

NEW YORK STATE DEPARTMENT OF HEALTH CLINICAL LABORATORY EVALUATION PROGRAM

COMMENTS and RESPONSES to PROPOSED CYTOPATHOLOGY STANDARDS

The Proposed Standards in the areas of Cytopathology were circulated for comment on August 6, 2015. The announcement and copies of the proposed standards with a crosswalk were sent to NYS-permitted facilities that held or were in application for a permit (facilities). This distribution was by e-mail to the facility and laboratory contact person's e-mail address.

The comment period ended September 24, 2015. There were 13 commenters from regulated parties and coalitions. Minor modifications were made to the proposed standards to provide additional clarification. The standards are considered to be generally accepted and will be adopted as of March 1, 2016 with an effective date of April 1, 2016.

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Proposed Standard	Proposed Guidance
<p>Cytopathology Sustaining Standard of Practice 3 (CY S3): Prevention of Cross Contamination Between Specimens During the Staining Process</p> <p>The laboratory shall ensure that:</p> <ul style="list-style-type: none"> a. gynecologic and non-gynecologic cytology slides are stained separately; b. non-gynecologic cytology slides that have high potential for cross-contamination are stained separately from other non-gynecologic slides, and the stains and solutions are filtered or changed following staining. 	<p>10NYCRR Section 58.13(b)(3)(iii) requires separate staining of gynecologic and non-gynecologic slides.</p> <p>In general, all stains and solutions should be filtered or changed at intervals appropriate to the laboratory’s workload, no less than each day of use, to ensure staining quality meets the laboratory’s pre-established criteria.</p>

Comment:

Regarding the guidance “In general, all stains and solutions should be filtered or changed at intervals appropriate to the laboratory’s workload, no less than each day of use...” the commenter states “Stain change is not needed each day of use if the specimen volume is so low. Changing too frequently at lower volume laboratories is wasting solutions. However if this just pertains to high potential cross-contamination cases then it should be filtered at daily.”

RESPONSE:

Proposed guidance was revised. “No less than each day of use” language was deleted. However, it is recommended that low volume laboratories implement methods to determine the number of slides that can be stained satisfactorily per unit volume of stain. Stains should be filtered or changed following staining of slides that have high potential for cross contamination. Additionally in accordance with federal requirements, we added to the guidance that a toluidine blue stain may be used to determine the cellularity of non-gynecologic specimens.

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Proposed Standard	Proposed Guidance
<p>Cytopathology Sustaining Standard of Practice 4 (CY S4): Targeted Re-examination</p> <p>The laboratory must establish a system for targeted re-examination of at least 10 percent of gynecologic slides interpreted as negative. Documentation of re-examination must be available in the laboratory for inspection by the Department and to ordering physicians and other practitioners.</p>	<p>Cases must be randomly selected from the total caseload and include negatives as well as those from patients who are at increased risk of developing cervical carcinoma, as determined based on available clinical information and/or results of previous studies.</p> <p>Slides reviewed as part of 10 percent re-examination must be included in the workload limit of the cytology supervisor or the cytotechnologist performing the review.</p> <p>The 10 percent re-examination of negative cases is not required for a one-person laboratory consisting of a pathologist or a laboratory which employs only pathologists. However, these laboratories must establish and follow a program to detect errors.</p> <p>This program must include, but is not limited to, cytologic/histologic correlations, retrospective review of negative cases, documentation of initial and rescreening results, and annual statistical evaluation.</p>

Comment 1:

Regarding the guidance “as determined based on available clinical information and/or results of previous studies” the commenter asks:

“Can you depend on clinical information alone and have the ordering physician identify high risk patients including early onset of sexual activity, multiple sexual partners, history of STD including HIV, daughter of a woman given DES in pregnancy, abnormal pap result?”

RESPONSE to comment 1:

Federal regulation at 42 CFR 493.1274(c)(1)(ii), states that cases chosen for re-examination must be selected “based on available patient information”, which would include results of previous studies, if performed. Laboratories must establish policy for selecting cases for re-examination. The NYS standard was revised to be consistent with the federal requirement.

Federal regulations, as well as our revised standards, do not require that all high risk cases be re-examined, although some laboratories may want to do so. Additionally there are no specific guidelines regarding “how far back to query the computer system for abnormal paps”. Without knowing the staffing situation (number of cytotechnologists and cytopathologists on staff, part time or full time), the annual number of cytology cases as well as nature of technical problems a laboratory may encounter with their old LIS, it is impossible to evaluate a laboratory’s specific situation and give specific recommendations.

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Comment 2:

The CY S4 Standard does not state that the 10% re-examination of gynecologic slides interpreted as negative is a requirement for each cytotechnologist performing primary screening. CLIA and CAP state this is a requirement for each individual cytotechnologist. Please clarify the requirement in the Standard.

