NEW YORK STATE DEPARTMENT OF HEALTH
CLINICAL LABORATORY EVALUATION PROGRAM

Crosswalk of adopted revisions to Cytopathology Standards

2005 Standard	2005 Guidance	2016 Standard	2016 Guidance
Cytopathology Standard 1 (CY S1) If the primary specimen is cellular, or examination at the cellular level is requested, the laboratory must hold a valid permit in the category of cytopathology.	Examination of non-gynecologic cellular material is allowed under a histopathology permit if such material has been collected concurrent with, or has been prepared from, the tissue specimen (e.g., lymph node imprints).	**Cytopathology Sustaining Standard of Practice 1 (CY S1): Department Approval** Laboratories that examine specimens submitted for cytologic evaluation must hold a valid permit in the category of Cytopathology.	~~Examination of non-gynecologic cellular material is allowed under a histopathology permit if such material has been collected concurrent with, or has been prepared from the tissue specimen (e.g., lymph node imprints).~~
Cytopathology Standard 2 (CY S2) The laboratory shall use a Papanicolaou or modified Papanicolaou staining method for gynecologic cytology slides.	While the actual staining technique may vary depending on the type of stain used and the modification of the method, any modification must include the four main steps of the standard Papanicolaou method: fixation, nuclear staining, cytoplasmic staining and clearing. Laboratories using instrumented examination methods should ensure that cytotechnologists receive adequate training in reading slides stained using proprietary formulas, and their proficiency is verified.	**Cytopathology Sustaining Standard of Practice 2 (CY S2): Staining of Gynecologic Slides** The laboratory shall use a Papanicolaou or modified Papanicolaou staining method for gynecologic cytology slides.	While the actual staining technique may vary depending on the type of stain used and the modification of the method, any modification must include the four main steps of the standard Papanicolaou method: fixation, nuclear staining, cytoplasmic staining, and clearing. ~~Laboratories using instrumented examination methods should ensure that cytotechnologists receive adequate training in reading slides stained using proprietary formulas, and their proficiency is verified.~~

NEW YORK STATE DEPARTMENT OF HEALTH
CLINICAL LABORATORY EVALUATION PROGRAM

Crosswalk of adopted revisions to Cytopathology Standards

2005 Standard	2005 Guidance	2016 Standard	2016 Guidance
Cytopathology Standard 3 (CY S3) All gynecologic smears interpreted to be showing reactive or reparative changes, and/or atypical squamous or glandular cells of undetermined significance shall be reviewed by a pathologist.	This standard applies in addition to 10NYCRR Subpart 58-1.12 requirements for pathologist review. This standard applies to narrative, non-Bethesda equivalents of the diagnostic categories listed. The laboratory should 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 discrepant.	**Cytopathology Sustaining Standard of Practice 13 (CY S13): Pathologist Review of Gynecologic Slides** A pathologist shall confirm interpretation of each gynecologic slide that has been interpreted as: 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; or f) Squamous cell carcinoma, adenocarcinoma or other malignant neoplasm.	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. ~~This standard applies in addition to 10NYCRR Subpart 58-1.12 requirements for pathologist review~~. ~~This standard also applies to narrative, non-Bethesda equivalents of the diagnostic categories listed.~~ ~~The laboratory should 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 discrepant.~~

NEW YORK STATE DEPARTMENT OF HEALTH
CLINICAL LABORATORY EVALUATION PROGRAM

Crosswalk of adopted revisions to Cytopathology Standards

2005 Standard	2005 Guidance	2016 Standard	2016 Guidance
Cytopathology Standard 4 (CY S4) The laboratory shall ensure that 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.	10NYCRR Subpart 58.13(b)(3)(iii) requires separate staining of gynecologic and non-gynecologic slides. 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.	**Cytopathology Sustaining Standard of Practice 3 (CY S3): Prevention of Cross Contamination Between Specimens During the Staining Process** The laboratory shall ensure that: a) gynecologic and non-gynecologic cytology slides are stained separately; and 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.	10NYCRR Section 58.13(b)(3)(iii) requires separate staining of gynecologic and non-gynecologic slides. 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. b) A toluidine blue stain may be used to determine the cellularity of non-gynecologic specimens.
Cytopathology Standard 5 (CY S5) Laboratory reports shall: a) use narrative descriptive nomenclature for all results; and b) for gynecologic	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. b) This standard applies to devices approved by	**Cytopathology Sustaining Standard of Practice 16 (CY S16): Reporting** Laboratory reports shall: a) use narrative descriptive nomenclature for all results; and b) for gynecologic cytology, indicate the ~~instrumented method~~ semi-automated	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.

