New York State Department of Health

Wadsworth Center

Clinical Laboratory Evaluation Program

Comments and Responses –
Clinical Laboratory Standards of Practice

General Systems Standards

Only regulated party comments and program responses to the General Systems Standards are included here

Proposed General Systems Standards – Comments and Responses

Comments on General Systems Standards received from regulated parties during the public comment period and program responses are shown here.

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.

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

General Comments and/or Comments on Multiple Standards

COMMENT 1:

I appreciate that the standard has been made more concise. However, I do have concerns about the detail that has been replaced by links to pages on the NYSDOH, Wadsworth Center website. I believe this will make it more difficult for new laboratories to find and adhere to all requirements.

RESPONSE 1:

As website content is frequently updated, providing a link to website content allows for the most up-to-date information to be readily accessible to laboratories. There is no change to the standards based on the comment received.

COMMENT 2:

When the revised standard is made effective how long will laboratories have to verify compliance with the new and revised content?

RESPONSE 2:

Laboratories are to comply with the Clinical Laboratory Standards of Practice on the effective date. The department does not feel that the changes in wording have altered the intent of the standards such that they are more stringent than the previous version. The only exception is the requirement for the laboratory director to review and approve all test procedures, as required under interpretive guidelines for CLIA regulation 493.1251 (d). The department will therefore allow a period of up to six months for the laboratory director to complete the review.

COMMENT 3:

Comment: New language Testing Personnel, Non Testing personnel previously Technical Personnel, Non-Technical personnel. There appears to be inconsistencies in the use of the new language in the listed standards. Some of the language still in use are Technical personnel, Non-Technical personnel, technical tasks, and technical functions. There is no definition listed for Testing and Non-Testing personnel or technical personnel functions or tasks.

RESPONSE 3:

Applicable standards have been revised to only indicate testing and non-testing personnel. Non-testing personnel do not have responsibilities related to the laboratory's analytic systems.

COMMENT 4:

- The new standards do not take into consideration how a small organization versus a large organization will implement the requirements. Many of the requirements are not viable options for a large organization or, are not applicable to a blood center. Examples include the following.
    - Director Standard of Practice 4 (DR S4): Director Responsibilities
      b) providing effective administrative direction, including budget planning and controls, in conjunction with the individual(s) responsible for the financial management of the laboratory
      e) selecting all reference laboratories
    - Quality Management System Standard of Practice 3 (QMS S3): Quality Indicators – all quality indicators listed are not applicable to a blood center.

RESPONSE 4:

All New York State Clinical Laboratory Standards of Practice are based on federal and/or state requirements for clinical laboratories, including DR S4 which specifies requirements under 10NYCRR section 58-1.2 and subdivision 19.3(c). Laboratories seeking or holding a New York State Clinical Laboratory Permit must comply with all applicable Clinical Laboratory Standards of Practice. Documentation of requirements that are not applicable is acceptable. There is no change to the standards based on the comment received.

COMMENT 5:

Please define the term 'owner'. If there is no owner, we assume this would not be applicable. Example for where this term is used is Director Standard of Practice 5 (DR S5): Document and Records Accessibility.

RESPONSE 5:

According to Article 5, Title 5 of NYS Public Health Law, Section 575(3), permits are issued jointly to the owner and the director. Laboratories disclose ownership information upon application using the Disclosure of Ownership, Controlling Interest, and Corporate Membership Statement. For laboratories that have already applied for a permit or currently hold a NYS Clinical Laboratory Permit,

laboratories provide information related to the ownership via eCLEP, the web-based portal on the Health Commerce System. There is no change to the standards based on the comment received.

COMMENT 6:

The streamlining of the wording for the new requirements has changed the intent of the standards and will take an inordinate amount of work and time to perform a gap analysis from the current standard operating procedures to what is required, edit or develop new SOPs, and train staff. Consideration needs to be given for the time it will take to implement these standards.

RESPONSE 6:

All New York State Clinical Laboratory Standards of Practice are based on federal and/or state requirements for clinical laboratories. The department does not feel that the changes in wording have altered the intent of the standards such that they are more stringent than the previous version. The only exception is the requirement for the laboratory director to review and approve all test procedures, as required under interpretive guidelines for CLIA regulation 493.1251 (d). The department will therefore allow a period of up to six months for the laboratory director to complete the review.

COMMENT 7:

The new standards are burdening the lab director/permit holder with responsibilities that are not their area of expertise and takes time away from the job they should be performing. Examples of such tasks include [not all inclusive] the following.

- the review of budgets [Director Standard of Practice 4 (DR S4): Director Responsibilities (b)]
- review of IT associated documents [Document Control Standard of Practice 5 (DC S5): Director Approval]
- review of safety associated documents [Laboratory Safety Standard of Practice 1 (LS S1): Safety Policy and Procedure Approval]
- review and signing of all deviations and customer complaint [Result Review Standard of Practice 3 (RR S3) Nonconformance Identification]
- compliance with all applicable local, state and federal laws, regulations and requirements for the packaging and shipping of hazardous chemicals and/or infectious substances [Laboratory Safety Standard of Practice 16 (LS S16): Packaging and Shipping Requirements]

Our laboratory does not operate as a single entity. We operate under a de-centralized model. All corporate SOPs are uniform under a single Document Management System, are utilized consistently throughout the laboratory, and are readily available electronically and can be accessed at any time through the laboratory intranet via the internet. It does not make sense for each lab director/permit holder to be signing all corporate SOPs.

RESPONSE 7:

The laboratory director is responsible for administration of laboratory services (CLIA 493.1407 and 10NYCRR section 58-1.2 and subdivision 19.3(c)) Responsibilities may be delegated in writing by the laboratory director 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)).

COMMENT 8:

- Delegation memos have not been accepted by surveyors during past inspections. Please verify these memos will be accepted during future inspections. Examples where delegation memos indicate they can be used are as follows.
    - Human Resources Standard of Practice 4 (HR S4): Supervisor Responsibilities
    - Specimen Processing Standard of Practice 2 (SP S2): Monitoring Specimen Submissions
    - Proficiency Testing Standard of Practice 10 (PT S10): Performance Review – All Results
    - Director Fundamental Standard of Practice (DR FS): Director and Assistant Director Oversight
    - Director Standard of Practice 4 (DR S4): Director Responsibilities

RESPONSE 8:

The department will require that the delegation of director duties and responsibilities be made in writing. Examples include a signed delegation memo, tasks listed in the delegate's job description and approved by the director, a written policy document or standard operating procedure. Note that the laboratory director may not delegate the review and approval of test procedures and testing responsibilities must be delegated to an assistant director or an individual that qualifies as a supervisor. The laboratory director is responsible for ensuring that delegated responsibilities are performed by staff (CLIA 493.1407(b) and 10NYCRR 19.3(c)).

COMMENT 9:

- Standards listing the requirement for the lab director to develop/review SOP.
    - Please clarify if a designee memo be required for each person that typically would approve an SOP. Examples where this is indicated in the standards are as follows.
        - Quality Management System Standard of Practice 4 (QMS S4): Quality Indicator Monitoring
        - Laboratory Safety Standard of Practice 1 (LS S1): Safety Policy and Procedure Approval

RESPONSE 9:

Procedure development and approval may be delegated in writing by the laboratory director for all procedures except for test procedures and documents (e.g., manufacturer instructions, operator manuals, package inserts, and/or or textbooks) used in total or in part of the test procedure. Signed delegation memos will be accepted. The laboratory director is responsible for ensuring that delegated responsibilities are performed by staff (CLIA 493.1407(b) and 10NYCRR 19.3(c)).

COMMENT 10:

QMS S4 and S5>QMS S6 and S7: Our laboratory would like to request a reversal of deviation from the consensus framework of an annual formalized Management Review, including inputs for previous management review, preventive action, and the internal audit program, as these speak to management of proactive quality continuous improvement not only reactive inspection compliance. Our laboratory would also like to request a switch in order of Management Review then Quality System Documentation to reflect the "required inputs and outputs" structure of consensus Management Review. See also QMS S1>QMS S5; DIR S3>DIR S4.

RESPONSE 10:

The frequency of management review under QMS S7 has been changed to annually based on the comment received and for consistency with QMS S4 and QMS S5. There is no change to the order of the standards based on the comments received.

COMMENT 11:

Comment on HR S8 and HR S9: Safety protocols have been replaced with safe practices

RESPONSE 11:

The change in language reflects that competency assessments must include observation of personnel engaging in safe practices required to perform their job. Observation of safe practices for competency assessments are separate from the requirements under the Laboratory Safety Standards of Practice for safety training.

COMMENT 12:

Question regarding HR S8 and HR S9: Is Direct Observation a required Procedure of Competency Assessment for the evaluation of competency or are each of the procedures listed for the evaluation of competency accomplished by a direct observation?

RESPONSE 12:

The language of HR S8 and HR S9 have been modified to indicate when direct observation is required.

COMMENT 13:

- Regarding HR S7 and HR S8: Human Resources Standard of Practice 7 (HR S7): Competency Assessment – Supervisory Personnel and Human Resources Standard of Practice 8 (HR S8): Competency Assessment – Testing Personnel
    - The standards contradict each other for competency assessments.

RESPONSE 13:

Laboratory personnel who have the responsibilities of a supervisor, as outlined in the Human Resources Standards of Practice, are required to have a supervisory competency. Should the individual have supervisory responsibilities and also function as testing personnel (e.g., perform patient testing), then the laboratory may (1) performing a supervisory competency (for the supervisor responsibilities) and a testing personnel competency (for the testing they perform) or (2) perform a testing personnel competency which will include the competency for the testing performed and a competency on any delegated supervisory functions. Individuals that only perform supervisory functions would only have a competency assessment that encompasses HR S7. Based on the comment received, there have been no changes to these standards.

COMMENT 14:

Process Review S4>RR S3, Nonconformance: Our laboratory requests harmonization to and consistency in use of the term “nonconformity” (event) or otherwise define “nonconformance” (state of), as well as the harmonized approach to make Preventive Action to prevent occurrence fully distinct for preventing recurrence as in Corrective Action. Regarding harmonization of the term “nonconformity”, see also QA_F1>ICA F6, Control of Non-conformities S1/S2>ICA S2/S3, and Complaint Resolution S1>ICA S1.

RESPONSE 14:

Although the comment is appreciated, the language in the standards is consistent with previous versions. There is no change to the standards based on the comment received.

COMMENT 15:

General Comment: Our laboratory requests retention of the line item when deleted. In some cases it is difficult to find where a previous citation may now be included in a new revision line item or explanatory justification for complete removal, e.g. relevancy or covered in statue or regulation.

RESPONSE 15:

Line item deletions and additions are provided in red text in this document to show changes to the proposed standards. A side-by-side comparison showing the proposed standards and changes to the adopted standards is also available on the website for review.

COMMENT 16:

Our laboratory agrees with the inclusion of a Definitions section to clarify the meaning of various terms as used within the Standards. However, LabCorp disagrees with the following definition:
Reagent – The inclusion of solvents within the definition of reagents differs from its use by CLIA and CAP. CAP specifically excludes "solvent or support material" from its definition. LabCorp suggests that the NYSDOH definition should match the CAP definition.

RESPONSE 16:

The New York State Clinical Laboratory Standards of practice require verification of solvents and support materials. There has been no change to the standards or definitions based on the comment received.

Quality Management System

Only comments and responses to the Quality Management System Standards are included here

Quality Management System	
Proposed Standard	***Proposed Guidance***
Quality Management System Fundamental Standard of Practice (QMS FS)~~: Quality Management System~~ The laboratory must have a Quality Management System (QMS) that continuously assesses and improves the quality of laboratory services and ensures compliance with regulatory requirements. The laboratory director, and where appropriate, the owner, must be involved in designing and implementing the QMS. The QMS must: a) set quality goals, quality indicators, and performance expectations and/or thresholds; b) ensure quality goals are reviewed on a scheduled basis, and performance expectations are met; c) continuously monitor for deviations from quality goals or performance expectations; d) include scheduled system and process audits, at least annually; and e) have a system for correcting and documenting problems uncovered by monitoring or audits. ***Statutory authority: Article 5, Title 5 Public Health Law Section 575(2) and (3)***	

Quality Management System Fundamental Standard of Practice (QMS FS)

COMMENT 1:
Provide definition for “Owner” is the term Owner being used when the Owner is also the Medical Director?

RESPONSE 1:
According to Article 5, Title 5 of NYS Public Health Law, Section 575(3), permits are issued jointly to the owner and the director. Laboratories disclose ownership information upon application using the Disclosure of Ownership, Controlling Interest, and Corporate Membership Statement. For laboratories that have already applied for a permit or currently hold a NYS Clinical Laboratory Permit, laboratories provide information related to the ownership via eCLEP, the web-based portal on the Health Commerce System.
There is not change to the standard based on the comment received.

COMMENT 2:
It is unrealistic to expect the QMS to continuously improve laboratory services no matter how great your QMS is. How does NYS intend to determine that we are always in a state of improvement compared to the day before?

RESPONSE 2:
The use of the term continuous is consistent with federal regulations according to CLIA 493.1200 Introduction (b), that states: Each of the laboratory’s quality systems must include an assessment component that ensures continuous improvement of the laboratory’s performance and services through ongoing monitoring that identifies, evaluates and resolves problems.
Examples of activities that contribute to continuous improvement include monitoring of environmental conditions, verification of reagents and media, and equipment and instruments, review of quality control data, on-going assessment of quality indicators and review of corrective actions. There is no change to the standard based on the comment received.