RESPONSE to comment 2:

The 10% re-examination of slides interpreted as negative is a requirement for each cytotechnologist. The NYS standard was revised. The language "each cytotechnologist" was added to the standard.

Comment 3:

Please clarify the intent to make re-examination documentation available to "ordering physicians and other practitioners". While we think it is appropriate to indicate to the ordering physician and other practitioners that a re-screen of a particular slide was performed, we do not think it is appropriate to either provide the specific findings of either the primary or re-examination of the slide; nor do we think it is appropriate to make available the 10% re-examination documentation to ordering physicians and other practitioners.

RESPONSE to comment 3:

Agree. The NYS standard was revised. The language "and to ordering physicians and other practitioners" was deleted.

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Proposed Standard	Proposed Guidance
<p>Cytopathology Sustaining Standard of Practice 6 (CY S6): Comparison of Results</p> <p>The laboratory must compare:</p> <ul style="list-style-type: none"> a. Clinical information with cytology final reports, if available; b. All gynecologic cytology reports with a diagnosis of high grade squamous intraepithelial lesion (HSIL), adenocarcinoma or other malignant neoplasms with the histopathology report, if available in the laboratory. 	<p>Cytology-histology correlation studies should be completed in a timely manner.</p> <p>For workload calculations, cytology-histology correlation studies are for quality assurance purposes and are considered a non-screening activity.</p> <p>Any discrepancies or inconsistent findings must be resolved.</p>

Comment:

Suggested guidance: “For workload calculations, cytology-histology correlation studies of concurrent samples conducted as part of the cytology evaluation leading to an interpretation of the cytology may be considered a screening activity. Retrospective cytology-histology correlation studies that occur after the cytology has been interpreted and reported are considered a non-screening activity.”

Rationale: Cytology interpretation does not occur in a vacuum. If there is available tissue correlation pending with a particularly challenging cytology, the review of and correlation with the tissue finding that assists in the interpretation of the cytology should be considered as screening time [if performed by cytotechnologist?]. Samples should be concurrent. This revised guidance would make the workload calculations of time spent screening easier.

RESPONSE:

For workload calculations, cytology-histology correlation studies of concurrent samples conducted as part of the cytology evaluation leading to an interpretation of the cytology are screening activity. The language of the proposed guidance was changed to clarify that “retrospective cytology-histology correlation studies” are considered a non-screening activity. The standard was clarified to describe that “available to laboratory” means “either on site or in storage”. Additional language was added to the guidance to clarify the timeliness of cytology-histology correlation studies; “In general, if cytology and biopsy specimens are obtained concurrently, both reports, as well as correlation studies, should be completed within one week”.

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<p>Cytopathology Sustaining Standard of Practice 7 (CY S7): Diagnosis of HSIL-Retrospective Review of Previous Gynecologic Slides</p> <p>For each patient with a current high grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasm:</p> <ol style="list-style-type: none"> a. the laboratory shall review all gynecologic slides received within the previous five years, including those that were interpreted as unsatisfactory, negative, or within normal limits, if available in the laboratory (either on-site or in storage); b. if significant discrepancies are found that would affect current patient care, the laboratory shall notify the patient’s medical practitioner and issue an amended report. The laboratory’s written procedures for retrospective review shall include time frames for completion. 	<p>Retrospective reviews have the potential for an amended report and are considered a screening activity.</p> <ol style="list-style-type: none"> 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. <p>“Affect current patient care” minimally includes situations where an archived slide indicates upon re-review a more serious disease state than that reported following initial examination, and/or abnormal cells identified upon re-review are of a cell type different from those present on current slide.</p>

Comment 1:

This federal requirement is becoming moot as screening intervals stretch from annual when this standard was written and implemented to 3 or 5 year intervals. The cost of doing this review factors into the overall cost of cervical cancer screening with cytology and is a small factor favoring primary hrHPV screening. The retrospective review of cases does nothing to protect the patient, provides little, if any, educational value to the cytology lab personnel. As hrHPV cotesting becomes more prevalent, the double negative cases within 5 years could be exempted from review, but documented as such why a review was not done. Current Federal requirements, however, fail to allow this exemption.

RESPONSE to comment 1:

The 5 year retrospective lookback is mandated by federal regulation at 42 CFR 493.1274(c)(3), therefore the NYS standard remains unchanged.