Crosswalk of adopted revisions to Cytopathology Standards

2005 Standard	2005 Guidance	2016 Standard	2016 Guidance
cytology, indicate the instrumented method used for examination, except that a laboratory that conducts only examinations using the conventional method need not indicate the method on the report.	the FDA for primary (initial) screening and/or re-screening for quality assurance purposes. Instrumented methods currently approved include location-guidance and slide profiling systems. Reports need not include the slide preparation method. Reports for slides that undergo initial screening using the FocalPoint slide profiler (TriPath Imaging) and are classified as requiring "no further review" need not identify technical personnel who prepared, processed or loaded slides, and/or reviewed archived review reports. Conventional examination means manual 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	gynecologic cytology screening device used for examination ~~except that a laboratory that conducts only examinations using the conventional method need not indicate the method on the report.~~, if any, and the slide preparation method used for such a device; 1) Laboratories that perform only examinations using manual screening need not indicate the method on the report.	This standard applies to devices approved by the FDA for primary (initial) gynecologic cytology screening. ~~and/or re-screening for quality assurance purposes~~. ~~Instrumented methods currently approved include location-guidance and slide profiling systems. Reports need not include the slide preparation method. Reports for slides that undergo initial screening using the FocalPoint slide profiler (TriPath Imaging) and are classified as requiring "no further review" need not identify technical personnel who prepared, processed or loaded slides, and/or reviewed archived review reports.~~ ~~Conventional examination~~ Manual screening means ~~manual~~ evaluation of material on a slide ~~conducted~~ performed by a ~~human being~~ person using~~, unassisted by other than~~ a microscope, in a manner that allows visualization and evaluation of the entire "viewable area"

Crosswalk of adopted revisions to Cytopathology Standards

2005 Standard	2005 Guidance	2016 Standard	2016 Guidance
	of the entire "viewable area" of a slide. Viewable area for a smear is the area under the cover slip; viewable area for slides prepared by an instrument's depositing a mono-layer of washed and re-suspended cellular material is the circular or other area pre-marked on the slide.		of a slide. Viewable area for a ~~smear~~ conventional slide preparation (a smear prepared by hand) is the entire slide. Viewable area for slides prepared ~~by~~ using liquid-based slide preparatory techniques (e.g., an instrument deposits a mono-layer of washed and re-suspended cellular material) is the circular or other area pre-marked on the slide.
Cytopathology Standard 6 (CY S6) For gynecologic cytology, the laboratory shall not release reports of results for slides selected for re-examination until the re-examination is completed and any discrepancies between initial and re-examination resolved.	For this standard, re-examination includes the 10%, targeted, and instrumented re-screening for QA purposes.	**Cytopathology Sustaining Standard of Practice 5 (CY S5): Reporting Results for Re-examined Slides** For gynecologic cytology, the laboratory shall not release reports of results for slides selected for re-examination until the re-examination is completed and any discrepancies between initial examination and re-examination are resolved.	For this standard, re-examination includes the targeted re-examination required in Cytopathology Sustaining Standard of Practice 4. ~~10%, targeted, and instrumented re-screening for QA purposes~~.
Cytopathology Standard 7 (CY S7) The laboratory shall require and document written acknowledgment for the loan of slides.	The laboratory should have an agreement with the entity borrowing the slides, e.g., a PT program, that loaned slides are retrievable on request.	**Cytopathology Sustaining Standard of Practice 19 (CY S19): Transfer of Slides** Documentation of slides referred for consultation must be maintained. Documentation of slides lent to a proficiency testing program or other entity, including an acknowledgment of receipt by the	~~The laboratory should have an agreement with the entity borrowing the slides, e.g., a PT program, that loaned slides are retrievable on request.~~

