

31 **Appendix C: Conformance Checklists**



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## QIBA Checklist:

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

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### INSTRUCTIONS

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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.

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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.

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

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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.

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

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**SITE CHECKLIST**

Site Checked:

Parameter	Conforms (Y/N)	Requirement
<b>Site Conformance (section 3.1)</b>		
Scanners		Shall confirm all participating scanners conform to this Profile.
Reconstruction Software		Shall confirm all participating reconstruction software conforms to this Profile.
Image Analysis Tools		Shall confirm all participating image analysis tools conform to this Profile.
Radiologists		Shall confirm all participating radiologists conform to this Profile.
Physicists		Shall confirm all participating physicists conform to this Profile.
Technologists		Shall confirm all participating technologists conform to this Profile.

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**PHYSICIST CHECKLIST**

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**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
<b>Periodic QA (section 3.4)</b>		
QC		Shall perform relevant quality control procedures as recommended by the manufacturer.
QC		Shall record the date/time of QC procedures for auditing.
<b>Protocol Design (section 3.5)</b>		
In-plane Spatial Resolution		Shall validate that the protocol achieves an f50 value between 0.3 mm <sup>-1</sup> and 0.5 mm <sup>-1</sup> for both air and soft tissue edges.  See 4.1. Assessment Procedure: In-plane Spatial Resolution
Voxel Noise		Shall validate that the protocol achieves a standard deviation < 60HU.  See 4.2. Assessment Procedure: Voxel Noise

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**IMAGE ANALYSIS TOOL CHECKLIST**

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

Parameter	Conforms (Y/N)	Requirement								
<b>Product Validation (section 3.2)</b>										
Multiple Tumors		Shall allow multiple tumors to be measured.								
Multiple Tumors		Shall either correlate each measured tumor across time points or support the radiologist to unambiguously correlate them.								
Reading Paradigm		Shall be able to present the reader with both timepoints side-by-side for comparison when processing the second timepoint.								
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).								
Tumor Volume Computation		Shall be validated to compute volume within 5% of the true volume.  See 4.3 Assessment Procedure: Tumor Volume Computation.								
Tumor Volume Repeatability		Shall be validated to achieve tumor volume repeatability with: <ul style="list-style-type: none"> <li>• an overall repeatability coefficient of less than 0.16</li> <li>• a small subgroup repeatability coefficient of less than 0.21</li> <li>• a large subgroup repeatability coefficient of less than 0.21</li> </ul> See 4.4. Assessment Procedure: Tumor Volume Repeatability.								
Tumor Volume Bias & Linearity		Shall be validated to achieve: <ul style="list-style-type: none"> <li>• an overall tumor volume %bias of less than the Allowable Overall %Bias</li> <li>• a tumor volume %bias for each shape subgroup (spherical, ovoid, lobulated) of less than the Allowable Shape Subgroup %Bias</li> <li>• slope (<math>\hat{\beta}_1</math>) between 0.98 and 1.02</li> <li>• quadratic-term (<math>\hat{\beta}_2</math>) between -0.05 and 0.05</li> </ul> The Allowable Overall %Bias and the Allowable Shape Subgroup %Bias are taken from Table 3.2.2-1 based on the overall repeatability coefficient achieved by the Image Analysis Tool using the assessment procedure in section 4.4.  See 4.5 Assessment Procedure: Tumor Volume Bias & Linearity.								
Confidence Interval of Result		Is encouraged to 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 border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th><math>D_1, D_2</math></th> <th>10-34mm</th> <th>35-49mm</th> <th>50-100mm</th> </tr> </thead> <tbody> <tr> <td><math>wCV_1,</math> <math>wCV_2</math></td> <td>0.141</td> <td>0.103</td> <td>0.085</td> </tr> </tbody> </table>	$D_1, D_2$	10-34mm	35-49mm	50-100mm	$wCV_1,$ $wCV_2$	0.141	0.103	0.085
$D_1, D_2$	10-34mm	35-49mm	50-100mm							
$wCV_1,$ $wCV_2$	0.141	0.103	0.085							

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**Table 3.2.2-1:  
Allowable Tumor Volume %Bias based on Overall Repeatability Coefficient**

<b>Overall Repeatability Coefficient</b> $\widehat{RC}$	<b>Allowable Overall %Bias</b> (RMSE Target: 7.1%)	<b>Allowable Shape Subgroup %Bias</b> (RMSE Target: 7.8%)
0.05	6.60%	7.32%
0.06	6.37%	7.11%
0.07	6.09%	6.86%
0.08	5.75%	6.56%
0.09	5.35%	6.20%
0.10	4.88%	5.79%
0.11	4.30%	5.31%
0.12	3.59%	4.75%
0.13	2.63%	4.06%
0.14	0.84%	3.17%
0.15	0.00%	1.84%
0.155	0.00%	0.00%
0.16	n/a (failed repeatability)	n/a (failed repeatability)

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**SCANNER AND RECONSTRUCTION SOFTWARE CHECKLIST**

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Scanner(s) Checked - Make/Model/Version :

<b>Parameter</b>	<b>Conforms (Y/N)</b>	<b>Requirement</b>
<b>Product Validation (section 3.2)</b>		
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.
		Shall prepare a protocol conformant with section 3.5.2 "Protocol Design Specification".
		Shall validate that the protocol achieves an f50 value that is between 0.3 mm <sup>-1</sup> and 0.5 mm <sup>-1</sup> for both air and soft tissue edges.  See 4.1. Assessment Procedure: In-plane Spatial Resolution
		Shall validate that the protocol achieves a standard deviation < 60HU.  See 4.2. Assessment Procedure: Voxel Noise
Reconstruction Protocol		Shall be capable of performing reconstructions and producing images with parameters set as specified in 3.5.2 "Protocol Design Specification".

