Proposed Pathology Standards – Comments and Responses

Proposed Standards were made available to New York State permitted laboratories and laboratories in application for a permit on March 4th, 2020. The announcement was by e-mail to the facility and laboratory contact person's e-mail address and the Proposed Standards were posted to the CLEP website.

The comment period ended June 15th, 2020. Comments received from any regulated parties and responses are shown here.

Standards will be adopted July 13th, 2020 with an effective date of August 1st, 2020.

General Comments on Cytopathology Standards

COMMENT:

Regarding CY S8 and CY S11, We ask that instead of "laboratory director' and "director' it state: laboratory director or assistant director(s) holding a certificate of qualification in cytopathology.

RESPONSE:

Responsibilities may be delegated by the laboratory director in writing according to the New York State Clinical Laboratory Standards of Practice. The laboratory director is responsible for ensuring that delegated responsibilities are performed by staff (CLIA 493.1407(b) and 10NYCRR 19.3(c)). There is no change to the standard based on the comment received.

Cytopathology

Pathology	
Cytopathology	
Proposed Standard	***Proposed Guidance***
Cytopathology Standard of Practice 3 (CY S3): Targeted Re-examination The laboratory must establish a system for targeted re-examination of at least ten (10) percent of gynecologic slides interpreted as negative for each cytotechnologist. Documentation of re-examination must be available in the laboratory for inspection by the Department. Cases must be randomly selected from the total caseload including patients who are at increased risk of developing cervical carcinoma, as determined based on clinical information and results of previous studies, if performed.	Slides reviewed as part of ten (10) percent re-examination must be included in the workload limit of the cytology supervisor or the cytotechnologist performing the re-examination.

Cytopathology Standard of Practice 3 (CY S3): Targeted Re-examination

COMMENT:

"Random" is no longer random when you specify high risk patients; it becomes haphazard. In practice, random selection of each cytotechnologist gynecologic slides interpreted as negative (not less than 10%) occurs only in the low or unknown risk patient cases. High risk patient cases that are screened as negative are selected at 100% for rescreening, for how can one ethically choose one high risk patient and not another. This is a welcome burden to laboratories, for it is in the best interest of the patient and focuses laboratory activity to produce the best result for patient care.
Suggested text: "Cases must be randomly selected from the total caseload. Patients who are at increased risk of developing cervical carcinoma, as determined based on clinical information and results of previous studies, if performed, are specifically targeted for re- examination in addition to the randomly selected cases. The director must define in policy the criteria that meet the increased risk of developing cervical carcinoma.

RESPONSE:

The comment is appreciated, however, the suggestion would result in more stringent requirements to the standard. There is no change to the standard based on the comment received.

Pathology	
Cytopathology	
Proposed Standard	***Proposed Guidance***
Cytopathology Standard of Practice 6 (CY S6): Diagnosis and Retrospective Review of Previous Gynecologic Slides For each patient with a current high grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasm: a) the laboratory must review all gynecologic slides received within the previous five (5) years, including those that were interpreted as unsatisfactory, negative, or within normal limits, if available to the laboratory (either on-site or in storage); b) if significant discrepancies are found that could affect current patient care, the laboratory must notify the patient's medical practitioner and issue an amended report according to the laboratory's written procedures for retrospective review, including time frames for completion; and c) results of initial examinations and all re-examinations must be documented.	**Guidance –** Retrospective reviews have the potential for an amended report and are considered a screening activity. b) If discrepancies are found that would <u>not</u> affect <u>current</u> patient care, the laboratory need not issue an amended report, but need only document that finding in its records. "Could affect current patient care" minimally includes situations where an archived slide indicates upon re-examination: • a more serious disease state than that reported following initial examination, and/or abnormal cells identified upon re-examination are of a cell type different from those present on a current slide; or • an absence of disease, and abnormal cells were reported following initial examination.

Cytopathology Standard of Practice 6 (CY S6): Diagnosis and Retrospective Review of Previous Gynecologic Slides

COMMENT:

"a) the laboratory must review all gynecologic slides received within the previous five (5) years, including those that were interpreted as unsatisfactory, negative, or within normal limits, if available to the laboratory (either on-site or in storage);"

Criticism: The beginning of sentence defines that ALL gynecologic slides…within the previous 5 years be reviewed. The language following introduces ambiguity (to surveyors and laboratories) as to which cases need to be reviewed; "only" the unsatisfactory, negative or within normal limit cases? Then ALL does not mean ALL. Reviewing ASCUS, LSIL, HSIL cases that preceded a current HSIL by a few months is a waste of time, especially when some patients and/or providers want to verify the abnormality by repeating it rather than scheduling the required colposcopy for HSIL.

