change (d) for each target tumor as $d_i = \log(Y_{i2}) - \log(Y_{i1})$.

4.4.3 CALCULATE STATISTICAL METRICS OF PERFORMANCE

The assessor shall calculate the within-subject Coefficient of Variation (wCV), where N=31 and

$$wCV = \sqrt{\sum_{i=1}^{N} d_i^2 \,/(2 \times N)}$$

The assessor shall estimate the Repeatability Coefficient (RC) as

$$\widehat{RC} = 2.77 \times wCV$$

The assessor shall convert the Repeatability Coefficient (RC) estimate to a percentage as

$$\widehat{RC}_p = \left(\exp(\widehat{RC}) - 1\right) * 100\%.$$

The assessor shall divide the target tumors into a small subgroup (containing the 15 target tumors with the smallest measured volumes) and a large subgroup (containing the 16 tumors with the largest measured volumes). The assessor shall repeat the above calculations on both subgroups to estimate a small subgroup repeatability coefficient and a large subgroup repeatability coefficient.

The assessor is recommended to also compute Bland-Altman plots of the volume estimates as part of the assessment record.

For further discussion/rationale, see Annex E.2 Considerations for Performance Assessment of Tumor Volume Change.

4.5. Assessment Procedure: Tumor Volume Bias and Linearity

This procedure can be used by a manufacturer or an imaging site to assess the bias and linearity with which the volume of a single tumor is measured. Bias is assessed in terms of the percentage population bias when segmenting and calculating the volume of a number of tumors with known truth. Linearity is assessed in terms of the slope of an OLS regression fit to the volume data.

4.5.1 OBTAIN TEST IMAGE SET

The test image set consists of scans from two different scanners of an anthropomorphic ("Lungman") phantom with multiple synthetic target tumors of different shapes and sizes in the lung.

The assessor shall obtain the test files in DICOM format from the CT Volumetry Profile Conformance section of the Quantitative Imaging Data Warehouse (QIDW http://qidw.rsna.org/) by selecting the FDA Lungman N1 data subset of the RIDER Lung CT Dataset.

The test files represent 3 repeated scans of the FDA Lungman N1 phantom on each of 2 CT scanners. The phantom contains 7 synthetic tumors, each with a different combination of shape and diameter (see Table 4.5.1-1). The list of 7 target tumors and coordinates are provided in a .csv file associated with each study in the Dataset download package. Note that the images contain half a dozen or so additional tumors that are not identified in the .csv file. Do NOT include measurements of the additional tumors in the results or calculations described in sections 4.5.2 & 4.5.3.

Table 4.5.1-1: Phantom Target Tumor Characteristics

Shape	Nominal Diameter	Nominal Density
Spherical	10 mm 20 mm 40 mm	+100 HU
Ovoid	10 mm 20 mm	+100 HU
Lobulated	10 mm 20 mm	+100 HU

The target tumors have been placed to be measureable (as defined in the Profile) and have a range of volumes and shapes to be representative of the scope of the Profile.

The test image set has been acquired according to the requirements of this Profile (e.g. patient handling, acquisition protocol, reconstruction). See Table 4.5.1-2.

Table 4.5.1-2: Test Image Set Acquisition and Reconstruction Parameters

Scanner	Key Parameters	
Philips 16 (Mx8000 IDT)	KVp: Pitch: Collimation: Exposure: Slice Thickness: Increment: Filter: Repeat Scans:	120 1.2 16x1.5 100 mAs 2 mm 1 mm Medium 3
Siemens 64	KVp: Pitch: Collimation:	120 1.2 64x0.6

	Exposure:	100 mAs
	Slice Thickness:	1.5 mm
	Increment:	1.5 mm
	Filter:	Medium
	Repeat Scans:	3

4.5.2 DETERMINE VOLUME CHANGE

The assessor shall segment each of 42 target tumors (7 tumors in 3 scans for each of 2 scanners) as described in the Image Analysis Activity (See 3.9).

The assessor is permitted to edit the tumor segmentation or seed point if that is part of the normal operation of the tool. If segmentation edits are performed, results shall be reported both with and without editing.