Crosswalk of adopted revisions to Cytopathology Standards

2005 Standard	2005 Guidance	2016 Standard	2016 Guidance
	This standard is NOT applicable to slides sent to another laboratory for consultation.	other party, must be maintained. All slides must be retrievable upon request.	~~This standard is NOT applicable to slides sent to another laboratory for consultation.~~
Cytopathology Standard 8 (CY S8) The laboratory shall establish and implement a system for timely retrieval of results and other information pertinent to the generation of results.	Information pertinent to the generation of results, which includes, but is not limited to, instrument printouts of QC data and archived review reports, should be retained by the laboratory as required in 10NYCRR Part 58. Records that duplicate information on reports should be searchable numerically (accession number) and alphabetically (patient name).	**Cytopathology Sustaining Standard of Practice 18 (CY S18): Results Retrieval** The laboratory shall establish and implement a system for timely retrieval of results and other information pertinent to the generation of results.	Information pertinent to the generation of results, which includes, but is not limited to, instrument printouts of quality control data and archived review reports, shall be retained by the laboratory as required in 10NYCRR Subpart 58-1. In accordance with Records Retention Sustaining Standard of Practice 2: Reports, requests for reports must be fulfilled within 24 hours. Records that duplicate information on reports should be searchable numerically (accession number) and/or alphabetically (patient name).
Cytopathology Standard 9 (CY S9)		**Cytopathology Sustaining Standard of Practice 10 (CY S10): Workload Calculation**	~~This standard refers to~~

NEW YORK STATE DEPARTMENT OF HEALTH
CLINICAL LABORATORY EVALUATION PROGRAM

Crosswalk of adopted revisions to Cytopathology Standards

2005 Standard	2005 Guidance	2016 Standard	2016 Guidance
For purposes of calculating workload: a) gynecologic cytology slides prepared using liquid-based slide preparatory methods shall be counted as one slide; and b) non-gynecologic cytology slides prepared using liquid-based slide preparatory methods may be counted as one half of one slide.	This standard refers to slide preparatory techniques, not liquid based cover slips. Any instrument used to assist in the adherence of cells to the slide is covered by this standard.	For purposes of calculating slide examination workload: a) gynecologic cytology slides prepared using liquid-based slide preparatory methods and examined using manual screening shall be counted as 1 slide; ~~and~~ 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 may be 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 shall be counted as 1.5 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 may be counted as 0.5 slide; and e) gynecologic and non-gynecologic slides prepared by conventional smear techniques shall be counted as 1 slide.	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.

NEW YORK STATE DEPARTMENT OF HEALTH
CLINICAL LABORATORY EVALUATION PROGRAM

Crosswalk of adopted revisions to Cytopathology Standards

2005 Standard	2005 Guidance	2016 Standard	2016 Guidance
Cytopathology Standard 10 (CY S10) The laboratory director shall ensure that each individual's examination volume limitation is: a) assessed at least every six months, except that cytotechnologists using instrumented examination methods for gynecologic cytology slides shall be assessed at least every three months for the first year they use the device; and b) adjusted as necessary, and reasons for any adjustment are documented.	Documentation of assessments should be maintained for at least two years. 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.	**Cytopathology Sustaining Standard of Practice 9 (CY S9): Establishing a Workload Limit** The laboratory director shall establish a maximum slide examination workload limit for each individual who performs primary screening and shall ensure that the examination workload is: a) not greater than 80 gynecologic slides examined per 24-hour period, in no less than 8-hour workday, calculated using guidance set forth in Cytopathology Sustaining Standard of Practice 10 or; b) a combined total of 100 gynecologic and non-gynecologic slides examined per 24 hour period, in no less than 8-hour workday, provided that the number of gynecologic slides does not exceed 80; the slide calculation is done using calculation guidance set forth in Cytopathology Sustaining Standard of Practice 10; 1) The 100 slide limit represents an absolute maximum and shall not be exceeded; c) prorated based on the actual number of hours spent examining; d) includes examination of slides at all sites or laboratories where the screener is employed; 1) Records of the total number of slides examined by each individual who performs primary screening and the	~~Documentation of assessments should be maintained for at least two years.~~ Input from an assistant director responsible for cytopathology, supervisors, and pathologists performing testing onsite at the laboratory should be considered in establishing a workload limit. ~~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.~~ This slide examination workload limit is applicable to cytotechnologists and pathologists who examine previously unevaluated cytology slides. A period of 8 hours is used to