Comment 2:

Upon review of the standards my only concern is the re-review parameters and only entering an amended report if the change would affect patient care. I think this is the wrong route to go. Any changes to a report needs to be reported to the physician of order no matter how small. Even if the outcome is not changing treatment course, patients have increased access to their reports. While we as laboratory professionals can sit and understand the similarities and differences of different statements, most patients do not. The lack of full understanding by patients of changes to reports after diagnosis only promotes confusion amongst patients. Patients read every word of a report and if they go back and re-review and find a different wording it could potentiate a mistrust in their diagnosis. However, if even

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small minor corrections are made, and brought to the attention of the physician of order, they can explain to the patient why there is not a clinical relevance to their case. It will also allow a patient to seek a second opinion if they are concerned and most likely hear the same answer, maintaining a confidence in their original provider of care.

RESPONSE to comment 2:

It appears that the comment suggests that any identified discrepancy, whether it would or would not affect patient care, should generate an amended report. The NYS standard was drafted in accordance with federal regulation. 42 CFR 493.1274(c)(3) states: "If significant discrepancies are found that will affect current patient care, the laboratory must notify the patient's physician and issue an amended report." A given lab may adopt a policy that is more stringent than the NYS standard.

Comment 3:

Currently there is no requirement in either CLIA or CAP to include "unsatisfactory" gynecologic slides in the Retrospective Review. Our current practice is to re-screen all "unsatisfactory" findings prior to original report release. Based on a prospective screening practice, there is no value in the retrospective review of a "confirmed" unsatisfactory slide. We request that if a laboratory is following this practice, a provision be included in the Standard that "unsatisfactory" slides need not be included in the Retrospective Review.

RESPONSE to comment 3:

It may not be a standard practice at all laboratories to re-examine all unsatisfactory slides prior to issuance of the report. Adding requested provision to the standard would require providing detailed guidance regarding documentation of such prospective re-examination of unsatisfactory slides, as well as guidance for laboratories that do not follow this practice, and would make the standard too complex.

Additional RESPONSE:

In accordance with federal regulation, we added the following language to the standards: "Results of initial examinations and all re-examinations must be documented". We also further clarified guidance on "Could affect current patient care" to include situations such as where an archived slide indicates upon re-examination... an absence of disease, and abnormal cells were reported following initial examination."

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<p>Cytopathology Sustaining Standard of Practice 8 (CY S8): Laboratory Statistical Evaluations</p> <p>The laboratory must conduct and document an annual evaluation of cytology cases to include the following data:</p> <ul style="list-style-type: none"> a. The number of cytology cases examined; b. The specimens processed sorted by specimen type; c. The patient cases reported sorted by diagnosis; d. The gynecologic cases with a diagnosis of high grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasm for which histology results are available for comparison; e. Gynecologic cases where cytology and histology are discordant; f. Gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), high-grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasm. 	

Comment 1:

Please consider edits which provide additional clarity in data required for the annual evaluation of cytology cases.

- c. The patient number of gynecologic cases reported sorted by diagnosis;
- d. The number of gynecologic cases with a diagnosis of high grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasm for which histology results are available for comparison;
- e. The number of gynecologic cases where cytology and histology are discordant;
- f. The number of gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), high-grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasm.

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RESPONSE to comment 1:

Language of the standard was changed to “The laboratory must conduct and document an annual evaluation to determine the number of:”. Please refer to federal regulation at 42CFR 493.1274(c)(5). Please note that the requirement for an annual statistical laboratory evaluation is not limited to evaluation of gynecologic cases only.

Comment 2:

This poorly written at best. Cases vs. accessions? For some lab they accession each cytologic sample. For others, multiple samples from one procedure are accessioned as one case with multiple parts. The latter statistic by diagnosis would be counted as 1 accession for the primary part only. Programmers apparently don't know, don't want, or will not make that statistic by each part.

Is the query for the number of patients in each diagnostic category or are you looking for the number of diagnoses for each patient? There is no guidance on whether to split this statistic by gyn or non-gyn or by part type. Just reporting there were 15% of patients with a malignant diagnoses doesn't provide a meaningful number to compare over time or compare to lab to lab when the mix of gyn/non-gyn or part type vary over time and by lab. Even breaking apart by gyn vs.non-gyn doesn't tell you anything of the non-gyn, unless sorted by part type.

RESPONSE to comment 2:

Please refer to federal regulation 42 CFR 493.1274(c)(5). The laboratory needs to establish a policy describing how to accession cytology specimens and how the cases will be counted for statistical analysis. For a purpose of performing statistical evaluation, cases should be sorted by diagnosis, as well as by specimen type.