When evaluating an Image Analysis Tool, a single reader shall be used for this entire assessment procedure. When evaluating a Radiologist, a single tool shall be used for this entire assessment procedure.

The assessor shall calculate the volume (Y) of each target tumor (denoted Y_i) where *i* denotes the *i*-th target tumor.

4.5.3 CALCULATE STATISTICAL METRICS OF PERFORMANCE

The natural log of the true volumes (X_i) of each target tumor are known and are provided in the dataset.

The assessor shall calculate the individual bias (b_i) of the measurement of each target tumor as
$b_i = logY_i - log\ X_i$

The assessor shall estimate the population bias over the N target tumors as
$\widehat{D} = \sqrt{\sum_{i=1}^{N} b_i\ /N}$

The assessor shall convert to a percentage bias estimate as
$\%\widehat{bias} = \left(\exp\left(\widehat{D}\right) - 1\right) \times 100.$

The assessor shall fit an ordinal least squares (OLS) regression of the $\log Y_i$ on $\log X_i$ and shall estimate the slope ($\hat{\beta}_1$).

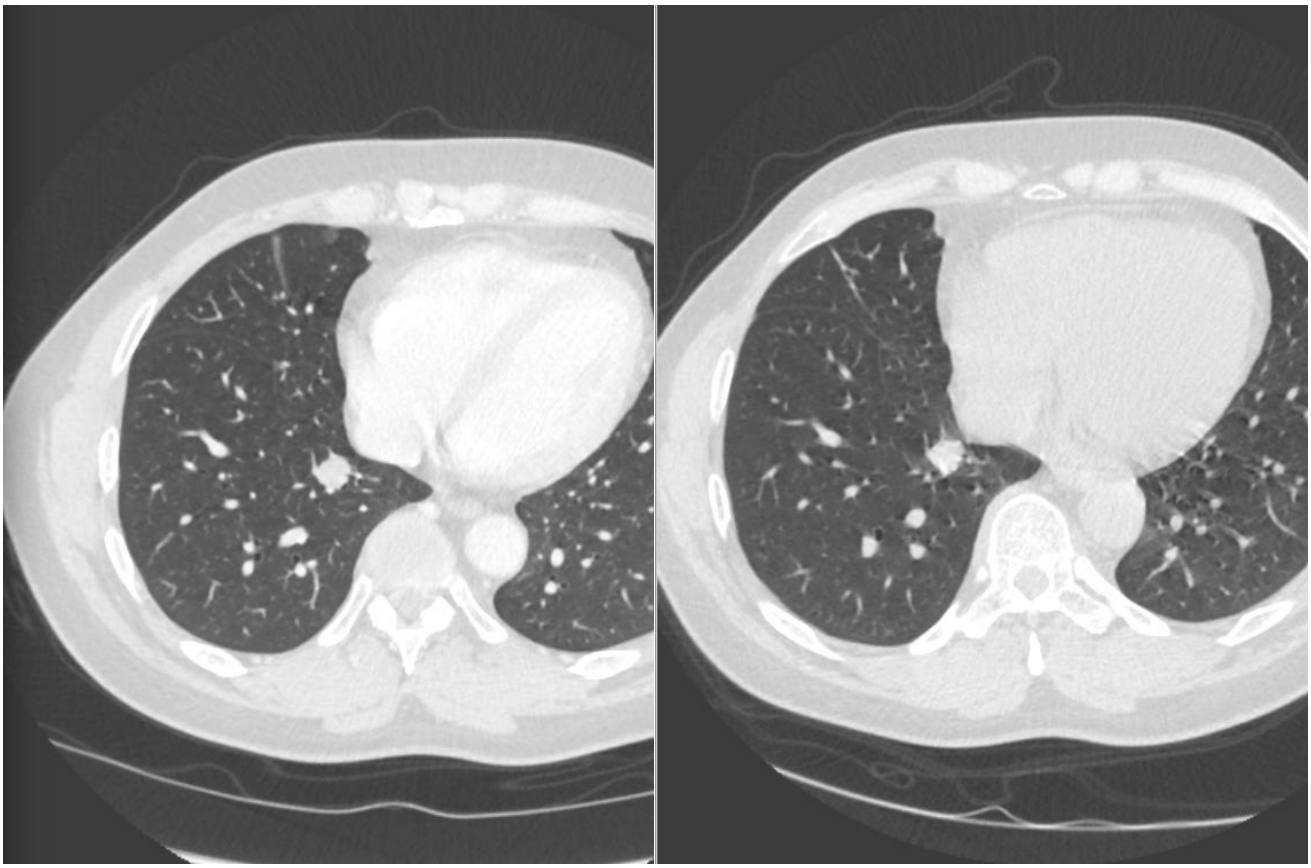
The assessor shall divide the target tumors into three subgroups (containing the spherical, ovoid and lobulated target tumors respectively). The assessor shall repeat the percentage population bias calculation on each subgroup to estimate a spherical subgroup percentage bias, an ovoid subgroup percentage bias and a lobulated subgroup percentage bias.