Quality Management System	
Proposed Standard	***Proposed Guidance***
Quality Management System Standard of Practice 1 (QMS S1): Quality Goals and Performance Expectations The laboratory's Quality Management System (QMS) must define quality goals and performance expectations that ensure the quality and timeliness of laboratory services. The QMS must meet New York State Clinical Laboratory Standards of Practice and any other applicable requirements for all laboratory processes. ~~The laboratory must have a quality manual for their QMS that addresses the following:~~ The laboratory's QMS must be documented and address the following: a) quality indicators (QI); b) director responsibilities; c) human resources; d) facility design; e) laboratory safety; f) laboratory information systems (LIS); g) resource management; h) document control; i) pre-analytic systems; j) analytic systems; k) post-analytic systems; l) document and specimen retention; m) proficiency testing; and	The Quality Management System (QMS) must include documents to describe personnel roles and responsibilities, and the processes they must use to meet quality goals and performance expectations. The laboratory should document how QMS requirements for (a) through (n) are met. Documentation may be in the form of a quality manual, master index or cross reference system. Examples of QMS documents include, but are not be limited to: • standard operating procedures, policies, plans, etc.; • maintenance procedures; and • forms, instructions, and client information. Please see additional information related to quality indicators at: https://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/on-site-survey.

n) investigations and corrective actions. ***Statutory authority: Article 5, Title 5 Public Health Law Section 575(2) and (3),*** ***Regulatory authority: 10 NYCRR subdivision 58-1.2(c) and paragraph 19.3(c)(3)***	

Quality Management System Standard of Practice 1 (QMS S1): Quality Goals and Performance Expectations

COMMENT 1:

Please do not refer to this document set as a "quality manual". This term is outdated and may be interpreted to limit our flexibility in providing more modern approaches to information mapping and electronic systems.
Suggest changing the sentence "The laboratory must have a quality manual for their QMS that addresses the following":
to: The laboratory's QMS must be documented and address the following:

RESPONSE 1:

The language of the standard has been changed based on the comment received. Guidance has been added indicating that documentation may be, for example, in the form of a quality manual, master index or cross reference system.

COMMENT 2:

QMS S2 (deleted)>QMS S1: Understanding that the intent is to be less proscriptive, Our laboratory would like to request retention of language to keep that QMS documents are referenced in the Quality Manual document, as this is good Document Control practice to demonstrate reinforcing documentation hierarchy by clearly tying QM policy to applicable SOP.

RESPONSE 2:

The standard has not been changed based on the comment received. Quality manual is listed as an example in the guidance.

Quality Management System	
Proposed Standard	***Proposed Guidance***
Quality Management System Standard of Practice 2 (QMS S2): Quality Systems Manager The laboratory director must designate a quality systems manager or quality assurance officer who has the experience and authority to ensure communication, training, competency assessment and ongoing compliance monitoring with all requirements of the laboratory's Quality Management System (QMS). ***Regulatory authority: 10 NYCRR subdivision 58-1.2(c)***	There must be a designated position for a quality systems manager or quality assurance officer and a job description. The designated individual must have the education, experience and authority to discharge the responsibilities of the position and must have access to personnel at all levels of the laboratory organization as required. The designated individual is expected to be a resource person to the Department when there is a need for document review and compliance assessment. The laboratory director may serve as the quality systems manager. Persons who limit their scope of activity to oversight of quality system activities do not require licensure by the New York State Education Department.

Quality Management System Standard of Practice 2 (QMS S2): Quality Systems Manager

COMMENT 1:
What is the difference between a Quality Systems Manager vs Quality Assurance Officer? Are the responsibilities for these titles different? Comment: In the guidance for this standard it is not clear about training requirements for the job title.

RESPONSE 1:
For the purposes of the New York State Clinical Laboratory Standards of Practice, the quality systems manager and quality assurance officer are synonymous. The laboratory must have a job description that defines education and training requirements that are consistent with commonly accepted qualifications for the job title. There is no change to the standard based on the comment received.

COMMENT 2:

This standard seems to assume that the laboratory director is the highest level authority in the organization. For large organizations, this is not always the case and the quality manager may be designated by someone above the lab director to help ensure separation of authority and function.

RESPONSE 2:

The laboratory director is responsible for administration of laboratory services (CLIA 493.1407 and 10NYCRR section 58-1.2 and subdivision 19.3(c)) Responsibilities may be delegated in writing by the laboratory director 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.

Quality Management System	
Proposed Standard	***Proposed Guidance***
Quality Management System Standard of Practice 3 (QMS S3): Quality Indicators The laboratory must establish quality indicators (QI) that assess the quality of laboratory services and identify processes that do not meet Quality Management System (QMS) requirements for quality goals and performance expectations. The laboratory must establish QI for the following, at a minimum: a) monitoring specimen submissions, including compliance with test request requirements and the laboratory's specimen submission instructions; b) timeliness and completeness for personnel training and competency; c) performance on proficiency testing and alternative assessments of test accuracy and reliability;	**Guidance –** a) Examples include specimens with missing information (e.g., time of collection when required) or incorrect labels, etc. d) Examples include numbers of corrected test reports and timeliness of client notification. e) The laboratory must select a representative sampling of STAT or urgent tests for turnaround time monitoring. Additional examples of areas where QI are valuable in assessing performance include acceptable specimen transport and storage, acceptable performance by contract and reference laboratories, verification of materials, quality control records and review, temperature and humidity records and comparability of test results.

d) corrected test reports; e) turnaround times for urgent or STAT tests; f) complaint investigations; and g) nonconformances. ***Statutory authority: Article 5, Title 5 Public Health Law Section 575(2) and (3)***	

Quality Management System Standard of Practice 3 (QMS S3): Quality Indicators

COMMENT 1:
The QI's listed are directed toward patient testing and not product testing. Please clarify if an organization is required to monitor all QI's if they are not applicable.

RESPONSE 1:
Laboratories seeking or holding a New York State Clinical Laboratory Permit must comply with all applicable New York State Clinical Laboratory Standards of Practice. In addition to establishing QI, the laboratory must document review of QI at least annually for compliance with QMS S4. For QI that do not apply to laboratory practices, the laboratory must document that the QI are not applicable. There is no change to the standard based on the comment received.

COMMENT 2:
Require clarification on "Acceptable Specimen Transport and Storage" and "Verification of Materials"

RESPONSE 2:
The guidance provides examples of QI that the laboratory may choose to monitor. The laboratory may monitor if specimens are transported and/or stored under required conditions, as applicable (e.g., transported to the laboratory within a required time frame and at the appropriate temperature, stored within the laboratory at the required temperature, or discarded within required timeframes). Regarding verification of materials, the laboratory may monitor, for example, how often materials are received that do not meet the laboratories performance specifications and if it is consistently the same material and/or a specific manufacturer. There is no change to the guidance based on the comment received.

COMMENT 3:

NYS defines QI as Quality indicator (QI): Data identified/chosen by the laboratory as part of the Quality Management System (QMS) to monitor conformance with laboratory performance expectations.
Why then, is NYS defining Qis for us? This goes against basic quality principles. Indicators should be relevant to current operations and the state of quality within our organization. If a specific area is in control, we prefer the flexibility to drop that indicator to focus on areas where there is a problem.

RESPONSE 3:

The laboratory may define and monitor QI that are not required in the standard. However, at a minimum, laboratories are required to monitor QI specified by the standard, as applicable. For QI that do not apply to laboratory practices, the laboratory must document that the QI are not applicable. There is no change to the standard based on the comment received.

COMMENT 4:

The decision of which quality indicators to monitor should be evaluated by laboratory management and be based on the needs and services of the laboratory. Our recommendation is for the state to provide examples of quality indicators to monitor, but not mandate specific quality indicators.
For example the proposed quality indicator under (a) "monitoring specimen submissions, including compliance with test request requirements and the laboratory's submission instructions"; instructions are provided to the client/provider and feedback may be given in the case of incorrect submission, ultimately it is the responsibility of the client/provider to follow those instructions. Corrective and prevention action may be suggested by the laboratory, but the laboratory cannot dictate how the client will respond to the suggestions.

RESPONSE 4:

Minimum requirements for QI that must be monitored have been defined in the standard. Laboratories are required to monitor QI specified by the standard, as applicable. For QI listed in the standard that do not apply to laboratory practices, the laboratory must document that the QI are not applicable. There is no change to the standard based on the comment received.

Quality Management System	
Proposed Standard	***Proposed Guidance***
Quality Management System Standard of Practice 4 (QMS S4): Quality Indicator Monitoring The laboratory must have standard operating procedures and/or policies describing the process for monitoring quality indicators (QI). For QI, the laboratory director is responsible for establishing: a) the frequency for monitoring, which must be at least annually; b) how data will be collected, analyzed and documented; c) acceptable performance and/or threshold(s) for each indicator; and d) actions to be taken for QI that do not meet defined performance expectations and/or threshold(s), including notifications to appropriate parties, if applicable. ***Statutory authority: Article 5, Title 5 Public Health Law Section 575(2) and (3)***	Examples of documentation may include: (1) continued acceptable performance expectations (e.g., measured against a threshold or benchmark); (2) areas in need of improvement; and/or (3) non-conforming events as indicated when performance expectations are not met. Actions may include notifying clients or other appropriate parties when requirements for the laboratory are not met (e.g., specimen collection instructions or test request requirements).

Quality Management System Standard of Practice 4 (QMS S4): Quality Indicator Monitoring

COMMENT:

We ask that instead of “laboratory director” it state: laboratory director or delegated assistant director(s)

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

Quality Management System	
Proposed Standard	***Proposed Guidance***
Quality Management System Standard of Practice 5 (QMS S5): System and Process Audits The laboratory must perform internal audits designed to identify systems and processes that do not meet quality goals and performance expectations as defined by the laboratory's Quality Management System (QMS). Standard operating procedures and/or policies must define the audit processes, including, but not limited to: a) audit methods; b) audit frequency, which must be at least annually; c) preventive and/or corrective action of problems and non-conformances identified during the audit process; and d) designation of staff responsible for audits that, to the extent possible, limit personnel from auditing their own activities. ***Regulatory authority: 10 NYCRR subdivision 58-1.2(c) and paragraph 19.3(c)(3)***	The laboratory must perform internal audits. Audits or "mock inspections" that are performed to assess the laboratory's compliance with the requirements of regulatory or accreditation programs may not be used as the only means to meet this requirement. Audits must be performed annually; however, these audits may be performed for specific areas of the laboratory such that the entire laboratory is audited over a two (2) year period.

Quality Management System Standard of Practice 5 (QMS S5): System and Process Audits

COMMENT 1:

Require clarification on frequency for internal audits – Guidance Section "Audits **must** be performed **annually**; however, these audits may be performed for specific areas of the laboratory such that the entire laboratory is audited over a **two (2) year period**.
How is this satisfied?

RESPONSE 1:

The laboratory may audit specific areas/categories of the laboratory (e.g., accessioning or microbiology) annually. If the laboratory chooses to audit specific areas/categories, the entire laboratory must still be covered under the auditing procedure over a 2-year period. For example, if the laboratory holds the following categories: chemistry, microbiology, hematology, and diagnostic immunology, audits could be scheduled for 2020 as accessioning, chemistry, microbiology and for 2021 as hematology, diagnostic immunology, and referral testing areas so that the entire laboratory has been audited over a 2-year period. There is no change to the standard based on the comment received.

COMMENT 2:

QMS S3>QMS S5: Our laboratory appreciates the added clarification speaking specifically to both system and process audits. Our laboratory would like to request that the requirement for internal auditors to be qualified to be retained, as qualified personnel have the skillset to perform according to good auditing practice leading to more productive internal auditing.

RESPONSE 2:

The standard requires designation of staff responsible for audits. There is no change to the standard based on the comment received.

Quality Management System	
Proposed Standard	***Proposed Guidance***
Quality Management System Standard of Practice 6 (QMS S6): Quality Management System Documentation All Quality Management System (QMS) activities must be documented, including: a) quality indicator (QI) identification and monitoring; and b) findings and the actions taken from all audits and inspections.~~; and~~	

~~c) director review of QMS activities as documented by signature and date.~~ ***Statutory authority: Article 5, Title 5 Public Health Law Section 575(2) and (3)*** ***Regulatory authority: 10 NYCRR subdivision 58-1.2(c) and paragraph 19.3(c)(3)***	

Quality Management System Standard of Practice 6 (QMS S6): Quality Management System Documentation

COMMENT 1:
Suggest that the standard be clarified further to indicate that director review of QMS activities may be captured through hard copy signature and date on the associated records and that electronic signature, or an alternative system, may be substituted for hard copy, as long as it is a password protected signature.

RESPONSE 1:
Password protected electronic signature is acceptable documentation of director review. The requirement in the standard has been revised, as managerial review is required under QMS S7.

COMMENT 2:
The guidance was removed from the new standard regarding reports of management review being available for CLEP. The laboratory currently provides internal audit summaries when requested during inspection. Since the guidance was removed with the new standard, please clarify whether these summaries are no longer required to be provided.

RESPONSE 2:
Under QMS S7, managerial review of all QMS activities, including internal systems and process audits and external inspection reports, are required to be available to the department upon request. These documents must be retained for 2 years according to DSR S1. There is no change to the standard based on the comment received.

COMMENT 3:

What directory are you referring to, Laboratory Director or Quality Director?
What exactly do you mean by Director review of QMS activities documented by signature and date? The way the QMS is described in these Standards, it appears to encompass every activity performed in the facility, including operational, quality, and administrative functions. Are you implying that the laboratory director must sign every document and record produced during the course of operating our facility?

RESPONSE 3:

The requirement in the standard has been removed as managerial review is required under QMS S7.

COMMENT 4:

We ask that instead of "director" it state: laboratory director or delegated assistant director(s)

RESPONSE 4:

The requirement in the standard has been revised as managerial review is required under QMS S7. 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)).

Quality Management System	
Proposed Standard	***Proposed Guidance***
Quality Management System Standard of Practice 7 (QMS S7): Management Review Laboratory management must review~~,~~ and document outcomes of findings related to Quality Management System (QMS) activities. The director must set a review schedule. ~~to sign and date the reviews~~ Documentation of laboratory director review	Director review of summarized QMS activities from delegated individuals may be documented through signature and date, or documented attendance at a meeting where the information is discussed. Password protected electronic signatures are acceptable to demonstrate required review.

must be at least annual. Laboratory staff must be informed of management review findings and the resulting decisions. Areas of mandatory management review include: a) quality indicators (QI); b) internal system and process audits; c) external inspection reports; d) changes in workload or test menu; e) proficiency testing (PT) and alternatives to PT to assess test accuracy and reliability; f) nonconformances, including QI that do not meet laboratory performance expectations, and any resulting actions; and g) feedback or suggestions from any source, including complaints. Reports of management review must be retained according to Document and Specimen Retention Standard of Practice 1 and must be available to the Department upon request. ***Regulatory authority: 10 NYCRR subdivision 58-1.2(c) and paragraph 19.3(c)(3)***	

Quality Management System Standard of Practice 7 (QMS S7): Management Review

COMMENT 1:

Require clarification “The Director must set a review schedule to sign and date the reviews”

RESPONSE 1:

A set schedule, as determined by the director, ensures periodic review. The standard has been revised to require laboratory director review at least annually. The laboratory director must review QMS activities, via signature and date, or through documented attendance at a meeting where the information is discussed/presented. Guidance has been added based on the comment received.