2005 Standard	2005 Guidance	2016 Standard	2016 Guidance
		number of hours spent examining slides in a 24 hour period must be maintained by the laboratory, irrespective of the site or laboratory where the examinations are performed; e) assessed at least every six months, except that screeners using ~~instrumented examination~~ a semi-automated gynecologic cytology screening device shall be assessed at least every three months for the first year they use the device; and f) adjusted as necessary, and reasons for any adjustment are documented.	prorate the number of slides that may be examined. Only the actual number of hours spent examining slides (excluding the time spent on non-screening duties and breaks) is used for calculation. Formula #1: (Number of hours examining slides X 80) ÷ 8 Formula #2: (Number of hours examining slides X 100) ÷ 8 Example: An individual who performs primary screening and spends 4 hours examining slides may examine a maximum of: • 40 gynecologic slides or • a combined total of 50 gynecologic and non-gynecologic slides, provided that the number of gynecologic slides

Crosswalk of adopted revisions to Cytopathology Standards

2005 Standard	2005 Guidance	2016 Standard	2016 Guidance
			does not exceed 40.
Cytopathology Standard 11 (CY S11) As part of cytotechnologists' competency assessments, the laboratory director shall ensure: a) the performance of each individual is evaluated against the laboratory's overall statistical values; and b) the reason for any deviation and the corrective action is documented.	Individuals should be given the opportunity to discuss instances of misdiagnosis. a) Performance includes: false-negative and false-positive rates (or number of over- and under-read slides); and rate of referral for pathologist review.	**Cytopathology Sustaining Standard of Practice 11 (CY S11): Establishing a Workload Limit: Measures of Performance** ~~As part of cytotechnologists' competency assessments, the laboratory director shall ensure:~~ ~~a) the performance of each individual is evaluated against the laboratory's overall statistical values; and~~ ~~b) the reason for any deviation and the corrective action is documented.~~ The slide examination workload limit shall be established based on the screener's performance using assessment of the following, with documentation of assessments being retained for two years: a) comparison of the screener's interpretation with a 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; b) evaluation of each screener's interpretations against the laboratory's overall statistical values. Discrepancies must be documented, including the reason for any deviation and corrective action taken; and	~~Individuals should be given the opportunity to discuss instances of misdiagnosis.~~ ~~b) Performance includes: false-negative and false-positive rates (or number of over- and under-read slides); and rate of referral for pathologist review.~~ The laboratory director may delegate responsibility for screeners' assessment to an assistant director responsible for cytopathology. Input from supervisors and pathologists performing testing onsite at the laboratory should be considered. Screeners should be given an opportunity to discuss discrepancies. a) The requirement for 10 precent review pertains only to cytotechnologists. b) Refer to Cytopathology Sustaining Standard of

NEW YORK STATE DEPARTMENT OF HEALTH
CLINICAL LABORATORY EVALUATION PROGRAM

Crosswalk of adopted revisions to Cytopathology Standards

2005 Standard	2005 Guidance	2016 Standard	2016 Guidance
		c) verification of negative cases, to include; 1) for cytotechnologists, a 10 percent re-examination by a pathologist, cytology supervisor, or cytotechnologist with three years of experience, of gynecologic slides interpreted as negative by the cytotechnologist; 2) for pathologists who performing screening, a method for verifying negative cases initially screened by him or her, such as exchanging slides with another pathologist or sending slides out for secondary review.	Practice 13 (CY S13): Pathologist Review of Gynecologic Slides. _____ c) The laboratory director, or Assistant Director responsible for cytopathology, shall determine the definition of a discrepancy for the laboratory.
Cytopathology Standard 12 (CY S12) For each patient with a current high grade squamous intraepithelial lesion (HSIL) or equivalent, or malignancy: a) the laboratory shall review all gynecologic slides interpreted as unsatisfactory, negative or within normal limits received within the previous five years, if available to the laboratory; b) if significant	Available to the laboratory means either on-site or retrievable within 24 hours. Retrospective review and the histology-cytology correlation are part of quality control procedures and, as such, should be completed in a timely manner. b) If discrepancies are found that would not affect current patient care, the laboratory need not issue an amended report, but need only document	**Cytopathology Sustaining Standard of Practice 7 (CY S7): Diagnosis of HSIL-Retrospective Review of Previous Gynecologic Slides** For each patient with a current high grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or ~~equivalent, or malignancy~~ other malignant neoplasm: 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 to the laboratory (either on-site or in storage); b) if significant discrepancies are found that could affect current patient care, the laboratory shall notify the patient's medical	~~Available to the laboratory means either on-site or retrievable within 24 hours.~~ Retrospective reviews ~~and the histology-cytology correlation are part of quality control procedures and, as such, should be completed in a timely manner.~~ have the potential for an amended report and are considered a screening activity. b) If discrepancies are found that would not affect current patient care, the laboratory need not issue an amended report, but