The assessor is recommended to also plot the volume estimate ($\log Y_i$ versus $\log X_i$) and the OLS regression curve of the volume estimates as part of the assessment record.

Appendix A: Patient Scans

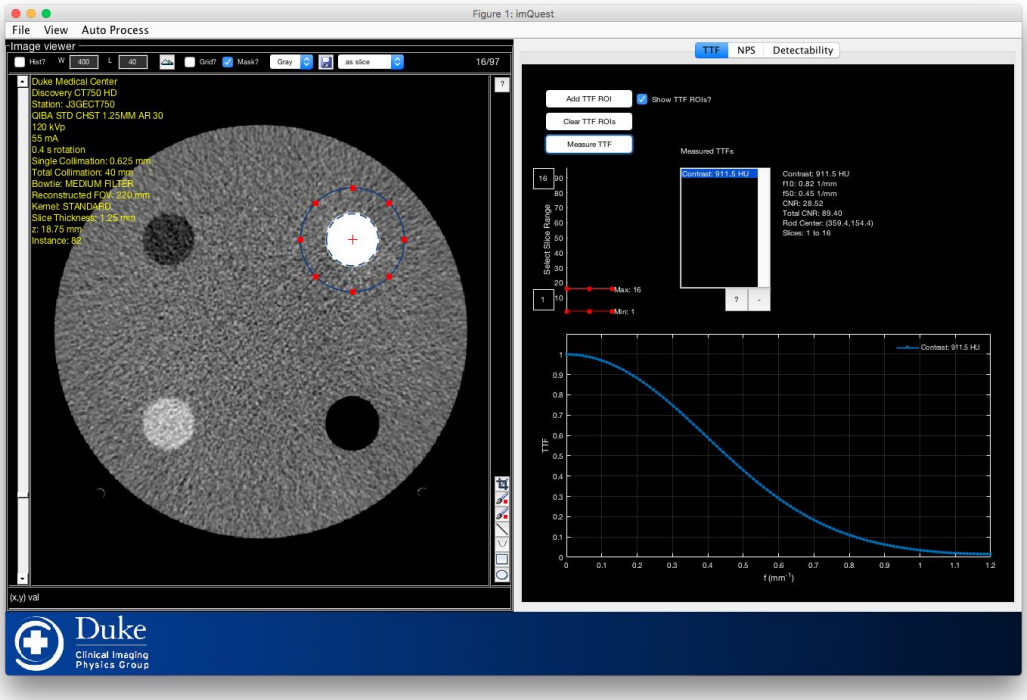
Volume and longest in-plane diameter measures on a solitary pulmonary nodule with small mediastinal attachment. Images at both timepoints meet the QIBA profile requirements. See image attached.