COMMENT 2:

Why would we have a schedule for signing and dating reviews? If these reviews are communicated in a presentation format that includes participation by the laboratory director, that should be sufficient. Again, you are forcing us into a single, outdated solution for management reviews.

RESPONSE 2:

A set schedule, as determined by the director, ensures periodic review. The standard has been revised to require laboratory director review at least annually. The laboratory director must review QMS activities, via signature and date, or through documented attendance at a meeting where the information is discussed/presented. Guidance has been added based on the comment received.

COMMENT 3:

The director must set a review schedule to sign and date the reviews.

- The laboratory does not operate as a single entity. We operate under a de-centralized model. Review meetings are established in accordance with established SOPs. It does not make sense for each lab director/permit holder to be signing all management review meetings that took place for the organization.

RESPONSE 3:

The standard has been revised to require laboratory director review at least annually. The laboratory director must review QMS activities, via signature and date, or through documented attendance at a meeting where the information is discussed/presented. Guidance has been added based on the comment received.

COMMENT 4:

We ask that instead of “director” it state: <u>laboratory</u> director or <u>delegated assistant director(s)</u>

RESPONSE 4:

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.

Director Responsibilities

Only comments and responses to the Director Responsibility Standards are included here

Director Responsibilities	
Proposed Standard	***Proposed Guidance***
Director Standard of Practice 1 (DR S1): Compliance with Local, State and Federal Statutes and Regulations The laboratory director and owner are jointly and separately responsible for ensuring that the laboratory complies with all applicable local, state and federal laws, regulations and requirements. ***Statutory authority: Article 5, Title 5 Public Health Law Section 575(3)*** ***Regulatory authority: 10 NYCRR paragraph 19.3(c)(14)***	

Director Standard of Practice 1 (DR S1): Compliance with Local, State and Federal Statutes and Regulations

COMMENT 1:
Require clarification on how the laboratory documents compliance with federal laws.

RESPONSE 1:
Article 5, Title 5 of NYS Public Health Law Section 576(3) requires that the department develop standards and that such standards be at least as stringent as federal standards promulgated under the federal clinical laboratory improvement amendments of nineteen hundred eighty-eight. Federal CMS regulation under CLIA 493.1101 Standard: Facilities (c) states that the laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. There is no change to the standard based on the comment received.

COMMENT 2:

Clarify what jointly and separately means. Is this in regards to legal and financial ramifications for non-compliance? Currently the practice for a laboratory finding during an audit is that the lab director and owner both have to sign off on corrective action from the NYS inspection.

RESPONSE 2:

According to Article 5, Title 5 of NYS Public Health Law, Section 575(3), permits are issued jointly to the owner and the director, and the owner and director are jointly and severally responsible for the maintenance and operation of the clinical laboratory or blood bank. There is no change to the standard based on the comment received.

Director Responsibilities	
Proposed Standard	***Proposed Guidance***
Director Standard of Practice 2 (DR S2): Health Commerce System The laboratory director must: a) obtain and affiliate a Health Commerce System (HCS) account as part of the requirements for a clinical laboratory permit; b) assign an HCS coordinator, either themselves or another person; c) have a standard operating procedure and/or polices for the HCS, including a schedule for maintaining the currency and accuracy of all HCS user accounts for their facility; and d) ensure that all personnel with HCS access agree to comply with the terms of the HCS security and use policies.	Information on obtaining an HCS account is available at: https://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/health-commerce. The HCS coordinator is responsible for requesting additional HCS accounts and assigning personnel roles in the HCS Communications Directory.

Statutory authority: Public Health Law Article 5, Title 5 Sections 575(1)	

Director Standard of Practice 2 (DR S2): Health Commerce System

COMMENT:

Please clarify why an organization is required to have a standard operating procedure for a process that is already in place by CLEP. Why do I need an SOP and schedule for the HCS? It is not appropriate to include these kinds of administrative activities in quality standards.

RESPONSE:

The Health Commerce System (HCS) is a secure website used for many department applications, including communication of important health notification with laboratories/facilities. The requirement for maintaining the accuracy of accounts ensures that the department is able to contact current and appropriate staff. This requirement also assists in ensuring the security of the HCS, as laboratories are responsible for removing staff that are no longer employed at a laboratory/facility. The standard allows for standard operating procedures and/or policies. There is no change to the standard based on the comment received.

Director Responsibilities	
Former Standard and Guidance	***Proposed Standard and Guidance***
Director Sustaining Standard of Practice 2 (DIR S2): Director Affiliations The director shall serve a laboratory full time, or on a regular part-time basis, to perform the duties listed in these Standards, and in 10NYCRR Part 58 and 10NYCRR Part 19. Regular part-time basis shall mean assumption of full responsibility for direction, technical operation and the quality management system of the laboratory. An individual shall serve as director or sole Certificate of Qualification holder for a permit category for no more than two	**Standard deleted** **Required under 10 NYCRR subdivisions 58-1.2(a) and (b)**

clinical laboratories or blood banks, except that a clinical laboratory and blood bank on the same premises shall count as one affiliation, and An individual may be authorized to serve as laboratory director or sole certificate of qualification holder for one or more permit categories for more than two but no more than five laboratories or blood banks, provided: a) the immediate patient care needs of an area can be met only by allowing an individual to exceed the number of directorships allowed; b) the total volume and types of laboratory services provided by the several laboratories are not such as to require the services of more than one director; c) laboratories under the director's oversight are operated in compliance with department requirements. Such authorizations must be renewed biennially. ***Regulatory authority: 10 NYCRR subdivisions 58-1.2 (a) and (b)*** **Guidance -** A sole director is an assistant director who is the only Certificate Qualification holder designated as responsible for a specific laboratory permit category. Regular part-time is considered 20 hours per week of on-site presence. Other arrangements for minimum on-site presence may be considered based on the complexity and volume of testing at the laboratory. Please refer to the guidance provided in Director Sustaining Standard of Practice 1: Director and Assistant Director Involvement and Time Commitment.	

Former Standard (deleted) Director Sustaining Standard of Practice 2 (DIR S2): Director Affiliations

COMMENT 1:
Since the standard was deleted, please clarify if 10 NYCRR subdivisions 58-1.2(a) and (b) remains in place.

RESPONSE 1:
10 NYCRR subdivisions 58-1.2(a) and (b) remains in place. A laboratory's compliance with this requirement is verified prior to issuance of a permit. Laboratories are not eligible to receive a New York State Clinical Laboratory Permit unless this requirement is fulfilled. There is no change based on the comment received.

COMMENT 2:
This standard is proposed as being deleted because it is required under 10 NYCRR subdivisions 58-1.2(a) and (b). It is helpful for the laboratory as well as surveyors to have, as much as possible, a single source of requirements and not be required to reference multiple documents to determine how to be compliant. Recommend this standard not be deleted.

RESPONSE 2:
A laboratory's compliance with this requirement is verified prior to issuance of a permit. Laboratories are not eligible to receive a New York State Clinical Laboratory Permit unless this requirement is fulfilled. There is no change based on the comment received.

Director Responsibilities	
Proposed Standard	***Proposed Guidance***
Director Standard of Practice 4 (DR S4): Director Responsibilities The laboratory director and sole assistant director(s) must ensure compliance with all New York State Clinical Laboratory Standards of Practice. Responsibilities may be delegated in	Director responsibilities are available in Part 19 of 10 NYCRR, available at: https://www.wadsworth.org/regulatory/clep/laws. Director responsibilities related to testing must ~~not~~ be delegated to personnel ~~designated as a technician~~ that are an assistant director or individual that qualifies as a supervisor.

writing by the director ~~to staff, as specified by job title~~. The director remains responsible for all delegated responsibilities and must provide evidence of ongoing evaluation for those delegated duties. The director is responsible for: a) compliance, evaluation and monitoring of laboratory's Quality Management System (QMS) according to New York State Clinical Laboratory Standards of Practice, including but not limited to: i. the appropriateness of laboratory services, including test procedures ~~and the selecting/taking of specimen portions that are appropriate for laboratory tests and~~ that meet the needs of the users of laboratory services; ii. requirements for quality indicators (QI), quality goals and performance expectations; iii. scheduled review of audits, outcomes, management reviews, and on-going monitors of conformance; and b) providing effective administrative direction, including budget planning and controls, in conjunction with the individual(s) responsible for the financial management of the laboratory; c) providing advice to clients regarding the significance of laboratory findings and ensuring that test reports include information required for interpretation; d) monitoring all work performed in the laboratory to ensure that analytically and clinically valid data are generated; e) selecting all reference laboratories; f) ensuring that sufficient and qualified personnel are	

employed including: i. defining the qualifications and responsibilities of all laboratory ~~technical~~ testing personnel and documenting training and/or competency; ii. where applicable, personnel are not engaged in practices limited by license or beyond the scope of licensure; and g) ensuring that supervisors have sufficient time to perform their supervisory functions even if they have testing/bench responsibilities; h) competency assessment of assistant directors and direct-report personnel; i) specifying in writing the technical and administrative responsibilities and duties of all laboratory personnel and comply with all Human Resource Standards of Practice; j) ensuring that all delegated duties are performed by staff at defined intervals, and as needed; k) promoting a safe laboratory environment to protect the public and personnel, including, as required, limited or restricted access; l) providing continuing education to laboratory ~~technical~~ testing personnel that is relevant to laboratory practices; m) ensuring that current and approved test procedures are available and accessible to all personnel; n) effectively implementing a plan of correction to deficiencies identified; o) ensuring that the laboratory complies with all proficiency testing requirements within the New York State Clinical Laboratory Standards of Practice; p) maintaining an effective working relationship with	g) Ability to perform supervisory functions are determined by compliance with requirements in Human Resources Standard of Practice 4. m) Approval of new and revised test procedures may not be delegated by the laboratory director or sole assistant director.

applicable accrediting and regulatory agencies, administrative officials, and the medical community; and q) directors who also function as supervisors must also meet the requirements under Human Resources Sustaining Standard of Practice 4. ***Regulatory authority: 10 NYCRR section 58-1.2 and subdivision 19.3(c)***	

Director Standard of Practice 4 (DR S4): Director Responsibilities

COMMENT 1:

DR S4- Director Responsibilities has omitted that language.
Director Responsibilities includes in the guidance section certain responsibilities that the lab director cannot delegate.
Our laboratory suggests clarification regarding whether the proposed revision means that the lab director can delegate all of their responsibilities to qualified individuals

RESPONSE 1:

All responsibilities may be delegated in writing by the laboratory director, except for signing and approving new and revised test procedures (CMS interpretive guidelines for CLIA regulation 493.1251 (d)). Guidance has been added DR S4 indicating that approval of new and revised test procedures may not be delegated by the laboratory director or sole assistant director. For any delegated responsibilities, the laboratory director is responsible for ensuring that delegated responsibilities are performed by staff (CLIA 493.1407(b) and 10NYCRR 19.3(c)).

COMMENT 2:

We ask that instead of “laboratory director and sole assistant director(s)” it state: laboratory director, sole assistant director(s) or delegated assistant director(s)
In the current version of the standard guidance, there is a list of items the director may not delegate. Can you also list any activities that may not be delegated in the guidance section.

RESPONSE 2:

According to interpretive guidelines for CLIA 493.1251 (d), approval of test procedures and changes to test procedures is the responsibility of the laboratory director and this responsibility cannot be delegated. For New York State Clinical Laboratory Permit holders, this responsibility must be fulfilled by the laboratory director or sole assistant director. All other responsibilities may be delegated in writing by the director. The laboratory director is responsible for ensuring that delegated responsibilities are performed by staff (CLIA 493.1407(b) and 10NYCRR 19.3(c)). Guidance has been added to the standard based on the comment received.

COMMENT 3:

The proposed language "Responsibilities may be delegated in writing by the director to staff, as specified by job title" should be changed to "as specified by job title OR NAME". In many instances job titles alone do not link to all activities that may be delegated by the laboratory director and individuals with the same job title are not delegated the same responsibilities. Recommend allowing delegation to be assigned by name or job title because of the lack of correlation between job title and activities.

RESPONSE 3:

The requirement of the standard has been changed to indicate that responsibilities are delegated in writing by the director. The laboratory director is responsible for ensuring that delegated responsibilities are performed by staff (CLIA 493.1407(b) and 10NYCRR 19.3(c)).

COMMENT 4:

A statement has been added that " Director responsibilities must not be delegated to personnel designated as a technician." Please clarify. Does this mean that the director can only delegate to someone who is a Certified Technologist and above, regardless of experience and education?

RESPONSE 4:

Based on the comment received, the language in the guidance has been changed to state that director responsibilities related to testing must be delegated to personnel that are an assistant director or an individual that qualifies as a supervisor.

COMMENT 5:

Question/Comment: What are the requirements of the staff that can be delegated to perform these duties (specific education or experience)? Can detailing the duties in the job description and having the Director sign be the equivalent of delegating in witting or having a formal competency document?

RESPONSE 5:

The laboratory director is responsible for determining the appropriate staff and qualifications when delegating duties. Director responsibilities related to testing must be delegated to personnel that are an assistant director or an individual that qualifies as a supervisor. Delegation of duties by the laboratory director must be documented in writing. The laboratory director is responsible for ensuring that delegated responsibilities are performed by staff (CLIA 493.1407(b) and 10NYCRR 19.3(c)). An example of delegation could be the inclusion of responsibilities in a job description which is approved by the laboratory director, constituting delegation in writing. The guidance has been revised based on the comment received.