Suggested text: rewriting the sentence without the comma and specify the interpretations of the previous cases that need to be reviewed (unsatisfactory, negative, within normal limits), such as:
"a) the laboratory must review all gynecologic slides received within the previous five (5) years that were interpreted as unsatisfactory, negative (and reactive), or within normal limits, if available to the laboratory either on-site or in storage;" **or rewrite to encompass "<u>all</u>":**

***Suggested text*:** "a) the laboratory must review all gynecologic slides received within the previous five (5) years if available to the laboratory either on-site or in storage;"

Background: The standard complies with state statute written in 1988 when screening guidelines were recommending annual Pap testing. The statute has become obsolete since screening intervals have been lengthened to every 3-5 years with liquid-based testing, the longer period with HPV co-testing. Patients effectively string out the 3 year requirement to 5 years or more and the 5 year guidelines to almost 10 years in some cases. "Time flies" is a common excuse. It is an unproductive, time wasting, and costly regulatory burden on the laboratory with no discernable benefit for the patient or the laboratory. If it was deleted from the standards, there would be rejoicing throughout the land!

RESPONSE:

The current standard requires that all slides be reexamined and (a) indicates if they are available to the laboratory. There is no change to the standard based on the comment received.

Pathology	
Cytopathology	
Proposed Standard	***Proposed Guidance***
Cytopathology Standard of Practice 9 (CY S9): Workload Calculation Records must be available for the calculation of workloads for each individual who performs primary screening. For purposes of calculating slide examination workload: a) gynecologic cytology slides prepared using liquid-based slide preparatory methods and examined using manual screening must be counted as one (1) slide: i. including slides screened using FDA-approved semi-automated gynecologic cytology screening device's full manual review feature; and b) gynecologic cytology slides screened using an FDA-approved semi-automated gynecologic cytology screening device with field of view only review counted as 0.5 slide; c) gynecologic slides that are screened using both field of view and subsequent full manual review on a semi-automated gynecologic cytology screening device counted as 1.5 slides; d) non-gynecologic cytology slides prepared using a liquid-based slide preparatory method that result in cell dispersion over one-half or less of the total available slide counted as 0.5 slide; and e) gynecologic and non-gynecologic slides prepared by conventional smear techniques counted as one (1)	Liquid-based slide preparatory techniques include cytocentrifugation, filtering, and monolayering techniques, but not liquid-based cover slips. Any instrument used to assist in the adherence of cells to the slide is covered by this standard. "Field of view" is an identified microscopic area, selected based on processed image data from an entire scanned slide, presented to a screener for review by the screening device software.

slide.	

Cytopathology Standard of Practice 9 (CY S9): Workload Calculation

COMMENT:

Criticism: The lack of a definitive verb raises ambiguity if laboratories have the preferred patient's best interest option of counting these slides as 1. Some cases prepared in this manner can be evaluated quickly, but there are still others where the interpretation may take time while applying criteria, considering differentials and reviewing the history. Also, some computer systems may have difficulty counting slides as 0.5, especially when there are other preparation types for the case counted as 1. It would be better for the patient if the option of counting as 1 vs 0.5 this was left to the laboratory as defined in their policy. For laboratories that must use manual slide counting, counting some as 0.5 and 1 makes the manual slide counting unnecessarily burdensome. The same concern and rationale that prevents counting manually examined GYN slides as 0.5 applies here as well. Counting slides as 0.5 allows a laboratory to push cytotechnologist productivity to meet artificial quotas to the potential detriment of the patient. The decision should be left to the laboratory director as written in their policy based on human resource characteristics and patient case mix unique to the laboratory.

Suggested text:

d) non-gynecologic cytology slides prepared using a liquid-based slide preparatory method that result in cell dispersion over one-half or less of the total available slide **may** counted as 0.5 slide;

RESPONSE:

The standard states that the slide is counted as "0.5 slide" and therefore, there is no change to the standard based on the comment received.

Pathology	
Cytopathology	
Proposed Standard	***Proposed Guidance***
Cytopathology Standard of Practice 11 (CY S11): Exceeding Gynecologic Slide Workload Limit Screeners must not exceed the slide examination workload limit without express written approval of the laboratory director. The director may consider increasing the gynecologic slide examination workload limit, for a particular screener who performs only gynecologic slide examinations, based on the screener's experience, documented accuracy assessed according to Cytopathology Standard of Practice 10, and performance on proficiency testing. The upper limit of such approval is ninety-six (96) gynecologic slides examined per twenty-four (24) hour period, in no less than an eight (8) hour workday, calculated using Cytopathology Standard of Practice 9. This must include work performed at other laboratories.	This standard applies to all slides examined manually and/or using a FDA-approved semi-automated gynecologic cytology screening device. The director must notify the Department by submitting a Documentation of Increased Workload Limit Form for each screener.