Crosswalk of adopted revisions to Cytopathology Standards

2005 Standard	2005 Guidance	2016 Standard	2016 Guidance
discrepancies are found that would affect current patient care, the laboratory shall notify the patient's medical practitioner and issue an amended report; and c) the laboratory's written procedures for retrospective review and histology-cytology correlation activities shall include reasonable time frames for completion.	that finding in its records. "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 than that involved in the current disease state. For workload calculations, histology-cytology correlation studies are for quality assurance purposes and are considered a non-screening activity. Retrospective reviews have the potential for an amended report and are considered a screening activity.	practitioner and issue an amended report. The laboratory's written procedures for retrospective review ~~and histology-cytology correlation activities~~ shall include time frames for completion; and c) results of initial examinations and all re-examinations must be documented.	need only document that finding in its records. "Could affect current patient care" minimally includes situations where an archived slide indicates upon re-examination: 1. 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 ~~than that involved in the current disease state~~ from those present on a current slide; or 2. an absence of disease, and abnormal cells were reported following initial examination. ~~For workload calculations, histology-cytology correlation studies are for quality assurance purposes and are considered a non-screening activity. Retrospective reviews have the potential for an amended report and are considered a screening activity.~~

NEW YORK STATE DEPARTMENT OF HEALTH
CLINICAL LABORATORY EVALUATION PROGRAM

Crosswalk of adopted revisions to Cytopathology Standards

2005 Standard	2005 Guidance	2016 Standard	2016 Guidance
Cytopathology Standard 13 (CY S13) No laboratory and no cytotechnologist shall exceed the work standard without express written permission of the Department. Each laboratory intending for one or more of the cytotechnologists in its employ to use an instrumented method for initial examination of gynecologic cytology slides in excess of the work standard of 80 slides per work day as set forth in 10NYCRR Part 58-1 of shall submit a written request for approval to the Department.	This standard applies to instrumented methods that employ both a human reviewer and an FDA-approved device for primary screening (i.e., initial examination) of gynecologic cytology slides that employs location guidance technology.	**Cytopathology Sustaining Standard of Practice 12 (CY S12): Exceeding Workload Limit** ~~No laboratory and~~ No screener shall exceed the ~~work standard~~ slide examination workload limit without express written ~~permission of the Department~~ approval of the laboratory director. ~~Each laboratory intending for one or more of the cytotechnologists in its employ to use an instrumented method for initial examination of gynecologic cytology slides in excess of the work standard of 80 slides per work day as set forth in 10NYCRR Part 58-1 of shall submit a written request for approval to the Department.~~ 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 and documented accuracy assessed according to Cytopathology Sustaining Standard of Practice 11, and performance in proficiency testing. The upper limit of such approval is 96 gynecologic slides and a total of 100 gynecologic and non-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.	This standard applies to ~~instrumented methods that employ both a human reviewer and FDA-approved device for primary screening (i.e., initial examination) of gynecologic cytology slides the employs location guidance technology~~ all slides examined either 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 14 (CY S14)	a) The work standard for	**STANDARD DELETED**	