COMMENT 6:

Regarding (a)(i): What does this mean? Selection/taking of specimen portions that meet the needs of users of the laboratory services???

RESPONSE 6:

This requirement was formerly under Validation Sustaining Standard of Practice 1, Selection of Examination Procedures and stated: The laboratory shall use examination procedures, including those for selecting/taking specimen portions appropriate for the examinations, which meet the needs of the users of laboratory services. The language in the standard has been changed based on the comment received.

COMMENT 7:

Regarding (b): Why does NYS dictate who manages the finances of our organization and why do you think it has to be the laboratory director? In large organizations, the Laboratory Director may not play this role even within the laboratory that they direct.

RESPONSE 7:

This laboratory director responsibility is required under 10NYCRR Section 19.3(c)(12) and states: provide effective administrative direction of the laboratory, in conjunction with the individual(s) responsible for financial management of the laboratory, to ensure adequate resources are available to operate the laboratory in a manner consistent with all state and federal requirements. This

responsibility may be delegated in writing by the laboratory director to the appropriate person within a facility/organization. The standard has not been changed based on the comment received.

Director Responsibilities	
Proposed Standard	***Proposed Guidance***
Director Standard of Practice 5 (DR S5): Document and Records Accessibility The laboratory director and owner are jointly and separately responsible for ensuring that all standard operating procedures, policies, manuals, plans, corrective actions, investigations and any other associated documents are: a) available for the recreation of the test process for reported specimens; b) available to the Department for review within twenty-four (24) hours of the Department's request; c) provided for the Department's records when requested; and d) compliant with Document and Specimen Retention Standards of Practice or according to other applicable state and federal requirements, whichever is longer. ***Statutory authority: Article 5, Title 5 Public Health Law Section 577*** ***Regulatory authority: 10 NYCRR subdivisions 58-1.10(c) and 58-1.11(c)***	Off-site or electronic storage systems are acceptable, provided the laboratory can produce duplicates within twenty-four (24) hours of a request from the Department.

Director Standard of Practice 5 (DR S5): Document and Records Accessibility

COMMENT 1:

Define “Laboratory Director and Owner are jointly and separately responsible…”
b) Comment - Document and Record Accessibility within twenty-four (24) of the Department’s request – maybe too short notice. Off-Site Storage Facilities maybe out of state. Very limited time and may not be reasonable.

RESPONSE 1:

According to Article 5, Title 5 of NYS Public Health Law, Section 575(3), permits are issued jointly to the owner and the director, and the owner and director are jointly and severally responsible for the maintenance and operation of the clinical laboratory or blood bank. The requirement for availability of requested records within 24 hours is mandated in 10 NYCRR 58-1.11(c). The standard has not been changed based on the comment received. The suggestion will be considered when future regulation revisions are deliberated.

COMMENT 2:

The new standard requirement for having documents available for review within 24 hours is not practical when documents are stored in off-site facilities. FDA allows 48 hours to provide documents. Please clarify what would occur if requested documents cannot be available within this timeframe.

RESPONSE 2:

The requirement for availability of requested records within 24 hours is mandated in 10 NYCRR 58-1.11(c). The standard has not been changed based on the comment received. The suggestion will be considered when future regulation revisions are deliberated.

COMMENT 3:

Can you please put some parameters around this? If you show up on a Saturday night and request an old, archived record that has been sent for off-site storage, it may take longer than 24 hours to physically retrieve it. Unless there is a critical emergency that impacts the safety of a patient, why the urgency?

RESPONSE 3:

The requirement for availability of requested records within 24 hours is mandated in 10 NYCRR 58-1.11(c). The standard has not been changed based on the comment received. The suggestion will be considered when future regulation revisions are deliberated.

Human Resources

Only comments and responses to the Human Resources Standards are included here

Human Resources	
Proposed Standard	***Proposed Guidance***
Human Resources Fundamental Standard of Practice (HR FS): Staff Qualifications The laboratory must have effective leadership and personnel with the education, training and experience necessary for the delivery of laboratory services. ***Statutory authority: Public Health Law Article 5, Title 5 Sections 575(2) and (3)***	~~Technical~~ Testing personnel credentials, duties and responsibilities are specified in 10 NYCRR Part 19 and in the following subdivisions of 10 NYCRR Part 58: 58-1.2 Laboratory director~~,~~ 58-1.3 Clinical laboratory supervision~~,~~ 58-1.4 Qualifications of laboratory supervisor~~,~~ and 58-1.5 Duties and qualifications of clinical laboratory technical personnel. 10 NYCRR Parts 19 and 58 ~~is~~ are available at: https://www.wadsworth.org/regulatory/clep.

Human Resources Fundamental Standard of Practice (HR FS): Staff Qualifications

COMMENT 1:

I would like to state a negative is the requirement that supervisors must have 6 years-experience, has been unchanged. In the NYS laboratories, personnel are turned off that they must wait 6 years to be promoted. They can go to other states, and get a supervisory position with much less. We are struggling to keep talent but if unable to promote this talent, they will go elsewhere or other types of jobs and not even enter the MLS field.

RESPONSE 1:

Six years of experience for a laboratory supervisor is required under 10NYCRR Section 58-1.4. The New York State Clinical Laboratory Standards of Practice must be as stringent as required by regulation. The suggestion will be considered when future regulation revisions are deliberated. There is no change to the standard based on the comment received.

COMMENT 2:

Ask that the guidance have separate lines for positions – easier to read.
Technical personnel credentials, duties and responsibilities are specified in 10 NYCRR Part 19 and in the following subdivisions of 10 NYCRR Part 58:
58-1.2 Laboratory director,
58-1.3 Clinical laboratory supervision,
58-1.4 Qualifications of laboratory supervisor, and
58-1.5 Duties and qualifications of clinical laboratory technical personnel.

RESPONSE 2:

The guidance has been revised based on the comment received to show relevant sections of 10 NYCRR Part 58 on individual lines.

COMMENT 3:

What is the intent of the word “effective” under the heading of staff qualifications? How do intend to evaluate the effectiveness of leadership? This can be quite subjective.

RESPONSE 3:

Effectiveness of an individual is assessed through competency assessments, as outlined within these standards. There is no change to the standard based on the comment received.

Human Resources	
Proposed Standard	***Proposed Guidance***
Human Resources Standard of Practice 1 (HR S1): Organization Charts and Job Descriptions Laboratory management must have an organizational chart(s) and job descriptions for all personnel. Job descriptions must be: a) consistent with responsibilities and duties described in the New York State Clinical Laboratory Standards of Practice; and b) specified in writing for all ~~personnel~~ positions and titles within the laboratory, including positions/titles held by consultants. ***Regulatory authority: 10 NYCRR paragraph 19.3(c)(6) and subdivision 58-1.2(d)***	Job descriptions should include, but are not limited to: specimen collection personnel; ~~technical~~ testing personnel; supervisors; laboratory managers; administrators; assistant director(s); and laboratory director(s).

Human Resources Standard of Practice 1 (HR S1): Organization Charts and Job Descriptions

COMMENT 1:

- The standard implies that job descriptions need to be a 1:1 for each employee. Please clarify how a large organization would manage such a task.

RESPONSE 1:

Job descriptions are required for all positions/titles. The language of the standard has been modified based on the comment received.

COMMENT 2:

Are you really expecting a job description for every consultant that we may hire for a particular task or project??? Or are you specifically referring to the CLIA role of "technical consultant"

RESPONSE 2:

Job descriptions are required for all positions/titles. The language of the standard has been modified based on the comment received.

Human Resources	
Proposed Standard	***Proposed Guidance***
Human Resources Standard of Practice 2 (HR S2): Personnel Records The laboratory must document dates of employment for testing personnel and verify the following~~for all personnel~~: a) relevant licensure when required by state law; and b) educational and professional qualifications.~~; and~~ c) ~~dates of employment.~~ Personnel records must be retained according to Document and Specimen Retention Standard of Practice 2. ***Regulatory authority: 10 NYCRR subdivision 58-1.2(d)***	Duties and qualifications for laboratory supervisors and cytology supervisors are described 10 NYCRR subpart 58-1, available at www.wadsworth.org/regulatory/clep. Requirements for licensure through the New York State Education Department are available at: www.op.nysed.gov. For out-of-state laboratories: diplomas, transcripts, curriculum vitae, and/or work history; letters from former employers; or other records should be maintained to establish that education and experience requirements have been met. If the diploma does not state the specific academic major, then transcripts are required. Individuals educated in a college or university outside the United States should refer to the CLEP Program Guide for a description of acceptable credentials and evaluation policies, available at: https://www.wadsworth.org/regulatory/clep.

Human Resources Standard of Practice 2 (HR S2): Personnel Records

COMMENT:

What do you mean by verifying dates of employment? Are you asking us to verify dates of employment at previous jobs when we hire? What are you expecting to see here?

RESPONSE:

Dates of employment are required to demonstrate the experience needed to qualify personnel for the position of supervisor. The language of the standard has been modified based on the comment received.

Human Resources	
Proposed Standard	***Proposed Guidance***
Human Resources Standard of Practice 3 (HR S3): Supervisor Staffing The laboratory must have a supervisor or supervisor-qualified individual ~~technologist~~, as delegated by the laboratory director in writing ~~by job title~~, that is on the laboratory premises during all hours in which tests are performed. This requirement does not apply to testing for emergency purposes, provided: a) the person performing the test qualifies as a clinical laboratory technologist; b) the director has defined requirements for supervisory review of test results, including quality control; c) the results are reviewed by the supervisor or director during his or her next duty period; and d) a record is maintained to reflect review by the	For emergency testing performed without a supervisor on-site, the director should establish the maximum time period between reporting of test results and the review.

supervisor or director. ***Regulatory authority: 10 NYCRR subdivision 58-1.3(d)***	

Human Resources Standard of Practice 3 (HR S3): Supervisor Staffing

COMMENT 1:
HR S3 still requires on-site supervision and it is difficult for her lab to meet this requirement.

RESPONSE 1:
On-site supervision is required under 10NYCRR Section 58-1.3 (d). The New York State Clinical Laboratory Standards of Practice must be as stringent as required by regulation. The suggestion will be considered when future regulation revisions are deliberated. There is no change to the standard based on the comment received.

COMMENT 2:
c) Question – would a 72 hour period be acceptable if Supervisor worked last on Friday night and possible not returned till Tuesday due to holidays that may fall on Monday?

RESPONSE 2:
As guidance states, for emergency testing, the director should establish the maximum time period between reporting of test results and the review. There is no change to the standard based on the comment received.

COMMENT 3:
Question/Comment: What are the expectations for how this must be delegated in writing or is this at the discretion of the facility (exmples, written delegation form versus competency documents versus sign job description)?

RESPONSE 3:
Delegation of this responsibility must be documented in writing. The laboratory director must ensure that testing responsibilities are delegated to an individual that is an assistant director or individual that qualifies as a supervisor. The laboratory director is responsible for ensuring that delegated responsibilities are performed by staff (CLIA 493.1407(b) and 10NYCRR 19.3(c)).

COMMENT 4:

We ask that instead of “director or supervisor” it state: supervisor, assistant director(s) or director.
In the Guidance section we ask that instead of “director” it state: assistant director(s) or director.
I addition, if he intent is that the Guidance applies to testing for “emergency purposes“, then we request that this information be added to the Guidance section.
Guidance – For emergency testing performed without a supervisor on-site, the assistant director or director should establish the maximum time period between reporting of test results and the review.

RESPONSE 4:

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 language of the requirements. The guidance applies to emergency testing and the language has been modified based on the comment received.

COMMENT 5:

The proposed language "The laboratory must have a supervisor or supervisor-qualified technologist, as delegated in writing by job title, that is on the laboratory premises during all hours in which tests are performed." should be changed to "as delegated in writing by job title OR NAME". In many instances job titles alone do not link to all activities that may be delegated by the laboratory director and individuals with the same job title are not delegated the same responsibilities. Recommend allowing delegation to be assigned by name or job title because of the lack of correlation between job title and activities.

RESPONSE 5:

Based on the comment received, the language in the standard has been changed to indicate that the laboratory director may delegate responsibilities in writing. The laboratory director is responsible for ensuring that delegated responsibilities are performed by staff (CLIA 493.1407(b) and 10NYCRR 19.3(c)).

Human Resources	
Proposed Standard	***Proposed Guidance***
Human Resources Standard of Practice 4 (HR S4): Supervisor Responsibilities Laboratory supervisors must fulfill the requirements of this Standard. Responsibilities may be delegated in writing to an individual that qualifies as a laboratory supervisor but does not hold the title of laboratory supervisor. Supervisors remain responsible for all delegated activities and must provide evidence of ongoing evaluation for those duties at regular intervals, as defined by the laboratory director. Laboratory supervisor responsibilities include: a) supervising testing personnel; b) monitoring and ensuring that acceptable performance specifications are maintained, including: i. review of quality control; ii. scheduled instrument and equipment maintenance; iii. other quality assurance activities as assigned; and c) ensuring test system performance: i. by initiating preventive and/or remedial actions when test procedures deviate from the laboratory's established performance specifications; ii. in the event of non-conformances, ensuring that test results are not reported until corrective action has been taken and the test is performing	Qualifications for laboratory supervisors and cytology supervisors are described 10 NYCRR Part 58, available at: https://www.wadsworth.org/regulatory/clep/laws. For individuals not previously qualified under 10 NYCRR Part 58 to serve as a technologist or cytotechnologist, the experience requirement must be met subsequent to obtaining a license issued by the New York State Education Department. Personnel assigned ~~technical~~ testing supervisory duties must meet the education and experience requirements of a supervisor regardless of the title (i.e., lead tech) the laboratory uses for the position.

according to laboratory established performance specifications; and d) verifying that personnel are trained and deemed proficient prior to performing testing on patient specimens independently; e) ensuring that staff have competency assessments as needed; and f) ensuring action is taken when personnel do not perform as expected on competency assessments. ***Regulatory authority: 10 NYCRR sections 58-1.3 and 58-1.4***	

Human Resources Standard of Practice 4 (HR S4): Supervisor Responsibilities

COMMENT:

Question/Comment: What are the expectations for how this must be delegated in writing or is this at the discretion of the facility (exmples, written delegation form versus competency documents versus sign job description)?