Timepoint 1			Timepoint 2		
TeraRecon	**Philips**	**Syngo.vya**	**TeraRecon**	**Philips**	**Syngo.vya**
1.29 cm^3	**1.67 cm^3**	**1.73 cm^3**	**1.41 cm^3**	**1.52 cm^3**	**1.82 cm^3**
15.7 mm	**16.6 mm**	**16.6 mm**	**16.0 mm**	**16.1 mm**	**17.4 mm**



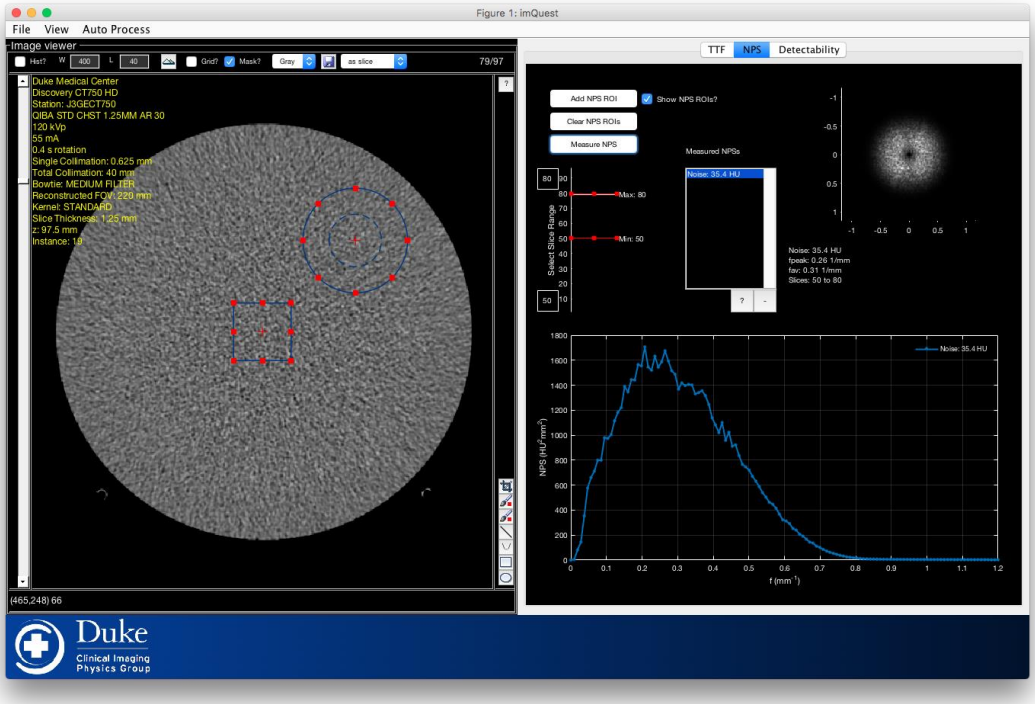
Appendix B: Physics

MTF measurement



In-plane spatial resolution:
f50 -> 0.45 mm^{-1}
Voxel noise:
standard deviation -> 35 HU

Noise measurement



Appendix C: Estimability index (e')

Noise and resolution (f50) are helpful but do not fully capture the technical specifications for volume quantification. As a more appropriate quantification scheme for conformance purposes, we suggest a performance estimation method. As a means to model factors known to influence lesion quantification performance, we have developed a surrogate of volume quantification precision called the estimability index (e'). This mathematical model considers the following factors: the image quality (noise and resolution), a set of nodule characteristics, and the volume segmentation software. Essentially, the volume estimation task is modeled based on the non-prewhitening matched filter model observer employed for detection tasks. It will be useful for determining appropriate limits of noise and resolution for a given lesion size.

Development

Image Quality: The noise and resolution properties of the test images are characterized in terms of noise power spectrum (NPS) and task transfer function (TTF), respectively. NPS is the square of the image noise (variance) as a function of spatial frequency, which describes both the magnitude and the texture of the noise. TTF is an extension of the modulation transfer function (MTF) to accommodate potential non-linearity of iterative reconstruction algorithms by describing the image resolution as a function of object contrast and background image noise.

Nodule Characteristics: The physical properties of the nodule are mathematically modeled in terms of a task function, W_{task}. The task function is the 3D Fourier transform of the nodule's edge profile, containing information about the size, contrast, and edge profile of the nodule.

Volume Segmentation Software: The nodule segmentation process is modeled as a cross-correlation between the nodule and a template, described in Fourier domain as a template function, W_{temp}. If the template matches the nodule, the segmentation is optimized; if not, the segmentation is biased towards the template. Since the morphological processes employed by most commercial segmentation software favor spherical or lobular nodules, if nodule shapes do not fit the spherical assumption of most segmentation algorithms, they are penalized.