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Proposed Standard	Proposed Guidance
<p>Cytopathology Sustaining Standard of Practice 9 (CY S9): Establishing a Workload Limit</p> <p>The laboratory director shall establish a maximum slide examination workload limit for each cytotechnologist and shall ensure that the examination workload is:</p> <ul style="list-style-type: none"> a. not greater than 80 gynecologic slides or a combined total of 100 gynecologic and nongynecologic slides examined per 24 hour period, in no less than 8-hour workday, calculated using calculation guidance set forth in Cytopathology Sustaining Standard of Practice 10. <ul style="list-style-type: none"> 1) The 100 slide limit represents an absolute maximum and shall not be exceeded; 2) The maximum number of slides that may be examined must be prorated based on the actual number of hours spent examining; b. assessed at least every six months, except that cytotechnologists using a semi-automated gynecologic cytology screening device shall be assessed at least every three months for the first year they use the device; c. adjusted as necessary, and reasons for any adjustment are documented. 	<p>This slide examination workload limit is also applicable to those pathologists who examine previously unevaluated cytology slides.</p> <ul style="list-style-type: none"> a. The laboratory must maintain records of the total number of slides examined by each Cytotechnologist during each 24-hour period and the number of hours spent examining slides in the 24-hour period irrespective of the site or laboratory (screening at all work locations must be tracked). a,2) Time spent on non-screening duties and breaks does not count toward the allowed prorated time for screening.

Comment 1:

- a. There is no responsibility or need for a lab to know how many slides were screened at another facility when the cytotechnologist was not scheduled to work. The laboratories only need to know the number of slides screened for same day work at both labs. Tracking of screening irrespective of the site or laboratory, therefore, should only be required for same day work at other facilities. It is the responsibility of the cytotechnologist to keep and track and record all work at all locations per day. Professional responsibility by the licensed cytotechnologist needs to be incorporated into your laboratory oversight.
- a,2. This guidance allows laboratories to violate the spirit of the workload limit. The purpose is to prevent cytotechnologists from being exhausted as they screen slides. By not counting non-screening time and breaks in the calculation, allows labs to assign non-screening duties that may negatively impact cytotechnologists screening. A fairer guidance is “time spent on non-screening activities must be

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calculated from the total worked hours less time spent screening. If screening time plus non-screening time is more than paid time, there is something wrong and should be investigated. Cytotechnologists should not be “punching out” and going back to screen more slides to meet productivity goals. Productivity should (as number of slides) not be tied to compensation, including hourly salary, annual bonus, stock option or merit increases. This standard as written surreptitiously allows lab administrations to do just that.

RESPONSE to comment 1:

Guidance was revised to clarify how to prorate the number of slides that may be examined. Please note that a clinical laboratory is required to record and document the total number of slides examined by a screener to include all places of employment. Please refer to New York State regulation at 10 NYCRR section 58-1.12(b)(1) and federal regulation at 42 CFR 493.1274 (d)(3).

Comment 2:

Please clarify for us how to interpret Paragraph a. of the Standard. The following are questions which will provide guidance for us beyond what is required by CLIA:

- Can a cytotechnologist screen up to 99 gynecologic slides if one single non-gynecologic slide is examined?
OR is the intent that only 80 gynecologic slides can be screened and the other 20 **must** be all non-gynecologic slides?

RESPONSE to comment 2:

The standard was revised to clarify that the number of gynecologic slides may not exceed 80 in a 24 hour period for those screeners who examine both gynecologic and non-gynecologic slides.

Comment 3:

Please clarify if screening >80 gynecologic slides, must the total gynecologic slides screened include QC re-screening slides or can they be all first screens?

RESPONSE to comment 3:

Please refer to Cytopathology Sustaining Standard of Practice 4 (CY S4): Targeted Re-examination. Slides reviewed as part of 10 percent re-examination must be included in the workload limit of the cytology supervisor or the cytotechnologist performing review.

Comment 4:

In accordance with the first sentence of the Proposed Guidance, please include the edit “and Pathologist (who examines previously unevaluated cytology slides)” which upholds the applicability of the Standard to Pathologists.

RESPONSE to comment 4:

The standard was revised to state that the workload limit is applicable to “each individual who performs primary screening”. The guidance was revised for clarity to include the statement “This slide

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examination workload limit is applicable to cytotechnologists and pathologists who examine previously unevaluated cytology slides.”

Comment 5:

The proposed Standard states “The **laboratory director** shall establish a maximum slide examination workload limit for each cytotechnologist”. As the CY S10 Standard currently states “The director may delegate responsibility for cytotechnologists’ assessment”. A delegated CQ holder may better know the capability of each cytotechnologist and their assessment of an appropriate workload limit would be more effective in assuring quality. Please consider adding back in the ability for the laboratory director to delegate the establishment of the workload limit.

RESPONSE to comment 5:

Guidance was revised to clarify that input from an assistant director with responsibility for the cytopathology category, supervisors, and pathologists performing testing onsite at the laboratory should be considered in establishing workload limit.