RESPONSE:

Delegation of supervisor responsibility must be documented in writing. Examples of delegation documentation include a signed delegation memo, tasks listed in the delegate's job description and approved by the director, a written policy document or standard operating procedure. The laboratory director is responsible for ensuring that delegated responsibilities are performed by staff (CLIA 493.1407(b) and 10NYCRR 19.3(c)). Staff performing these functions must meet the qualifications required for a supervisor, but do not need to have the title of supervisor.

Human Resources	
Proposed Standard	***Proposed Guidance***
Human Resources Standard of Practice 5 (HR S5): Testing Personnel Responsibilities Testing personnel must fulfill the requirements of this Standard. Testing personnel responsibilities include: a) following the laboratory's pre-analytic and analytic procedures and maintaining records of tests; b) maintaining records that demonstrate that proficiency testing samples are tested in the same manner as patient specimens; c) adhering to the laboratory's quality assurance procedures, including documenting all: i. quality control activities; ii. instrument and equipment verifications; iii. maintenance and preventive maintenance; and d) following the laboratory's policies and procedures whenever test systems are not within the laboratory's established performance specifications; e) identifying and documenting problems that may adversely affect test performance and notifying the supervisor, assistant director(s) or director; and f) documenting all corrective actions taken when test systems deviate from the laboratory's established performance specifications. ***Regulatory authority: 10 NYCRR section 58-1.5***	

Human Resources Standard of Practice 5 (HR S5): Testing Personnel Responsibilities

COMMENT:

We ask that instead of "supervisor or director" it state: supervisor, **assistant director(s) or** director.

RESPONSE:

The requirement of the standard has been modified based on the comment received.

Human Resources	
Proposed Standard	***Proposed Guidance***
Human Resources ~~Sustaining~~ Standard of Practice 6 (HR S6): Training for Testing and Non-~~testing technical~~ Personnel Laboratory management must have standard operating procedures for the training and documentation of training for all testing and non-~~testing technical~~ staff. Personnel must be trained and deemed proficient in all tasks for which they are responsible. Training of testing personnel must be performed at the site where they perform their job, and re-training must be performed anytime that the test method or instrument changes. Training must be documented for all personnel, including healthcare providers performing testing at the point of care, staff engaged in the performance of supportive tasks such as data entry, accessioning and reporting, and supervisory and management staff. Training, and documentation of such, must include the following:	See specialty standards for additional training requirements, including blood and transfusion services. Off -site ~~Technical~~ testing training, for example by test system manufacturers, ~~(e.g.,~~ super user, ~~or~~ train the trainers~~)~~, training at other networks/affiliates/health care systems or through industry-sponsored workshops can be used in addition to ~~cannot be substituted for~~ documentation of on-site specific training ~~calibration, quality control and maintenance training and demonstration of technical proficiency~~. Following off-site training, staff must still demonstrate testing capabilities (e.g., calibration, quality control and maintenance training and demonstration of testing proficiency) at the site where testing is performed through the documentation required to meet this standard.

a) date of training and date deemed proficient to perform tasks; b) objectives of training; c) methods to be used in training; d) materials to be used in the training; e) data ~~ethics and~~ integrity; and f) criteria to assess the effectiveness of training and personnel proficiency prior to clearing them to perform tasks independently. Documentation of training must be retained according to Document and Specimen Retention Standard of Practice 2. ***Regulatory authority: 10 NYCRR subdivision 58-1.2(d)***	

Human Resources Standard of Practice 6 (HR S6): Training for Testing and Non-testing Personnel

COMMENT 1:

Per HR S6, training of testing personnel must be performed at the site where they perform their job. We do have some trainings performed by the vendors via webinars, and even trainings/demonstration at the vendor location, followed up competency assessment at our actual task location. Are those formats no longer allowed?
We are also confused about how to interpret this guidance for compliance.

- Is manufacturer training no longer acceptable? But we do need manufacturer trainings for many of our test systems at the beginning before we can train the rest of the team ourselves.
- Or does it mean for training documentation specifically? I.e. vendor training certificates are not sufficient. We need to document the vendor training using our training checklists, including objectives, methods, materials, and criteria. But how can each lab controls all outside vendors fully understand each company-specific training checklists and document accordingly?
- Or does it mean vendor must come onsite for training regardless?

RESPONSE 1:

Staff may participate in off-site training and webinars. In order to meet the requirements of the standard, staff must still demonstrate testing capabilities (e.g., calibration, quality control, maintenance training, demonstration of testing capability, etc.) at the site where

testing is performed and include on-site documentation of training. Vendor approved training onsite may be solely used if the laboratory has reviewed and attests (via signing) that the training covers all onsite specific requirements such as type and frequency of quality control, frequency of calibration, etc. The guidance of the standard has been revised based on the comment received.

COMMENT 2:

The standard states that training must be performed at the site where staff perform their job. There are some instances where staff may need to go to another facility to complete on-the-job training (OJT). Our laboratory recommends that the standard be revised to allow situations where equivalent training can be performed at another facility.

RESPONSE 2:

Staff may participate in OJT at another facility. In order to meet the requirements of the standard, staff must still demonstrate testing capabilities (e.g., calibration, quality control, maintenance training, demonstration of testing capability, etc.) at the site where testing is performed and include on-site documentation of training. The guidance of the standard has been revised based on the comment received.

COMMENT 3:

Question/Comment: If vendor training is performed offsite but competency assessed onsite, is this acceptable? There are times when we implement a new platform and training is performed at the vendors' facility. This may also be an issue with training across sites (labs have the same procedures and processes).

RESPONSE 3:

Staff may participate in off-site/vendor training. In order to meet the requirements of the standard, staff must still demonstrate testing capabilities (e.g., calibration, quality control, maintenance training, demonstration of testing capability, etc.) at the site where testing is performed and include on-site documentation of training. The guidance of the standard has been revised based on the comment received.

COMMENT 4:

- Personnel must be trained and deemed proficient in all tasks for which they are responsible. Training of testing personnel must be performed at the site where they perform their job.

- Our laboratory has multiple laboratories where training can occur. All corporate SOPs are uniform under a single Document Management System, are utilized consistently throughout the laboratory, and are readily available electronically and can be accessed at any time. It is not helpful and a waste of time to train an individual on the same SOP multiple times at each lab with which they perform testing. Please clarify if the same training is to be given to staff when working in different laboratories but under the same SOPs.
- Please clarify the definition for non-technical personnel.

RESPONSE 4:

Staff may participate in off-site training at another lab/facility. In order to meet the requirements of the standard, staff must still demonstrate testing capabilities (e.g., calibration, quality control, maintenance training, demonstration of testing capability, etc.) at the site where testing is performed and include on-site documentation of training. The guidance of the standard has been revised based on the comment received. Non-technical has been changed to non-testing based on the comment received. Non-testing personnel do not engage in laboratory analytic systems.

COMMENT 5:

How do you expect the person who was trained by the test system manufacturer to be trained if no one else in the laboratory is already familiar with it? Are you saying that the manufacturer has to provide the training at the lab's facility, not their own? Or that the lab staff, who are themselves not trained has to provide that training instead of the manufacturer?

RESPONSE 5:

Staff may participate in off-site manufacturer training. In order to meet the requirements of the standard, staff must still demonstrate testing capabilities (e.g., calibration, quality control, maintenance training, demonstration of testing capability, etc.) at the site where testing is performed and include on-site documentation of training. For training that is performed at the vendors facility, personnel coming back to the laboratory would be required to have an addendum to this training that would outline this sites director's requirements for type and frequency of quality control, frequency of calibration, maintenance, etc. which may be more stringent. The guidance of the standard has been revised based on the comment received.

COMMENT 6:

If personnel work at multiple testing sites under the same management and exact same procedures, are you expecting us to repeat and document the same training at each site?

RESPONSE 6:

In order to meet the requirements of the standard, staff must still demonstrate testing capabilities (e.g., calibration, quality control, maintenance training, demonstration of testing capability, etc.) at the site where testing is performed and include on-site documentation of training. If staff work at multiple sites, training must occur and be documented at each testing site. The guidance of the standard has been revised based on the comment received.

COMMENT 7:

Data ethics appears to be a training topic, not a step in the training process itself. This is out of place in your list.

RESPONSE 7:

The term ethics has been removed from the standard based on the comment received.

COMMENT 8:

We would like the following guidance to remain in the standard.
Guidance - Training should also be provided on ensuring data ethics and integrity. Data integrity is defined as: generating, transforming, maintaining and assuring the accuracy, completeness and consistency of data for a specimen over its entire life cycle (i.e., from collection to reporting and including quality assessment and improvement) in compliance with applicable regulations. Data, in this instance, is meant to encompass all manner of data generated to produce a test result.
Also, please include the definition of "Data Ethics" in the definitions.

RESPONSE 8:

The definition for data integrity appears in the definitions section of the standards. There is no change to the standard based on the comment received.

COMMENT 9:

Under Section E of this standard, the components of “data ethics and integrity” are outlined as a necessary component that should be included in training of personnel. We interpret this component as dealing with the handling and protection of PHI and with LIS measures in place to protect any PHI.

Is the above interpretation accurate? Can you please offer some clarity as to what exactly is referenced by 'data ethics and integrity' and what measures need to be in place to meet this requirement?

RESPONSE 9:

Data integrity is essential to the test process and defined as: Generating, transforming, maintaining and assuring the accuracy, completeness and consistency of data for a specimen. Data encompass all information collected, and data generated, to produce a test result. The term ethics has been removed from the standard based on the comment received.

COMMENT 10:

Comment: Regulation title includes the word sustaining however it is removed from all other HR standards of practice (HR S1-HR S10)

RESPONSE 10:

The word Sustaining has been removed from the title of the standard based on the comment received.

Human Resources	
Proposed Standard	***Proposed Guidance***
Human Resources Standard of Practice 7 (HR S7): Competency Assessment – Supervisory Personnel Supervisors must be assessed in their responsibilities according to Human Resources Standard of Practice 4 and their competency documented. Competency assessments must be performed annually for all tasks for which the supervisor is responsible and include, as applicable: a) the date of the assessment; b) compliance with policies and procedures; c) communication, including bringing problems and non-	If a supervisor or director/assistant director also functions as testing personnel, he or she must also be competency assessed for those ~~technical~~ functions as required in Human Resources Standard of Practice 8. ~~Technical~~ Testing personnel performing delegated supervisory functions must also be competency assessed for those supervisory functions.

conformities to the attention of laboratory management; d) leadership and problem-solving capabilities; e) allocation of assets for effective daily laboratory operations; and f) personnel management. Competency assessments must be performed by delegated ~~supervisory staff, as specified by job title,~~ supervisor qualified staff or the director or assistant director(s). For direct report supervisors and assistant directors, the laboratory director must approve these competencies. Documentation of competency must be retained according to Document and Specimen Retention Standard of Practice 2. ***Regulatory authority: 10 NYCRR subdivision 58-1.2(d)***	

Human Resources Standard of Practice 7 (HR S7): Competency Assessment – Supervisory Personnel

COMMENT 1:

Question/Comment: We have a large number of competency assessments that our technical staff must complete annually and these are currently being performed by CLIA delegated staff. Is this requirement stating that only supervisor delegated staff (BS degree with 6 years of exp) can perform all competencies?

RESPONSE 1:

Competency assessments must be performed by delegated supervisory qualified staff, the director or assistant director(s). There is no change to the standard based on the comment received.

COMMENT 2:

- Competency assessments must be performed by delegated supervisory staff, as specified by job title, or the director or assistant director(s).

- Please clarify whether all supervisory staff must perform all assessments. A Technologist who is a subject matter expert should be able to administer competency assessments. A supervisor will still be required to review the assessment.

RESPONSE 2:

A technologist that has been delegated this duty in writing and that is supervisor qualified may perform competency assessments. There is no change to the standard based on the comment received.

COMMENT 3:

The proposed language “Competency assessments must be performed by delegated supervisory staff, as specified by job title” should be changed to “as specified by job title OR NAME". In many instances job titles alone do not link to all activities that may be delegated by the laboratory director and individuals with the same job title are not delegated the same responsibilities. Recommend allowing delegation to be assigned by name or job title because of the lack of correlation between job title and activities.

RESPONSE 3:

Based on the comment received, the language in the standard has been changed to indicate that delegated staff (supervisor qualified, director or assistant director(s)) perform competency assessments. The requirement for specification by job title has been deleted. The laboratory director is responsible for ensuring that delegated responsibilities are performed by staff (CLIA 493.1407(b) and 10NYCRR 19.3(c)).

Human Resources	
Proposed Standard	***Proposed Guidance***
Human Resources Standard of Practice 8 (HR S8): Competency Assessment – Testing Personnel Testing personnel must be assessed in their responsibilities according to Human Resources Standard of Practice 5, and their competency documented. Competency assessments must be performed at least semiannually during the first year the individual tests patient	Documentation of the personnel’s test performance on the competency assessment must contain enough specific detail so that the evaluation can be substantiated. When using previously analyzed specimens or samples, such as quality controls or previously reported proficiency testing samples, documentation must include both the original testing and competency assessment test results.

specimens and annually thereafter. If there is a change to the test method or instrument, that causes testing personnel to alter their test process, ~~the individual's~~ competency must be reevaluated and documented prior to reporting patient test results~~,~~ and include use of the new test method or instrument. Competency assessments of testing personnel must be performed at the site where personnel perform their job. Competency assessments must be performed ~~by direct observation of~~ for all tasks for which the testing personnel are responsible and include, as applicable: a) the date of the assessment and the ability to recreate the test process used for the competency; b) assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; c) direct observation of employee's duties by supervisor qualified staff for compliance with each test procedure~~s~~ performed; d) direct observation of compliance with safe practices required to perform specimen testing; e) direct observation of compliance with procedures for instrument maintenance and function checks and/or ~~preventative~~ preventive maintenance and proper documentation, as applicable; f) review of intermediate test results or worksheets, quality control records and proficiency testing results; g) recording and reporting of test results; h) assessment of problem-solving skills; and i) assessment of competency of any delegated supervisory functions.	Competency assessment must be performed and documented for all laboratory personnel, including healthcare providers performing testing at the point of care.