Mathematical description of e'

$$\frac{1}{e'^2} = \frac{\iiint NPS \cdot TTF^2 \cdot |W_{task}| \cdot |W_{temp}| \, dudvdw}{\left(\iiint TTF^2 \cdot |W_{task}| \cdot |W_{temp}| \, dudvdw\right)^2},$$

Discover e' relationship to Percent Repeatability Coefficient (PRC)

To validate the e' model, it was compared against lesion precision volume measurements experimentally acquired using an anthropomorphic chest phantom across 54 acquisition protocols (6 dose levels x 3 reconstruction algorithms x 3 slice thicknesses), 2 nodule sizes, and 2 volume segmentation software (Software A and B). The relationship between PRC and e' was demonstrated as $PRC = a\ln\left(b \cdot e'^{c} + 1\right)$. In general, the relationship is independent of nodule size, imaging dose, reconstruction algorithm, and slice thickness; but depend on the segmentation software, with Software A showing a stronger correlation than software B.

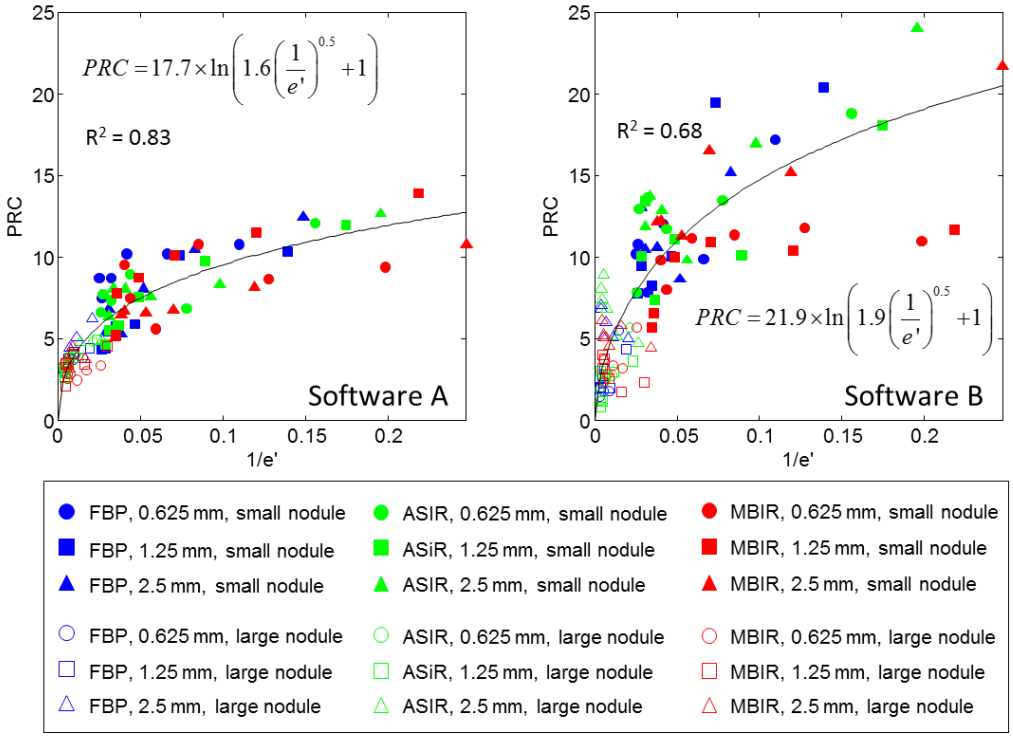


Figure 1: PRC verses 1/e' across 3 reconstruction algorithms, 3 slice thicknesses, 6 dose levels, 2 nodule sizes, and 2 segmentation softwares.

Improvements

Currently, work is ongoing to improve the estimability of lesion volume measurements. Improvement includes incorporating (1) anatomical complexity (local environment influences on detection), and (2) edge noise (heterogeneity of noise at the boundary of lesions).