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Proposed Standard	Proposed Guidance
<p>Cytopathology Sustaining Standard of Practice 10 (CY S10): Workload Calculation</p> <p>For purposes of calculating slide examination workload:</p> <ul style="list-style-type: none"> a. gynecologic cytology slides prepared using liquid-based slide preparatory methods and reviewed using manual screening shall be counted as one slide <ul style="list-style-type: none"> 1) This includes slides screened using FDA-approved semi-automated gynecologic cytology screening device’s full manual ;review feature; b. gynecologic cytology slides screened using an FDA-approved semi-automated gynecologic cytology screening device with field of view only review shall be counted as one half of one 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 shall be counted as one and one half slides; d. non-gynecologic cytology slides prepared using a liquid-based slide preparatory methods, that result in cell dispersion over one-half or less of the total available slide shall be counted as one half of one slide; and e. gynecologic and non-gynecologic slides prepared by conventional smear techniques shall be counted as one slide. 	<p>This standard refers to liquid based slide preparatory techniques, such as centrifugation, 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.</p> <p>“Field of view” is an identified microscopic area, selected based on processed image data from entire scanned slide, presented to a cytotechnologist for review by the screening device software.</p>

Comment 1:

Keep it simple for the laboratory and the cytotechnologist and count a slide a slide. Regardless of FOV, full manual review, etc. suggest counting it as 1 slide. A maximum of 100 actual glass slides is an acceptable limit.

RESPONSE to comment 1:

This standard was developed in accordance with federal regulations for slide calculation.

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Comment 2:

This should apply only to GYN cytology and not to non-GYN cytology – especially not to fine needle aspirations. The reason is that GYN cytology is a screening procedure and the majority of GYN pap smears are never seen by a pathologist. The purpose of workload limits is to maximize sensitivity in the laboratory, just as one would regulate hematology technologists manually examining differentials. When a pathologist examines a slide, he or she is engaging in the practice of medicine and should not be required to keep to the same regulations that a laboratory technologist does. When it comes to non-GYN slides, pathologists are not trained to screen slides in the same manner that cytotechnologists are. Pathologists are trained instead to first look at the whole slide at low power and then zoom in on the most salient areas with the best cells for evaluation to make a diagnosis. This takes much less time than the conventional cytotechnologist's screening of a slide. This works quite well for non-GYN specimens, but is, admittedly, an inappropriate way of approaching GYN pap smears.

RESPONSE to comment 2:

This standard was developed in accordance with federal regulations for slide calculation. Pathologists are subject to workload limit requirements when they examine previously unevaluated cytology slides, either gynecologic or non-gynecologic. Please refer to state regulation at 10 NYCRR 58-1.12(a)(5) and federal regulation at 42 CFR 493.1274(d)(2).

Comment 3:

Please consider the edit in Paragraph d. of the Standard (“that result in cell dispersion over one-half or less of the total available slide may be counted as one half of one slide”). This will not only match the wording in CLIA and CAP, but is consistent with the wording in the current CY S9 Standard.

RESPONSE to comment 3:

Language in the standard was changed from “shall” to “may”.

Comment 4:

d. Recommend “shall” be changed to “may”. Firstly, some laboratories recognize that one slide is one slide regardless of the preparation type in time spent screening and evaluating a sample. That cytotechnologists facilitate non-gyn sample evaluation seems to suggest they do not need to wholly evaluate the sample as that responsibility is the subsequent physician's evaluation is no excuse to short change the evaluation by the cytotechnologist. Second, it unnecessarily complicates workload reporting and verification, taking unnecessary time away from patient care activities and screening. Thirdly, this forces labs to use time-consuming manual methods of workload recording if the lab system cannot be altered to calculate ½ slide based on preparatory method. Fourth, this ½ slide option is to further pressure the cytotechnologist to speed reviews of cases to meet workload productivity quotas.

e. “Conventional” includes “used and accepted by most people” in the definition which has become untrue to a large degree across the state with various new methods of slide preparation. The term, “traditional smear techniques” may more accurately communicate intended meaning.

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RESPONSE to comment 4:

Language in the standard was changed from “shall” to “may”. FDA guideline “How Laboratorians Can Safely Calculate Workload for FDA-Approved Semi-Automatic Gynecologic Cytology Screening Devices uses word “conventional” when referring to gynecologic cytology slide preparations. The NYS standard remains unchanged.