Competency assessments must be performed by delegated supervisor~~y~~ qualified staff, ~~as specified by job title, or~~ the laboratory director or assistant director(s). For direct report supervisors and assistant directors, the laboratory director must approve these competencies. Documentation of competency must be retained according to Document and Specimen Retention Standard of Practice 2. ***Regulatory authority: 10 NYCRR subdivision 58-1.2(d)***	

Human Resources Standard of Practice 8 (HR S8): Competency Assessment – Testing Personnel

COMMENT 1:

The standard states that competency assessments must be performed by direct observation of all tasks for which the testing personnel are responsible and include, as applicable:
If techs are directly observed and found to be competent to perform a specific task (ex. type and screen, DAT) is it required to perform a direct observation of the tech performing proficiency testing where these same tests may be performed?
Does a direct observation need to be performed for each point of competency or just for the various tests that the tech performs?

RESPONSE 1:

The requirements for direct observation in the standard have been changed based on the comment received.

COMMENT 2:

It stated that the lab director must approve these competencies. Does it mean that the lab director must approve the competency checklist content or approve the competency results of each applicable staff?

RESPOSNE 2:

The director must approve competencies for staff that they supervise directly. There is no change to the standard based on the comment received.

COMMENT 3:

Clarification of “task”- We would like a definition or the expectations involved. Does the word “task” refer to every test, for example a Complete Metabolic Panel and a Lipid Panel which are both performed on the same instrument in the same manner, or does it refer to one platform or methodology that all those parameters are evaluated on?

RESPONSE 3:

Staff must be competency assessed on each procedure they have been trained to perform. For example, if a test procedure includes tasks such as preparation of solutions and samples, use of a balance for weighing, instrument maintenance, testing, and data review, then these responsibilities must be competency assessed. If separate test methods are performed on the same platform, each test method would be competency assessed. There is no change to the standard based on the comment received.

COMMENT 4:

Reword to: If there is a significant change to the test method or instrument, which would require the analyst to make a new or different safety or analytical decision, it may require reevaluation of an individual’s competence. If competence is checked, then it must be documented.

We are required to hire properly educated people and properly train and assess their competency before allowing them to test live patient samples. Part of being competent is being able to read and comprehend what they are reading. Methods on instruments are usually pre-programmed and labeled a specific name. An analyst just needs to pick the appropriate named test to run. They do not have to program an instrument with temperature ramps or pressure changes in order to run a test a validated test. There are other ways to make sure that the method that they are picking is also the correct method to run the test and not check line by line that it is the same validated test. Currently, if anything within a method has been changed, part of the requirement is that analysts that perform that method must read and acknowledge that they understand that change within the method. If there is an change which is not visible to an analyst since it is "inside" a secure method, there would be no need for a competency. It would be considered inconsequential to the analyst since they have nothing to do with the change and it is invisible to them. When an analyst is performing a test, they are required to have the method or bench excerpt in front of them. So as long as they are reading and following the test method/bench excerpt and picking an already programmed method on an instrument, there is no reason to competency them after a minor or "invisible" change. If there is a change where they are handling a different chemical with new and specific safety concerns, then it would be appropriate to make sure that they understand what new safety precautions would be needed during the test.

RESPONSE 4:

Based on the comment received, the standard has been modified to indicate that when changes that require testing personnel to alter their test process, competency must be reevaluated and documented prior to reporting patient test results and include use of the new test method or instrument.

COMMENT 5:

Question: Procedures of Competency Assessment are not in line with other regulatory and accreditation bodies (CLIA, CAP), due to the removal of (i) direct observation of employees duties by supervisory staff (v) direct observation of performance of instrument maintenance and function checks (vi) assessment of test performance through testing of previously analyzed specimens, internal blind, or external proficiency testing samples as procedures for the evaluation of competency. Although assessment of test performance through testing of previously analyzed specimens, internal blind, or external proficiency testing samples has been omitted the guidance includes this procedure; was this an oversight in the standard?

RESPONSE 5:

The requirements for direct observation in the standard have been changed based on the comment received.

COMMENT 6:

Question: Should testing personnel's' competency assessments be based on the tests/test systems ***and*** tasks that they perform? (Define tasks since the use of tests/ test systems have not been used)

RESPONSE 6:

Competency must be assessed on each test performed and all tasks for which the staff is responsible. If a test procedure includes tasks such as preparation of solutions and samples, use of a balance for weighing, instrument maintenance, testing, and data review, then these responsibilities must be competency assessed. There is no change to the standard based on the comment received.

COMMENT 7:

Question: Do we need to apply each of the listed Procedures of Competency Assessment for each test, test system or task performed unless not applicable?

RESPONSE 7:

Competency assessments must be performed for each test and task for which the staff member is responsible. There is no change to the standard based on the comment received.

COMMENT 8:

Question: How can e) review of intermediate test results or worksheets, quality control records and proficiency testing results, f) recording and reporting of test results be reviewed by a direct observation as these are record reviews?

RESPONSE 8:

The requirements for direct observation in the standard have been changed based on the comment received.

COMMENT 9:

- Competency assessments of testing personnel must be performed at the site where personnel perform their job.
    - Our laboratory has multiple laboratories where training can occur. All corporate SOPs are uniform under a single Document Management System, are utilized consistently throughout the laboratory, and are readily available electronically and can be accessed at any time It is not helpful and a waste of time to perform a competency on an individual for the same SOP multiple times at each lab with which they perform testing. Please clarify how this is to be managed.

RESPONSE 9:

Competency assessments must be performed at the site where staff perform testing. If staff work at multiple testing sites, competency assessments must be performed at each facility (PFI) where testing is performed by that staff member. There is no change to the standard based on the comment received.

COMMENT 10:

If staff work at multiple sites under same management and procedures, does the same competency have to be repeated at each location?

RESPONSE 10:

Competency assessments must be performed at the site where staff perform testing. If staff work at multiple testing sites, competency assessments must be performed at each facility (PFI) where testing is performed by that staff member. There is no change to the standard based on the comment received.

COMMENT 11:

Do you really mean that all competency assessment activities are by direct observation and only direct observation? Direct observation works well for verifying technical skills, but is less useful to evaluate judgement, knowledge, review of worksheets, reporting of results and other clerical, administrative activities.

a) – what do you mean by the competency assessments … include … the ability to recreate the test process used for the competency?

RESPONSE 11:

The requirements for direct observation in the standard have been changed based on the comment received.

COMMENT 12:

Please clarify. Administration of a competency assessment tool by a subject matter expert should be OK as long as a supervisor reviews the results of the assessment and determines final competency, right?

RESPONSE 12:

Competency assessments must be performed by delegated supervisory qualified staff, the director or assistant director(s). There is no change to the standard based on the comment received.

COMMENT 13:

This standard is inconsistent with **Human Resources Sustaining Standard of Practice 3 (HRS3) (e): Supervisor Responsibilities** which indicates supervisors are responsible for "ensuring that staff have competency assessments as needed". HR S8 indicates that "Competency assessments must be performed by delegated supervisory staff, as specified by job title, or the director or assistant director(s)." While it is agreed that delegated supervisory staff, or the director or the assistant director should have oversite of the process as indicated in HR S3, it is not necessary for a delegated supervisor to perform the assessment. This compounds the

challenges NYS laboratories face with the years of experience to qualify as a supervisor. Testing personnel who are trained and competent in the test system are more than capable to perform competency assessments under the direction of supervisory staff.

Additionally, the proposed language “Competency assessments must be performed by delegated supervisory staff, as specified by job title” should be changed to “as specified by job title OR NAME". In many instances job titles alone do not link to all activities that may be delegated by the laboratory director and individuals with the same job title are not delegated the same responsibilities. Recommend allowing delegation to be assigned by name or job title because of the lack of correlation between job title and activities.

RESPONSE 13:

The standard has been revised to indicate that competency assessments must be performed by delegate supervisor qualified staff, the direct or assistant director(s). Supervisor qualified staff do not need to have the title of supervisor. Qualifications to be a laboratory supervisor are specified under 10NYCRR Section 58-1.4. The requirement for delegation by job title in the standard has been changed based on the comment received.

COMMENT 14:

Our laboratory does not find the change in description of the competency elements (a – h) useful for assessing competency as it is now different from the CLIA-defined competency elements. If NYSDOH intends to clarify or add additional items to be reviewed during a competency assessment, then our laboratory strongly suggests adding those as notes or subsections within the existing element or as additional separate elements. Further, while the new guidance refers to the use of previously analyzed samples, the specific requirement to assess test performance through the analysis of blind or previously analyzed samples has been removed (currently HR S8 a(vi)) when it is still required by CLIA and CAP.

RESPONSE 14:

The requirements in the standard have been revised based on the comment received.

Human Resources	
Proposed Standard	***Proposed Guidance***
Human Resources Standard of Practice 9 (HR S9): Competency Assessment – Non-testing Personnel Non-testing personnel must be competency assessed if they perform pre-analytic~~, analytic~~ or post-analytic laboratory practices. Competency assessments must be performed annually ~~by direct observation~~ for all tasks for which non-testing individuals are responsible, and include, as applicable: a) direct observation of safe practices required to perform their duties; b) periodic review of work product for compliance with standard operating procedures and applicable workload limits; and c) assessment of problem-solving skills. Documentation of competency must be retained according to Document and Specimen Retention Standard of Practice 2. ***Regulatory authority: 10 NYCRR subdivision 58-1.2(d)***	Competency assessment is required for personnel under the authority of the laboratory director, including contract employees. Competency assessment must be documented for all non-testing individuals who perform support tasks that are not ~~technical~~ related to testing ~~in nature~~, such as data entry, accessioning, and phlebotomy.

Human Resources Standard of Practice 9 (HR S9): Competency Assessment – Non-testing Personnel

COMMENT 1:

Comment: Non testing personnel do not perform analytic practices: the following statement - Non-testing personnel must be competency assessed…pre-analytic, analytic, post-analytic as written in the standard.

RESPONSE 1:
The requirement of the standard has been revised and the word analytic removed based on the comment received.

COMMENT 2:
Our laboratory agrees with the proposed removal of the specific inclusion of biomedical engineering staff and LIS staff from the requirement for competency assessment, and limiting assessments only to those performing pre-analytic, analytic or post-analytic laboratory practices.

RESPONSE 2:
There is no change to the standard based on the comment received.

COMMENT 3:
Can the analytic phase be delted from this standard since this question is related to non-testing personnel? Analytic performance is really restricted to the testing phase.

RESPONSE 3:
The requirement of the standard has been revised and the word analytic removed based on the comment received.

COMMENT 4:
Suggested change to Guidance – Competency assessment is required for personnel under the authority of the laboratory director, including contract employees.
Competency assessment must be documented for all non-testing individuals (excluding licensed clinical personnel) who perform support tasks that are not technical in nature, such as data entry, accessioning, and phlebotomy.

RESPONSE 4:
The suggested revision, of excluding licensed clinical personnel, would not apply to all clinical laboratories and blood banks. There is no change to the standard based on the comment received.

Human Resources	
Proposed Standard	***Proposed Guidance***
Human Resources Standard of Practice 10 (HR S10): Continuing Education Continuing education must be provided to testing personnel by the laboratory director and owner, as applicable, and must be appropriately documented. A minimum of twelve (12) hours of continuing education must be performed by laboratory testing personnel per calendar year. Documentation of continuing education must be maintained in accordance with Document and Specimen Retention Standard of Practice 2. ***Regulatory authority: 10 NYCRR subdivision 58-1.2(d)***	Acceptable forms of continuing education include professional meetings or industry-sponsored training/workshops. ~~The twelve hours is prorated for the first year of hire.~~ Continuing education hours for part time or per diem staff may not be prorated. Cytotechnologists must follow the continuing education requirements of 10 NYCRR subdivision 58-1.12(c).

Human Resources Standard of Practice 10 (HR S10): Continuing Education

COMMENT 1:
Clarification of “laboratory personnel”- The current standard clearly stated “technical staff” whereas the revised standard says “lab personnel.” I would like clarification if “lab personnel” is now including non-technical staff as well?

RESPONSE 1:
The standard applies to testing personnel and the requirement has been revised based on the comment received.

COMMENT 2:
Question: Do all “laboratory personnel” as written in HR S10 include both Testing and Non Testing personnel, require 12 credits of continuing education annually as indicated? If so this contradicts the Directors standard DR D4 (l) which specifies laboratory technical personnel.

RESPONSE 2:
The standard applies to testing personnel and the requirement has been revised based on the comment received.

COMMENT 3:
Strike the sentence that, Continuing education hours for part time or per diem staff may not be prorated.
This is burdensome on staff that may only be onsite a short period of time. The focus should be that they are appropriately trained to perform their tasks in a safe environment, which also has its own requirements for specific training. Mandating that they also get the same number of CEU's as a full time analyst is overly burdensome.

RESPONSE 3:
Part time and per diem staff require 12 hours of continuing education. Continuing education may be accomplished through webinars, professional meetings or industry-sponsored training/workshops and is transferable between facilities (PFI). There is no change to the standard based on the comment received.

COMMENT 4:
Our laboratory recommends that NY remove the section that states "Continuing education hours for part time or per diem staff may not be prorated". Prorating the continuing education for part time or per diem staff does not impact their work. They are still required to receive all mandatory training and competency evaluations just like full-time employees and those with ASCP or other certifications using a Certification Maintenance Program will still need to obtain all of their continuing education to maintain certification status.

RESPONSE 4:
Part time and per diem staff require 12 hours of continuing education. Continuing education may be accomplished through webinars, professional meetings or industry-sponsored training/workshops and is transferable between facilities (PFI). There is no change to the Standard based on the comment received.

COMMENT 5:
Our laboratory agrees with this proposed change to specifically allow proration of CE hours for the employee’s first year, but to also disallow proration of CE hours for part-time employees.

RESPONSE 5:

The guidance related to prorating of continuing education in the first year of employment has been removed. There is no change to the standard based on the comment received.

