

Pathology

Current Standard	Current Guidance	Proposed Standard	Proposed Guidance
New Standard		<p>Pathology Standard of Practice 1 (PA S1): Whole Slide Imaging</p> <p>The use of whole slide imaging (WSI) must be validated to ensure the digital image(s) includes all cellular material and/or tissue fragments that would be visible on a glass slide such that a licensed pathologist is able to render a result from the digital images. The validation must be approved by the laboratory director.</p>	<p>Digital pathology that utilizes any algorithm, including artificial intelligence or machine learning models, to aid the pathologist in diagnosis may require approval from the Food and Drug Administration.</p> <p>The resolution of the remote viewing device (e.g., monitor) must be comparable to the resolution obtained by the scanning equipment.</p>
New Standard		<p>Pathology Standard of Practice 2 (PA S2): Quality Control of WSI</p> <p>The laboratory must have a mechanism to rescan images at the request of the reading pathologist.</p>	