Proposed Standard	Proposed Guidance
<p>Cytopathology Sustaining Standard of Practice 11 (CY S11): Establishing a Workload Limit: Measures of Cytotechnologist Performance</p> <p>The slide examination workload limit shall be established based on the cytotechnologist’s performance using assessment of the following, with documentation of assessments being retained for two years:</p> <ul style="list-style-type: none"> a. a 10 percent review of gynecologic slides interpreted as negative; b. comparison of the cytotechnologist’s interpretation with the pathologist’s confirmation of patient slides, including gynecologic slides interpreted to exhibit reactive changes, reparative changes or epithelial cell abnormality, and all non-gynecologic slides; c. evaluation of case reviews of each cytotechnologist against the laboratory’s overall statistical values. The reason for any discrepancy and the corrective action shall be documented. 	<p>The director may delegate responsibility for cytotechnologists’ assessment to the person(s) holding a certificate of qualification (CQ) and designated responsible for cytology in the laboratory. Input from the CQ holder, supervisors and pathologists should be considered.</p> <ul style="list-style-type: none"> c. Cytotechnologists should be given an opportunity to discuss discrepancies.

Comment 1:

Regarding CY S11, b and c. It would create a tremendous burden on my staff to generate a comparison of the cytotechnologists statistics with the overall laboratory statistics and to include reactive and reparative changes in the comparison of the cytotechnologists results with the pathologists interpretation. The reason this would be a great burden is that our current electronic medical record system does not have the capacity to generate these results and therefore they must all be calculated by hand.

RESPONSE to comment 1:

The performance measures presented in this standard are required under federal regulations. Please refer to 42 CFR 493.1274(c)(6), 493.1274(d)(1)(i)(B), and 493.1274(e)(1).

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Comment 2:

All non-gynecological slides are reviewed and resulted by the pathologist. The comparison between cytotechnologist and pathologist interpretation is challenging when additional information is only available to the pathologist such as additional cell block level cuts, special stains, immunohistochemistry, and direct submitting physician with pathologist case communication. Perhaps this is comparison is not needed.

RESPONSE to comment 2:

The performance measures presented in this standard are required under federal regulations. Please refer to 42 CFR 493.1274(d)(1)(i)(B) and 493.1274(e)(3).

Comment 3:

Regarding the proposed cytopathology standards I need clarification about Standard 11 (CYS11) b. workload standard that indicates "Comparison of Cytotechnologist interpretation with Pathologists confirmation of patient slides....."

I'm confused by this statement and wonder what it means and what and how we would provide documentation.

RESPONSE to comment 3:

Please refer to federal regulation 493.1274(d)(1)(i)(B). Documentation may be provided in a form of a Cytotechnologist-Cytopathologist discrepancy log.

Additional RESPONSE:

Additionally, the title of the standard was changed to "Measures of performance", and the word "cytotechnologist" was changed to "screener", to clarify that this standard is applicable to all individuals performing primary screening. Additional clarification was included in the standard to describe how the verification of negative cases must be assessed for pathologists who perform primary screening. The guidance was also revised to elucidate that the director may delegate responsibility for screeners' assessment to an assistant director responsible for the cytopathology category.

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Proposed Standard	Proposed Guidance
<p>Cytopathology Sustaining Standard of Practice 12 (CY S12): Exceeding Gynecologic Slide Workload Limit</p> <p>No cytotechnologist shall exceed the slide examination workload limit without express written approval of the laboratory director.</p> <p>The director may consider increasing the gynecologic slide examination workload limit, for a particular Cytotechnologist who performs only gynecologic slide examinations, based on a Cytotechnologist's experience, documented accuracy assessed according to Cytopathology Sustaining Standard of Practice 11, and performance on proficiency testing. The upper limit of such approval is 96 gynecologic slides examined per 24 hour period, in no less than 8-hour workday, calculated using Cytopathology Sustaining Standard of Practice 10. This must include work performed at other laboratories.</p>	<p>This standard applies to all slides screened either manually and/or using a FDA-approved semi-automated gynecologic cytology screening device.</p> <p>The director must notify the Department by submitting a Documentation of Increased Cytotechnologist Workload Limit.</p>

Comment:

In relation to CY S9, the maximum limit is 80 gynecological or 100 gynecological and non-gynecological slides. Stating the upper limit is 96 slides, for some cytotechnologists, is confusing. Recommend making it a flat 100 slides and remove the standard of requesting to exceed a slide workload limit.

RESPONSE:

Please refer to New York State Public Health Law Article 5, Title V, §576-a(1)(b)(ii). The proposed change would be inconsistent with the statute. The allowance to exceed workload limit is applicable to those screeners who perform primary examinations on only gynecologic slides. For screeners who examine both gynecologic and non-gynecologic slides, a maximum of 80 gynecologic slides may be examined in a 24 hour period.

Additional RESPONSE:

The standard was revised to state "no screener" rather than "no cytotechnologist" to reflect the applicability of this standard to pathologists who perform primary screening of gynecologic slides. The guidance was revised to indicate the new form name.