Facility Design

Only comments and responses to the Facility Design Standards are included here

Facility Design	
Proposed Standard and Guidance	***Adopted Standard and Guidance***
Facility Design Standard of Practice 1 (FD S1): Design and Environment The laboratory design and environment must be suitable for the tasks performed, including but not limited to, adequate: a) equipment, instruments, reagents, kits, supplies, and any other materials required to provide clinical testing service; b) space, such that the workload can be performed without compromising the quality of work or safety of personnel; c) furnishings and technology infrastructure, including communication and data processing systems; d) energy sources that mitigate fluctuations and interruptions, including applicable backup power; e) lighting, ventilation, water, waste and refuse disposal, and environmental controls; f) safeguards, including controlled access, to protect people, specimens, laboratory resources, data, and patient information; g) precautions to protect the integrity of specimens, equipment, instruments, reagents, materials, and supplies; and	

h) space and conditions to store all records and materials for the length of time specified in the Document and Specimen Retention Standards of Practice. ***Regulatory authority: 10 NYCRR section 58-1.6***	

Facility Design Standard of Practice 1 (FD S1): Design and Environment

COMMENT:

(h) does this mean that the temperature and humidity need to be recorded and monitored for the room or area where all paper records are stored?

RESPONSE:

The laboratory must have adequate space and conditions to store records. If a laboratory determines that there is a need to monitor/control the environment within a room to ensure the integrity of stored records, then monitoring the temperature and humidity would be required. There is no change to the standard based on the comment received.

Laboratory Safety

Only comments and responses to the Laboratory Safety Standards are included here

Laboratory Safety	
Proposed Standard	***Proposed Guidance***
Laboratory Safety Standard of Practice 1 (LS S1): Safety Policy and Procedure Approval The laboratory director, or individual ~~designated by job title and~~ delegated in writing by the director, must review and approve all new and revised safety standard operating procedures and/or policies before implementation. ***Regulatory authority: 10 NYCRR paragraph 19.3(c)(14)***	

Laboratory Safety Standard of Practice 1 (LS S1): Safety Policy and Procedure Approval

COMMENT 1:
Safety Policy and Procedure Approval – the designee should be someone with the title of Safety Officer.

RESPONSE 1:
The laboratory director or delegated individual is responsible for approving all new and revised safety standard operating procedures and/or policies before implementation. If this responsibility is delegated, the laboratory director determines staff qualifications. Not all facilities have the same titles for this individual. There is no change to the standard based on the comment received.

COMMENT 2:
The proposed language of individual designated by job title and delegated in writing by the director should be changed to "designated by job title OR NAME". In many instances job titles alone do not link to all activities that may be delegated by the laboratory director

and individuals with the same job title are not delegated the same responsibilities. Recommend allowing delegation to be assigned by name or job title because of the lack of correlation between job title and activities.

RESPONSE 2:

Based on the comment received, the language in the standard has been changed to indicate that the laboratory director may delegate responsibilities in writing and the requirement for delegation by job title has been deleted. The laboratory director is responsible for ensuring that delegated responsibilities are performed by staff (CLIA 493.1407(b) and 10NYCRR 19.3(c)).

COMMENT 3:

Our laboratory agrees with this proposed change as it would align requirements with existing CAP requirements.

RESPONSE 3:

There is no change to the standard based on the comment received.

Laboratory Safety	
Proposed Standard	***Proposed Guidance***
Laboratory Safety Standard of Practice 6 (LS S6): Chemical Hygiene Plan The laboratory must develop, where required, a Chemical Hygiene Plan (CHP) that defines the safety policies and procedures for all chemicals used in the laboratory according to the Occupational Safety and Health Administration's (OSHA) Laboratory Standard. ***Regulatory authority: 10 NYCRR paragraph 19.3(c)(14)***	For additional information on developing a chemical hygiene plan, see OSHA's standard on Occupational Exposure to Hazardous Chemicals in Laboratories (29 CFR 1910.1450) and the National Research Council's 2011 publication titled *Prudent Practices in the Laboratory – Handling and Management of Chemical Hazards*. Chemical Hygiene Plan(s) may be implemented at an institutional level by a Safety Office ~~and/or Officer~~.

Laboratory Safety Standard of Practice 6 (LS S6): Chemical Hygiene Plan

COMMENT:
Our laboratory suggests “Officer” be defined or the wording be amended.

RESPONSE:
The guidance has been revised based on the comment received.

Laboratory Safety	
Proposed Standard	***Proposed Guidance***
Laboratory Safety Standard of Practice 7 (LS S7): Biohazard Risk Assessment The laboratory must conduct and document a biohazard risk assessment for all sections and areas of the laboratory processing biohazardous agents or specimens that must include: a) identification of biohazardous agents and specimen types handled by the laboratory; b) identification of exposure risks associated with laboratory procedures, such as aerosol-generating procedures (e.g., centrifuging, vortexing, etc.) and the use of sharps; c) determination of the appropriate biosafety level and any additional or enhanced precautions needed as indicated by the risk assessment for each section and areas of the laboratory processing biohazardous agents or specimens; and	This Standard is not restricted to bloodborne pathogens and includes any potentially infectious specimen or sample (e.g., urine, stool, cultures, isolates, etc.). Guidance for conducting biohazard risk assessments can be found in the reference titled *Biosafety in Microbiological and Biomedical Laboratories* (BMBL), available from the Centers for Disease Control and Prevention (CDC).

d) documentation of review, initially, after revisions and annually, by the director or director designee, as delegated in writing by the director ~~and specified by job title~~. ***Regulatory authority: 10 NYCRR paragraph 19.3(c)(14)***	

Laboratory Safety Standard of Practice 7 (LS S7): Biohazard Risk Assessment

COMMENT:

The proposed language “documentation of review, initially, after revisions and annually, by the director or director designee, as delegated in writing by the director and specified by job title” should be changed to “as specified by job title OR NAME". In many instances job titles alone do not link to all activities that may be delegated by the laboratory director and individuals with the same job title are not delegated the same responsibilities. Recommend allowing delegation to be assigned by name or job title because of the lack of correlation between job title and activities.

RESPONSE:

Based on the comment received, the language in the standard has been changed to indicate that the laboratory director may delegate responsibilities in writing. The laboratory director is responsible for ensuring that delegated responsibilities are performed by staff (CLIA 493.1407(b) and 10NYCRR 19.3(c)).

Laboratory Safety	
Proposed Standard	***Proposed Guidance***
Laboratory Safety Standard of Practice 9 (LS S9): Biohazard Warning Signs and Labels Biohazard warning labels must be affixed to containers of regulated waste, sharps disposal containers, refrigerators, freezers and other containers used to store, transport or ship biohazardous agents or specimens. Biohazard warning signs must be posted at all laboratory work	For additional information, see the OSHA Bloodborne Pathogens (29 CFR 1910.1030) standard and the Centers for Disease Control and Prevention document *Biosafety in Microbiological and Biomedical Laboratories* (BMBL). Biohazard warning signs and labels must be designed to meet the requirements of the bloodborne pathogen standard where applicable.

areas used to store or handle biohazardous agents or specimens. Clerical or data entry stations not requiring the use of personal protective equipment (PPE) may be designated as such within posted laboratory work areas at the discretion of the laboratory director. However, these designated areas must be clearly described in plans or procedures and communicated to staff. Additionally, written procedures must be in place to prevent accidental cross-contamination of writing instruments, phones, keyboards, etc. in these clerical/data entry areas. ***Regulatory authority: 10 NYCRR paragraph 19.3(c)(14)***	

Laboratory Safety Standard of Practice 9 (LS S9): Biohazard Warning Signs and Labels

COMMENT:

We ask that instead of "laboratory director" it state: laboratory director or assistant director(s) holding an appropriate certificate of qualification.

RESPONSE:

This responsibility may be delegated in writing by the laboratory director 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.

Laboratory Information Systems

Only comments and responses to the Laboratory Information Systems Standards are included here

Laboratory Information Systems	
Proposed Standard	***Proposed Guidance***
Laboratory Information Systems Standard of Practice 2 (LIS S2): Laboratory Information Systems Standard Operating Procedure The laboratory must have standard operating procedures for laboratory information systems (LIS) that include: a) quality goals and performance expectations for the LIS, as described in the laboratory's Quality Management System (QMS); b) protection of personally identifiable information and protected health information; c) facility design requirements for proper system function, such as power protection; d) approval of procedures and LIS changes, as delegated in writing by the laboratory director ~~to an individual designated by job title~~; e) authorization for staff access and protection from unauthorized access; f) initial validation of system components and as required for changes; g) documentation of verification;	Explicit written policies that specify staff access, by job title, to the laboratory computer systems must be described and include how the access is obtained, maintained and inactivated. a) Examples of quality goals and performance expectations for an LIS may include accurate recording and transmission of data, protections against the loss of data and back-up systems for data, protection of confidential information, and timely reporting.

h) requirements and documentation for maintenance; i) mechanism to ensure that previous data is retrievable when the LIS is upgraded or replaced; j) requirements for tracking and audit trails; and k) steps to be followed if the system is not functioning. ***Regulatory authority: 10 NYCRR subdivision 58-1.2(c)***	

Laboratory Information Systems Standard of Practice 2 (LIS S2): Laboratory Information Systems Standard Operating Procedure

COMMENT 1:
(a) It is unclear what types of quality goals and performance expectations are acceptable for the LIS. The guidance should offer some examples.

RESPONSE 1:
Guidance has been added to include examples of LIS quality goals and performance expectations based on the comment received.

COMMENT 2:
The proposed language “approval of procedures and LIS changes, as delegated in writing by the laboratory director to an individual designated by job title” should be changed to “an individual designated by job title OR NAME". In many instances job titles alone do not link to all activities that may be delegated by the laboratory director and individuals with the same job title are not delegated the same responsibilities. Recommend allowing delegation to be assigned by name or job title because of the lack of correlation between job title and activities.

RESPONSE 2:
Based on the comment received, the language in the standard has been changed to indicate that the laboratory director may delegate responsibilities in writing. The laboratory director is responsible for ensuring that delegated responsibilities are performed by staff (CLIA 493.1407(b) and 10NYCRR 19.3(c)).

Laboratory Information Systems	
Proposed Standard	***Proposed Guidance***
Laboratory Information Systems Standard of Practice 3 (LIS S3): Laboratory Information System Training The laboratory must have standard operating procedures that instruct staff on the use of Laboratory Information Systems (LIS) as it relates to laboratory services. All appropriate staff must be trained on use of the LIS~~,~~ ~~including training~~, including necessary retraining as determined by the director, after any LIS modification. Training documentation must be retained according to Document and Specimen Retention Standard of Practice 2. ***Regulatory authority: 10 NYCRR subdivision 58-1.2(c)***	

Laboratory Information Systems Standard of Practice 3 (LIS S3): Laboratory Information System Training

COMMENT:

Training after any LIS modification is pretty broad. There are some modifications that are simple upgrades not impacting the operations or patient care information. Could this be spelled out in a little more detail.

RESPONSE:

Based on the comment received, the requirement in the standard has been revised to indicate that necessary retraining is determined by the director. This responsibility may be delegated in writing by the laboratory director. The laboratory director is responsible for ensuring that delegated responsibilities are performed by staff (CLIA 493.1407(b) and 10NYCRR 19.3(c)).

Laboratory Information Management System	
Former Standard and Guidance	***Proposed Standard and Guidance***
LIMS Sustaining Standard of Practice 4 (LIMS S4): Validation The laboratory shall validate any system changes, including new or revised software and/or hardware prior to their use for specimen testing, reporting and record keeping functions. ***Regulatory authority: 10 NYCRR subdivision 58-1.2 (c)*** **Guidance –** This should include new interfaces or printers to the system. The laboratory director and laboratory management must approve any installation and validation of new systems or changes to existing validated systems conducted by an IT Department or other entity outside the direct control of the laboratory.	**Standard incorporated into new LIS S2**

Former Standard (deleted) LIMS Sustaining Standard of Practice 4 (LIMS S4): Validation

COMMENT:

We noticed LIMS S4 Validation was removed from the new guidelines. Who is responsible for reviewing and approving the LIS validations and changes/updates?

RESPONSE:

The requirement from former LIMS S4 has been incorporated into the new LIS S2. Please see LIS S2, indicating requirements for standard operating procedures related to the laboratory's LIS.

Laboratory Information Systems	
Proposed Standard	***Proposed Guidance***
Laboratory Information Systems Standard of Practice 4 (LIS S4): Transcription Accuracy The laboratory must have a system to ensure that any manually transcribed information, including test request information and/or test results, or electronically interfaced request information and/or results, are accurately transcribed. ***Regulatory authority: 10 NYCRR subdivision 58-1.2(c)***	The laboratory must have ongoing mechanisms, such as double-keying or supervisory review, to ensure the accuracy of manual entries by ~~technical~~ testing and non-~~technical~~ testing personnel into the LIS. The laboratory director must define the periodicity of any supervisory review. Data-entry personnel must be trained and competency assessed as specified under the Human Resources section of these standards.

Laboratory Information Systems Standard of Practice 4 (LIS S4): Transcription Accuracy

COMMENT:

We ask that instead of "laboratory director" it state: laboratory director, or assistant director(s) holding an appropriate certificate of qualification.

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.

Laboratory Information Systems	
Proposed Standard	***Proposed Guidance***
Laboratory Information Systems Standard of Practice 6 (LIS S6): Systems Failure The laboratory must have policies to ensure that: a) electronic data are backed up at a frequency that minimizes the risk of data loss; b) systems are in place to ensure data integrity and timely reporting of results if the Laboratory Information System (LIS) is out of service; and c) data are retrievable within twenty-four (24) hours. ***Regulatory authority: 10 NYCRR subdivisions 58-1.2(c) and 58-1.11(c)***	Timely reporting should be appropriate to the clinical need of the test results. Hospitals that offer emergency room or acute care should have a manual system that can be in place within minutes. This standard applies to on-site and remote data storage.

Laboratory Information Systems Standard of Practice 6 (LIS S6): Systems Failure

COMMENT 1:
Section C) "Data are retrievable within twenty-four (24) hours." Is this referring to data loss or system/data downtime/availability?