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## 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 scanner. 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	
<b>Staff Qualification (section 3.3)</b>			
Tumor Volume Computation Repeatability		Shall, if operator interaction is required by the Image Analysis Tool to perform measurements, be validated to achieve tumor volume change repeatability with: <ul style="list-style-type: none"> <li>• an overall repeatability coefficient of less than 0.16</li> <li>• a small subgroup repeatability coefficient of less than 0.21</li> <li>• a large subgroup repeatability coefficient of less than 0.21</li> </ul> See 4.4. Assessment Procedure: Tumor Volume Change Repeatability.	
<b>Protocol Design (section 3.5)</b>			
Acquisition Protocol		Shall prepare a protocol to meet the specifications in this table.	
Acquisition Protocol		Shall ensure technologists have been trained on the requirements of this Profile.	
Total Collimation Width		Shall set to Greater than or equal to 16mm.	Total Collimation Width (0018,9307)
IEC Pitch		Shall set to Less than 1.5.	Spiral Pitch Factor (0018,9311)
Nominal Tomographic Section Thickness (T)		Shall set to Less than or equal to 1.5mm.	Single Collimation Width (0018,9306)
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)
Reconstruction Protocol		Shall prepare a protocol to meet the specifications in this table.	
Reconstruction Protocol		Shall ensure technologists have been trained on the requirements of this Profile.	
Reconstructed Image Thickness		Shall set to between 0.5mm and 2.5mm (inclusive).	Slice Thickness (0018,0050)
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)
<b>Subject Handling (section 3.6)</b>			
Contrast Protocol		Shall prescribe a contrast protocol (which may be No Contrast) that achieves	

Parameter	Conforms (Y/N)	Specification
		enhancement consistent with baseline.
Use of intravenous contrast		Shall determine whether the selected contrast protocol, if any, will achieve sufficient tumor conspicuity.
Use of oral contrast		Shall determine whether the selected contrast protocol, if any, will achieve sufficient tumor conspicuity.
<b>Image QA (section 3.9)</b>		
Patient Motion Artifacts		Shall confirm the images containing the tumor are free from artifact due to patient motion.
Dense Object Artifacts		Shall confirm the images containing the tumor are free from artifact due to dense objects, materials or anatomic positioning.
Clinical Conditions		Shall confirm that there are no clinical conditions affecting the measurability of the tumor.
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 cm <sup>3</sup> and 524 cm <sup>3</sup> .)
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.
Contrast Enhancement		Shall confirm that the phase of enhancement, if any, and degree of enhancement are consistent with baseline.
Patient Positioning Consistency		Shall confirm that any tumor deformation due to patient positioning is consistent with baseline (e.g. tumors may deform differently if the patient is supine in one scan and prone in another).
Breath Hold Consistency		Shall confirm that the breath hold state and degree of inspiration is consistent with baseline.
Scan Plane Consistency		Shall confirm that the anatomical slice orientation (due to gantry tilt or patient head/neck repositioning) is consistent with baseline.
Reconstructed Image Thickness		Shall confirm that the reconstructed image thickness is between 0.5mm and 2.5mm, and consistent with baseline (e.g. within 0.5mm).
Field of View		Shall confirm that the image field of view (FOV) resulting from acquisition and reconstruction settings appears consistent with baseline.
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.
<b>Image Analysis (section 3.10)</b>		
Reading Paradigm		Shall re-process the first time point if it was processed by a different Image Analysis Tool or Radiologist.
Result Verification		Shall review & approve margin contours produced by the tool.

**TECHNOLOGIST CHECKLIST**

Technologist(s) Checked:

Parameter	Conforms (Y/N)	Specification	
<b>Subject Handling (section 3.6)</b>			
Use of intravenous contrast		Shall use the prescribed intravenous contrast parameters.	
Use of oral contrast		Shall use the prescribed oral contrast parameters.	
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.	
Table Height & Centering		Shall adjust the table height for the mid-axillary plane to pass through the isocenter.	
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).	
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.	
<b>Image Data Acquisition (section 3.7)</b>			
Acquisition Protocol		Shall select a protocol that has been previously prepared and validated for this purpose (See 3.5.2 "Protocol Design Specification").	
Localizer		Shall confirm on the localizer (scout) image the absence of artifact sources that could affect the planned volume acquisitions or alter the attenuation of lung nodules.	
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)
<b>Image Data Reconstruction (section 3.8)</b>			
Reconstruction Protocol		Shall select a protocol that has been previously prepared and validated for this purpose (See section 3.5.2 "Protocol Design Specification").	
Reconstructed Image Thickness		Shall set to between 0.5mm and 2.5mm (inclusive) if not set in the protocol.	
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.	
Reconstruction Field 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)

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