Cytopathology Standard of Practice 11 (CY S11): Exceeding Gynecologic Slide Workload Limit

COMMENT:

Suggestion: Delete the standard. Why have two versions of workload limits in the state?
Alternate suggestion: Make this workload standard for the state. Count manually reviewed slides as 1 regardless of the preparation type.

RESPONSE:

This standard relates to requirements for exceeding the workload limit. There is no change to the standard based on the comment received.

Pathology	
Cytopathology	
Proposed Standard	***Proposed Guidance***
Cytopathology Standard of Practice 15 (CY S15): Reporting In addition to the requirements in Reporting Standard of Practice 2, laboratory reports must: a) use narrative descriptive nomenclature for all results; b) for gynecologic cytology, indicate the semi-automated gynecologic cytology screening device used for examination, if any, and the slide preparation method used for such a device: i. laboratories that perform only examinations using manual screening need not indicate the method on the report; and c) report any unsatisfactory slides or slide preparations that have been identified as unsatisfactory, if applicable.	Descriptive nomenclature must be specified. When cytotechnologists' interpretations are recorded on worksheets in "code", the laboratory should have a mechanism to ensure that the correct nomenclature is used in reporting results. This standard applies to devices approved by the FDA for primary (initial) gynecologic cytology screening. Manual screening means evaluation of material on a slide, performed by a person using a microscope, in a manner that allows visualization and evaluation of the entire viewable area of a slide. Viewable area for conventional slide preparation (a smear prepared by hand) is the entire slide. Viewable area for slides prepared using liquid-based slide preparatory techniques (e.g., an instrument deposits a monolayer of washed and re-suspended cellular material) is the circular or other area pre-marked on the slide.

Cytopathology Standard of Practice 15 (CY S15): Reporting

COMMENT:

Comment: paragraph b) is not clear for surveyors whose primary language is not English.
Comment: paragraph c) is ambiguous if unsatisfactory slides for a case with definitive results based on other slides of the case need to be reported to confuse the report. For example, a 10 slide thyroid aspiration case may have 1 or more unsatisfactory slides yet still may have a definitive result based on other slides of the case. Reporting that 3 of the 10 slides, for example, are unsatisfactory would only confuse the report result.

Suggested revision:

b) For semi-automated gynecologic cytology screening device examination, the method of preparation and method of semi-automated gynecologic cytology screening device used for examination must be indicated.
c) Laboratories that perform only examinations using manual microscopic screening need not indicate the method of examination on the report; and
d) Report the reason for any unsatisfactory slides or slide preparations for any case that has been identified as unsatisfactory, if applicable.

RESPONSE:

The suggested revisions are similar to the language in the standard. There is no change to the standard based on the comment received.

Histopathology

Pathology	
Histopathology	
Proposed Standard	***Proposed Guidance***
Histopathology Standard of Practice 3 (HT S3): Immunohistochemical and Gram Stain Controls Immunohistochemical, gram stains and acid-fast bacilli (AFB) must be checked for positive and negative reactivity with each patient slide or group of slides. Quality control run on continuous throughput slide stainers must be done every eight (8) hours for each stain tested. Reactions of the control slide with each special stain must be documented.	~~A continuous throughput slide stainer is an automated walk-away system that allows continuous loading of up to a specified number of slides at a time.~~ A continuous throughput slide stainer is an automated walk-away system that allows continuous loading of slides with reagents that remain on the stainer for at least 8 hours.

COMMENT 1:

We are asking for clarification on Histopathology Standard of Practice 3 (HT S3) Immunohistochemical and Gram Stain Controls. "Quality control run on continuous throughput slide stainers must be done every eight (8) hours for each stain tested." Is this referring to routine stainers for H&E? or IHC? Or does this apply to all continuous stainers? Some stainers will run "batches" based on the requests of Pathology, with the stain material being changed out. Would this be considered a continuous stainer? These stainers have unique continuous QA/QC characteristics that are applied to EACH stain being performed.

RESPONSE 1:

This standard applies to all immunohistochemical, gram stains and acid-fast bacilli (AFB) strainers as the standard states. Batch runs are not considered continuous runs of a stainer. A continuous throughput slide stainer is an automated walk-away system that allows continuous loading of slides with reagents that remain on the stainer for 8 hours. The guidance has been modified based on the comment received.

COMMENT 2:

We suggest the following: Replace "every eight (8) hours" to "every 24 hours"

RESPONSE 2:

A continuous throughput slide stainer is an automated walk-away system that allows continuous loading of slides with reagents that remain on the stainer for 8 hours. There is no change to the standard based on the comment received.