NEW YORK STATE DEPARTMENT OF HEALTH CLINICAL LABORATORY EVALUATION PROGRAM

Proposed Standard	Proposed Guidance
<p>Cytopathology Sustaining Standard of Practice 13 (CY S13): Pathologist Review of Gynecologic Slides</p> <p>A pathologist shall confirm interpretation of each gynecologic slide that has been interpreted as:</p> <ul style="list-style-type: none"> a. Reactive or reparative changes; b. Atypical or suspicious squamous or glandular cells; c. Squamous Intraepithelial Lesion, low or high grade; d. Dysplasia; e. Cervical Intraepithelial Neoplasia; f. Squamous cell carcinoma, adenocarcinoma or other malignant neoplasm. 	<p>The laboratory must specify the descriptive nomenclature used for reporting patient results. The Bethesda System is an example of a recognized system of narrative descriptive nomenclature for gynecologic cytology.</p> <p>This standard also applies to narrative, non-Bethesda equivalents of the diagnostic categories listed.</p>

Comment:

TBS (The Bethesda System) is the industry’s accepted system of nomenclature with specific criteria for each interpretive category to promote proper patient care based on those results. Reimbursement is tied to TBS nomenclature. New York should move out of the 1980’s and require TBS nomenclature. Patient management is based upon TBS result categories and is promoted to patients who want to take an active role in their management. Allowing non-TBS terminology and categorizations is confusing to patients and providers whose primary practice is not gynecology related.

“Diagnosis” and “diagnostic” terms when related to gynecological results should be changed to “Interpretation” or “result” as appropriate, to recognize that gynecological cytology preparations are a “screening test” and therefore cannot result in a “diagnosis”. The diagnosis is made by subsequent evaluation and tests triggered by the screening test. These terms are used freely and incorrectly with regard to gynecologic cytology throughout the document.

RESPONSE:

In response to your comment, guidance language “This standard applies to narrative, non-Bethesda equivalents of the diagnostic categories” was deleted.

NEW YORK STATE DEPARTMENT OF HEALTH CLINICAL LABORATORY EVALUATION PROGRAM

Proposed Standard	Proposed Guidance
<p>Cytopathology Sustaining Standard of Practice 15 (CY S15): Resolution of Discordant Interpretations</p> <p>The laboratory shall establish a procedure to resolve discrepancies, to be implemented whenever a slide is interpreted by more than one cytotechnologist (e.g., during hierarchical review) and the interpretations are discordant.</p>	

Comment 1:

Recommend further discordant clarification, based upon that ability of what both cytotechnologists are capable of signing out without pathologist review.

Comment 2:

Please define discordant. Does this refer to:

1. Unsat due to obscuring inflammation changed to unsat due to obscuring blood
2. Reactive changed to repair
3. Reactive changed to ASCUS
4. WNL to Unsat
5. Unsat to WNL
6. WNL to ASCUS
7. ASCUS to WNL
8. WNL to ASCH
9. ASCH to WNL
10. WNL to LSIL+
11. LSIL+ to WNL

These examples represent a list of “discordant” interpretations, some of which are discordant per se, but not meaningful changes to the severity of the interpretation. We would consider as discordances those that are meaningful changes based on the standard “two step discrepancy”, as in examples 8-11.

RESPONSE to comments 1 and 2:

The Laboratory Director needs to develop a policy that specifies how the discrepancies in interpretation will be resolved. Most of examples of gynecologic cytology interpretive categories listed in comment 2 would be referred to a pathologist for review. It is unclear from the comment how using the “two step discrepancy” definition would obviate the requirement for pathologist’s review.

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Proposed Standard	Proposed Guidance
<p>Cytopathology Sustaining Standard of Practice 16 (CY S16): Reporting</p> <p>Laboratory reports shall:</p> <ul style="list-style-type: none"> a) use narrative descriptive nomenclature for all results; and b) for gynecologic cytology, indicate the semi-automated gynecologic cytology screening device used for examination if any; <ul style="list-style-type: none"> 1) Laboratories that conduct only examinations using manual screening need not indicate the method on the report. 	<p>Descriptive nomenclature must be specified.</p> <p>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.</p> <ul style="list-style-type: none"> b) This standard applies to devices approved by the FDA for primary (initial) gynecologic cytology screening. Reports need not include the slide preparation method. <p>Manual screening means evaluation of material on a slide, conducted by a human being unassisted by other than 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 area under the cover slip. Viewable area for slides prepared using liquid-based slide preparatory techniques (e.g. an instrument's depositing a monolayer of washed and re-suspended cellular material) is the circular or other area pre-marked on the slide.</p>

Comment:

CAP requires the slide preparation method (ThinPrep or SurePath) as one of the elements of a cytopathology report – CYP.05300 and CYP.05350.