Crosswalk of adopted revisions to Cytopathology Standards

2005 Standard	2005 Guidance	2016 Standard	2016 Guidance
Cytotechnologists using the Thin-Prep Imaging System (Cytyc Corp) as approved by the FDA on June 9, 2003 shall comply with: a) a work standard of 140 gynecologic slides per work day for which examination is restricted to the 22 fields of vision selected by the device and their immediate vicinity as described in the manufacturer's instructions; b) an hourly examination rate that, on average, does not exceed 17.5 slides per hour, for such examinations; and c) for purposes of calculating workload, any slide for which a cytotechnologist engages the "full review" feature (i.e., *Auto-scan* mode) shall be considered as a conventional examination subject to the 80 slide work standard (or that individual's approved conventional	location guided methods set forth in Standard 14 may be exceeded by 20 slides, to a maximum of 160 gynecologic slides per work day, provided the examining cytotechnologist has a minimum of three months experience using the device and the cytotechnologist obtains Department approval for the 20 additional slides. Slides that undergo initial screening using the FocalPoint instrument (TriPath Imaging) and are classified as requiring "no further review" need not be counted in the workload of any cytotechnologist involved in the preparation, processing, loading of slides, and/or review of the archived review report. However, such tasks must be considered for pro-rating his or her individual examination volume limitation pursuant to 10NYCRR Subpart 58-1.13(b).		

2005 Standard	2005 Guidance	2016 Standard	2016 Guidance
examination standard of 96-100 slides)	The maximum hourly rates of 17.5 slides per hour for location-guided methods and 12.5 slides per hour for conventional examinations should be used to adjust workload.		
Cytopathology Standard 15 (CY S15) If, in a given work day, a cytotechnologist examines non-gynecologic or gynecologic cytology slides using the conventional method, the laboratory shall adjust his or her workload for instrumented examinations accordingly.		**STANDARD DELETED**	
Cytopathology Standard 16 (CY S16) When re-examining gynecologic cytology slides initially examined using a location guidance method, the laboratory shall use the conventional examination method or the device's "full review" feature.	Slides initially examined using the conventional method may be re-examined using either the conventional method or an instrumented method FDA-approved for initial or re-screening. The Thin-Prep Imaging System's Auto-scan mode is a full review feature.	**STANDARD DELETED**	

NEW YORK STATE DEPARTMENT OF HEALTH
CLINICAL LABORATORY EVALUATION PROGRAM

Crosswalk of adopted revisions to Cytopathology Standards

2005 Standard	2005 Guidance	2016 Standard	2016 Guidance
NEW STANDARD		**Cytopathology Sustaining Standard of Practice 4 (CY S4): Targeted Re-examination** The laboratory must establish a system for targeted re-examination of at least 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 and include patients who are at increased risk of developing cervical carcinoma, as determined based on available clinical information and/or results of previous studies, if performed.	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 re-examination.
NEW STANDARD		**Cytopathology Sustaining Standard of Practice 6 (CY S6): Comparison of Results** The laboratory must compare: a. clinical information with cytology final reports, if available; and 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 to the laboratory (either on site or in storage).	Cytology-histology correlation studies should be completed in a timely manner. In general, if cytology and biopsy specimens are obtained concurrently, both reports, as well as correlation studies, should be completed within one week. For workload calculations, retrospective cytology-histology correlation studies are for quality assurance purposes and are considered

2005 Standard	2005 Guidance	2016 Standard	2016 Guidance
			a non-screening activity. Any discrepancies or inconsistent findings must be reconciled.
NEW STANDARD		**Cytopathology Sustaining Standard of Practice 8 (CY S8): Laboratory Statistical Evaluations** The laboratory must conduct and document an annual evaluation to determine the number of: a. cytology cases examined; b. specimens processed sorted by specimen type; c. patient cases reported sorted by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation); d. 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; and f. gynecologic cases where any re-examination of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), high-grade squamous	

Crosswalk of adopted revisions to Cytopathology Standards

2005 Standard	2005 Guidance	2016 Standard	2016 Guidance
		intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasm.	
NEW STANDARD		**Cytopathology Sustaining Standard of Practice 14 (CY S14): Pathologist Review of Non-gynecologic Slides** All non-gynecologic slide preparations shall be reviewed by a pathologist.	
NEW STANDARD		**Cytopathology Sustaining Standard of Practice 15 (CY S15): Resolution of Discordant Interpretations** The laboratory shall establish a procedure to resolve discrepancies whenever a slide is interpreted by more than one cytotechnologist and the interpretations are discordant.	
NEW STANDARD		**Cytopathology Sustaining Standard of Practice 17 (CY S17): Correlation of Results** Cytologic diagnosis of non-gynecologic cases must be correlated with the results of ancillary studies, if any.	Ancillary studies may include immunohistochemistry, flow cytometry and molecular studies.