# NEW YORK STATE DEPARTMENT OF HEALTH
# CLINICAL LABORATORY EVALUATION PROGRAM

### COMMENTS and RESPONSES to PROPOSED PATHOLOGY STANDARDS

The Proposed Standards in the area of Pathology were circulated for comment on November 14, 2024. The announcement was sent to NYS-permitted facilities that held or were in application for one or more of the pathology categories. This distribution was by e-mail to the Director's e-mail address, and the laboratory contact person's e-mail address. The documents were posted to the CLEP website.

The comment period ended January 11, 2025. Three (3) comments were received.

The standards are considered to be accepted and will be adopted and effective as of February 12, 2026.

| *Proposed Standard* | *Proposed Guidance* |
|---|---|
| Pathology Standard of Practice 1 (PA S1): Whole Slide Imaging<br><br>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. | 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.<br><br>The resolution of the remote viewing device (e.g., monitor) must be comparable to the resolution obtained by the scanning equipment. |

Comment 1:

We have a question regarding the interpretation of the following proposed guidance:

> *The resolution of the remote viewing device (e.g., monitor) must be comparable to the resolution obtained by the scanning equipment.*

a) As worded, it is unclear how this can be determined, as the provided resolution specifications of the scanning equipment may not be in an equivalent format to the specifications of the viewing monitor.

b) Additionally, viewing software is utilized, which is assessed for the WSI comparability to the glass slide as stated in the Proposed Standard.

c) Could the statement above in the Proposed Guidance be clarified?

Response 1:

a) Calculation(s) are available that allow for the comparison of devices with different resolution formats.

b) Viewing software utilizes the whole slide images captured by the scanning equipment. The scanning equipment resolution is available from the manufacturer. The guidance is to ensure the hardware (monitor/screen) used to view the digital images has a comparable resolution to the highest resolution of the scanning equipment, as the viewing software itself provides images at different resolutions to allow for zooming in and out.

c) Guidance changed: "The resolution of the remote viewing device (e.g., monitor) must be comparable to the highest resolution obtained by the scanning equipment such that resolution meets the laboratory and

manufacturers specified criteria determined to be sufficient for the pathologist to render their diagnosis or findings."

Comment 2:
Regarding PA S1 Guidance "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", we would suggest that this statement be deleted from the proposed standards. The term "may" in existing standards typically refers to situations where there are a variety of ways to comply with aproposed standard, and the guidance therefore presents an example of a way to remain compliant (e.g. LISS2 "examples of quality goals and performance expectations for an LIS may include accurate recording and transmission of data..."). In the case of PA S1, however, the ambiguity that "may" refers could be interpreted as the FDA Final Rule's and the outcome of pending litigation (which may be resolved within the next calendar year). It is possible that this guidance may be inaccurate in several months if the pending litigation from ACLA and AMP is successful, and yet the guidance would remain part of the standard even if it is found that the FDA does not have the statutory authority to regulate digital pathology LDTs. Fortunately, labs have equal legal responsibility to follow federal regulations even in the absence of this guidance. If the FDA is successful in their lawsuit, labs will need to comply with FDA requirements (regardless of whether this proposed guidance is or is not included). Thus, for clarity, we propose that this guidance statement is unnecessary and therefore should not be included to remove any future confusion and need for short-term revision.

Response 2:

The word "may", in this instance, is used to indicate the possibility of approval from the Food and Drug Administration being required for digital pathology that utilizes any algorithm, including artificial intelligence or machine learning models, to aid the pathologist in diagnosis.

Comment 3:
a) Does New York have additional guidance on how to compare resolution of the remote viewing device (monitor) against resolution obtained by the scanning equipment?

b) Would a subjective assessment by the pathologist be adequate or are there certain metrics/measurements that can be utilized?

Response 3:

a) Calculation(s) are available that allow for the comparison of devices with different resolution formats.

b) Guidance changed: "The resolution of the remote viewing device (e.g., monitor) must be comparable to the highest resolution obtained by the scanning equipment such that resolution meets the laboratory and manufacturers specified criteria determined to be sufficient for the pathologist to render their diagnosis or findings."