RESPONSE:

Clarification was added to the standard to require the slide preparation method to be included on laboratory reports.

NEW YORK STATE DEPARTMENT OF HEALTH CLINICAL LABORATORY EVALUATION PROGRAM

Proposed Standard	Proposed Guidance
<p>Cytopathology Sustaining Standard of Practice 17 (CY S17): Correlation of Results</p> <p>Cytologic diagnosis of non-gynecologic cases must be correlated with the results of ancillary studies.</p>	<p>Ancillary studies may include immunohistochemistry, flow cytometry and molecular studies.</p>

Comment 1:

As written, this is vague, very burdensome, and would produce irrelevant results for the vast majority on non-GYN cytology cases. The purpose of correlating GYN pap smear cytology with follow-up biopsy results is to measure the efficacy of each cytotech’s screening against the published expected rates. This makes sense because the patients being screened are presumably asymptomatic and the screening smear is the only microscopic exam of their cervical cells that they will get until a worrisome symptom arises, such as non-menstrual vaginal bleeding. In the asymptomatic patient, the atypical and positive findings in pap smears still have a relatively strong predictive value for atypical and positive findings in the final diagnosis of cervical biopsies.

The one cytology procedure where one might be justified in looking for correlation of results is the thyroid fine needle aspiration. This is sort of a screening procedure meant to separate the patients whose thyroid nodules need to be removed from majority of those who do not. The thyroid FNA results that are suspicious or positive lead to an invasive surgical procedure and the suspicious or positive cytology results have a high correlation with positive results found in the follow-up surgical specimens. There are also published data, as established in the Bethesda System, establishing the predictive value of the various diagnostic categories of thyroid fine needle cytology. The correlation studies done in this subcategory on non-GYN cytology are reasonably useful in judging the quality of the interpreting pathologists.

Unlike the GYN pap smears screening for disease, the other non-GYN cytology cases are for diagnosis of a clinically suspected disease in a symptomatic patient and are usually invasive – eg: fine needle aspirations, body cavity fluids, endobronchial or endoscopic brushing/washing/etc. Unlike the thyroid fine needle aspirations, a large proportion of non GYN cytology cases are submitted with a histologic component such as a cell block or corresponding definitive tissue biopsy.

Since any definitive biopsies are going to be done in the same procedure as the collection of these other types of invasive cytology specimens, there is no future predictive value to be calculated. In many institutions, in fact, the biopsy and cytology results from a single procedural session are presented in a single report. One non-GYN cytology category that one might argue is a screening procedure is voided urine cytology. However, voided urine is notoriously insensitive and unreliable for detecting low grade papillary neoplasms of the urinary tract, and is still only indicated in a patient with symptoms (ie: hematuria). Unlike GYN pap smears, there is no indication for doing voided urine cytology on an asymptomatic patient. Correlation between urine cytology and bladder biopsies is poor enough for any correlation studies to be absolutely useless in evaluating the quality of the cytology interpretation.

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Comment 2:

Please consider the edit (“with the results of ancillary studies within the laboratory.”) in the Standard. Due to the referral of non-gynecologic specimens to other laboratories, it may not always be possible to correlate all results of ancillary studies for each non-gynecologic cytology case.

RESPONSE to comments 1 and 2:

This standard does not refer to a correlation of cytologic diagnosis with results of a biopsy, and proposed guidance clearly clarifies that ancillary studies may include immunohistochemistry, flow cytometry and molecular studies. These studies may be performed on cell blocks, but may also be performed using cellular material preserved on slides, or in the case of flow cytometry, material placed in a special transport medium. The comment also erroneously implies that cell blocks are separate specimens.

If ancillary studies are ordered in order to establish a more definitive cytopathologic diagnosis, (including, but not limited to, determining the type of tumor), these studies must be correlated with cytologic diagnosis, regardless of whether these studies were performed within the laboratory or sent to an outside laboratory.

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Proposed Standard	Proposed Guidance
<p>Cytopathology Sustaining Standard of Practice 18 (CY S18): Results Retrieval</p> <p>The laboratory shall establish and implement a system for timely retrieval of results and other information pertinent to the generation of results.</p>	<p>Information pertinent to the generation of results, which includes, but is not limited to, instrument printouts of QC data and archived review reports, shall be retained by the laboratory as required in 10NYCRR Subpart 58-1.</p> <p>Records that duplicate information on reports should be searchable numerically (accession number) and alphabetically (patient name).</p>

Comment:

Please consider the edit in the Proposed Guidance (“should be searchable numerically (accession number) ~~and~~ or alphabetically”). The search capability is programmed by the instrument manufacturer. We have found that the search criteria is only available by either accession number OR patient name.

RESPONSE:

The guidance was revised to use language “and/or”, instead of “and” as suggested.