RESPONSE 1:
The requirement for availability within 24 hours is mandated in 10 NYCRR 58-1.11(c). In the event of an LIS failure, the laboratory must have policies in place to ensure that data existing in the LIS at the time of the failure are retrievable within 24 hours. The standard has not been changed based on the comment received.

COMMENT 2:
In the context of a system failure, what is your intent for the requirement that data be available within 24 hours? Which data? Are you expecting that we can restore the system within 24 hours? Or are you asking that data generated during down-time are available within 24 hours?

RESPONSE 2:

The requirement for availability within 24 hours is mandated in 10 NYCRR 58-1.11(c). In the event of an LIS failure, the laboratory must have policies in place to ensure that data existing in the LIS at the time of the failure are retrievable within 24 hours. The standard has not been changed based on the comment received.

COMMENT 3:

The time frame to retrieve data of 24 hours may be unreasonable in the case of a catastrophic event. Recommend changing the language to "data are retrievable within a reasonable period of time, in most cases twenty-four (24) hours."

RESPONSE 3:

The requirement for availability within 24 hours is mandated in 10 NYCRR 58-1.11(c). The suggestion will be considered when future regulation revisions are deliberated. The standard has not been changed based on the comment received.

Resource Management

Only comments and responses to the Resource Management Standards are included here

Resource Management	
Proposed Standard	***Proposed Guidance***
General Resource Management	
General Resource Management Standard of Practice 1 (GRM S1): Continuity of Operations Plan The laboratory must have standard operating procedures and/or policies to provide services in the event of a natural, intentional, or unintentional event that impairs operations. The standard operating procedures and/or policies must include: a) contact numbers for key staff and their roles in an emergency/unexpected event; b) arrangements for communication with clients regarding the status of laboratory services; and c) pre-established arrangements for long-term storage of specimens and/or use of reference and contract laboratories to test critical specimens. ***Regulatory authority: 10 NYCRR paragraph 19.3(c)(2) and subdivision 58-1.10(g)***	A plan for continuity of operations may address internal and external events, such as electrical/heating/AC failures, fire, natural disasters (e.g. ice storm, earthquake), and terrorist events.

General Resource Management Standard of Practice 1 (GRM S1): Continuity of Operations Plan

COMMENT:

The policy may be that we do not provide services, is that OK? Some laboratory services are not critical and do not need to be performed in a disaster.

RESPONSE:

The policy may be that laboratory operations cease during an event that impairs services. However, the policy should consider, for example, arrangements for notifying clients, appropriate storage of specimens, protections for power/data, and other relevant information that may apply to your facility. There is not change to the standard based on the comment received.

Resource Management	
Proposed Standard	***Proposed Guidance***
General Resource Management	
General Resource Management Standard of Practice 2 (GRM S2): Testing Supplies The laboratory must have systems to ensure that supplies required for generating test results are available. Failure to have testing supplies available when needed must be regarded as a nonconforming event according to Investigation and Corrective Action Standard of Practice 3 and investigated according to Investigation and Corrective Action Standard of Practice 4. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	Testing supplies includes all materials and supplies used in the test process (e.g., pipettes, gloves, etc.).

General Resource Management Standard of Practice 2 (GRM S2): Testing Supplies

COMMENT:

Why would that be a nonconforming event? If at any time we are not able to get a supply delivered, we just delay testing. If it isn't a critical, emergency test request, does it really matter to you?

RESPONSE:

Having adequate supplies for testing is essential for laboratory services. Documenting these instances an a nonconformances may identify patterns/problems that may be prevented (e.g., you may need to use a different supplier). The inability to perform testing must be communicated appropriately to the laboratory director or other appropriate personnel and a nonconformance will that these issues are communicated. There is no change to the standard based on the comment received.

Resource Management	
Proposed Standard	***Proposed Guidance***
General Resource Management	
General Resource Management Standard of Practice 4 (GRM S4): Verification – General Requirement The laboratory must verify and document the suitability of ~~all~~ consumable materials, including acceptance and rejection criteria, that affect the quality and/or timeliness of test results. The laboratory must: a) document prior to use for patient testing, that all consumable materials used in testing meet manufacturer or laboratory specifications; b) maintain documents that include manufacturer instructions and communications related to material quality (e.g., manufacturer or vendor recall); and	Documentation must include the signature or initials of the person determining acceptability and the date that acceptability was determined. Acceptability may be accomplished by examining quality control samples and verifying that results are acceptable, provided the quality control challenge is designed appropriately to be sensitive to substandard equipment or supplies quality.

c) discontinue use of any material that fails to meet specifications and document actions taken. Performance verification requirements for equipment and instruments are provided in Laboratory Equipment and Instrument Standard of Practice 3. Verification of reagents and media must comply with Reagents and Media Standard of Practice 2. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g) and section 58-1.6***	

General Resource Management Standard of Practice 4 (GRM S4): Verification – General Requirement

COMMENT 1:
We would like the following guidance to remain in the standard.
Guidance - This may be accomplished by examining quality control samples and verifying that results are acceptable, provided the quality control challenge is designed appropriately to be sensitive to substandard equipment or supplies quality.

RESPONSE 1:
As requested, guidance has been added to the standard.

COMMENT 2:
It is unclear what type of documentation is required or what the documentation entails for verification of consumable materials prior to testing.

RESPONSE 2:
Written documentation stating that the consumable met or did not meet acceptance/rejection criteria is required. Documentation must include the signature or initials of the person determining the acceptability of the consumable, as well as the date that acceptability was determined. Guidance has been added based on the comment received.

COMMENT 3:

Our laboratory recommends retaining original language - "…consumable supplies that affect the quality of service…" instead of the new language "…all consumable materials…"
Our laboratory recommends retaining guidance - "This may be accomplished by examining quality control samples and verifying that results are acceptable, provided the quality control challenge is designed appropriately to be sensitive to substandard equipment or supplies quality."

RESPONSE 3:

This standard applies to consumable materials that affect the quality and/or timeliness of test results. There is no change to the standard based on the comment received.

Resource Management	
Proposed Standard	***Proposed Guidance***
General Resource Management	
General Resource Management Standard of Practice 6 (GRM S6): Expired Supplies The laboratory must: a) not use expired materials for testing unless the manufacturer has provided written authorization to do so; and b) not conduct its own validation studies to extend the shelf life of purchased reagents or other materials that have a manufacturer-stated expiration date. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	Performance verification requirements for equipment that can be reverified (e.g., thermometers, pipettes, timers, hygrometer etc.) are provided in Laboratory Equipment and Instrument Standard of Practice 3. For consumables provided without a manufacturer expiration date, the laboratory director must determine the expiration date with empirical data, when possible. Manufacturers may recommend expiration dates that are adopted by the laboratory following director approval. Expired items may be used for training, research or student use. These materials must be clearly labeled as for "Educational use only" or similar wording and be stored separately from materials used and verified for clinical testing. For panel cells, follow manufacture instructions.

General Resource Management Standard of Practice 6 (GRM S6): Expired Supplies

COMMENT 1:
We request guidance for the use of expired panel cells to supplement the information from in dated panel cells to determine the specificity of an antibody present in a patient's serum. The use of expired panel cells has been allowed in the past as long as appropriate controls have been performed to ensure that there has been no loss of antigenicity. Not being able to use expired panel cells as a resource will severely impact our ability to perform appropriate rule outs in complex antibody workups.

RESPONSE 1:
Guidance has been added to the standard based on the comment received. Laboratories and blood banks must follow manufacturer instructions for panel cells.

COMMENT 2:
The proposed standard seems to eliminate the possible use of expired panel cells even if they were quality controlled for functionality. Would use of expired panel cells still be allowed if appropriate controls have been performed to ensure there has been no loss of antigenicity? Not being able to use expired panel cells as a resource will impact our ability to perform appropriate rule outs in complex antibody workups.

RESPONSE 2:
Guidance has been added to the standard based on the comment received. Laboratories and blood banks must follow manufacturer instructions for panel cells.

COMMENT 3:
Our laboratory recommends that language be added to the standard to allow some exceptions to this requirement as there are instances where expired reagents must be used for testing when in-date reagents are not available (i.e. rare reagent red cells). In the exceptions, the laboratory should be allowed to determine the viability and suitability of the expired reagent prior to use.

RESPONSE 3:
Guidance has been added to the standard based on the comment received. Laboratories and blood banks must follow manufacturer instructions for panel cells.

Resource Management	
Proposed Standard	***Proposed Guidance***
Laboratory Equipment and Instrumentation	
Laboratory Equipment and Instrument Standard of Practice 5 (LEI S5): Instruction for Maintenance and Preventive Maintenance The laboratory must have standard operating procedures and/or policies for the maintenance and preventive maintenance of equipment and instruments that are readily available to laboratory staff. ***Regulatory authority: 10 NYCRR section 58-1.6***	The standard operating procedures and/or policies may refer to the use of up-to-date relevant manufacturer provided manuals and directions for instructions on the maintenance and use of equipment/instruments.

Laboratory Equipment and Instrument Standard of Practice 5 (LEI S5): Instruction for Maintenance and Preventive Maintenance

COMMENT:

Suggest adding the following to the guidance section:
Guidance: The standard operating procedures and/or policies may refer to the use of up-to-date relevant manufacturer provided manuals and directions for instructions on the maintenance and use of equipment/instruments. Relevant manuals must be readily available for use by laboratory personnel

RESPONSE:

As requested, guidance has been added to the standard based on the comment received.

Facility Design and Resource Management	
Former Standard and Guidance	***Proposed Standard and Guidance***
Laboratory Equipment	
Laboratory Equipment Sustaining Standard of Practice 7 (LE S7): UV Decontamination If ultraviolet light (UV) is used as part of the decontamination protocol, the laboratory shall: a) implement personal safety procedures; b) check the energy efficiency of the UV lights at least every six months; and, c) replace bulbs as needed to maintain the manufacturer's recommended UV levels. ***Regulatory authority: 10 NYCRR Section 58-1.6*** **Guidance –** The Centers for Disease Control (CDC) and the National Institute of Health (NIH) agree that UV lamps are not recommended nor required in biological safety cabinets (ABSA Position Paper on UV in BSCs). However, if used, it is recommended that a 10 - 15 minute UV exposure of the work area be performed at the beginning and end of the workday. It is recommended that the bulbs be cleaned weekly with 70% ethanol to optimize the light output and enhance germicidal effectiveness, taking proper precaution to prevent electric shock. Energy output should be no less than 40 microwatts per square centimeter at 254 nanometers. Plate irradiation testing may	**Standard deleted**

also be used to verify that the energy output is sufficient to kill microorganisms.	

Former Standard (deleted) Laboratory Equipment Sustaining Standard of Practice 7 (LE S7): UV Decontamination

COMMENT:

I recommend the standard remain because some laboratories still UV decontamination as an additional aid. Therefore, in order to ensure the proper use of UV, the standard should remain, giving he cleaning and QC requirements.

RESPONSE:

This standard remains deleted. Laboratories that utilize UV decontamination are expected to develop policies and/or standard operating procedures for use, and to verify performance and perform maintenance, according to LEI standards.

Resource Management	
Proposed Standard	***Proposed Guidance***
Reagents and Media	
Reagents and Media Standard of Practice 2 (RGM S2): Verification of Reagents and Media – Control Procedures The laboratory must follow the manufacturer instructions for using reagents, media and supplies. In addition, unless more stringent requirements are specified elsewhere in the New York State Clinical Laboratory Standard of Practice, the laboratory must: a) check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, and identification systems	The laboratory must establish and/or verify performance specifications prior to use for reporting patient specimens and ensure that performance specifications are maintained. Verification may be accomplished by examining quality control samples and verifying that results are acceptable, provided the quality control challenge is designed appropriately to be sensitive to substandard equipment or supplies quality. Antibody identification cell panels must be used according to manufacturer instruction.

(systems using two (2) or more substrates or two (2) or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable; b) each day of use, test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate; c) check fluorescent and immunohistochemical stains for positive and negative reactivity each time of use; d) before, or concurrent with the initial use: i. check each batch of media for sterility if sterility is required for testing; ii. check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and iii. document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	

Reagents and Media Standard of Practice 2 (RGM S2): Verification of Reagents and Media – Control Procedures

COMMENT 1:

We are requesting guidance on what is required to verify the acceptability of panels when they are received. Immunohematology Standard 5 was deleted which specifically stated "NYS does not require that each shipment of antibody identification cell panels be tested with a known antibody". The package insert for the antibody identification cell panel states that "in addition to visual inspection, antigen reactivity may be checked by testing a cell known to demonstrate deterioration (ex: Lea). Since the manufacturer states that the panel may be checked (not must or shall) we consider this to be a recommended practice and not a required practice.

Commercial antisera are very expensive and the cost to repeatedly test a panel would severely deplete both antisera and panel resources. If RGM-S2 is the standard which applies to antibody identification cell panels we request clarification as to:

- Does an antibody positive serum need to be run against every panel upon delivery before use?
- Does an antibody positive serum need to be run against every panel each day of use?
- Are there any restrictions on the antibodies chosen to control the panel?

RESPONSE 1:

Guidance related to the use of antibody identification cell panels has been added to the standard based on the comment received.

COMMENT 2:

We are requesting guidance on what is required to verify the acceptability of panels when they are received. Immunohematology Standard 5 was deleted which specifically stated "NYS does not require that each shipment of antibody identification cell panels be tested with a known antibody". The package insert indicates that visual inspection is required and anything beyond that is not mandatory. Requiring QC of each panel would be very expensive in terms of cost and time. Additionally, what exactly would be required for QC of these?

RESPONSE 2:

Guidance related to the use of antibody identification cell panels has been added to the standard based on the comment received.

COMMENT 3:

REAG S3>RGM S2, Reagent Verification: Our laboratory requests harmonization and clarification if the Guidance is binding or non-binding. May new reagent (calibrator and control) lots be verified concurrently with use, must they be verified prior to use, or must they be verified prior to reporting applicable results? See also QC Design S3>QC S5 and QC Design S4>QC S6 regarding control materials.

RESPONSE 3:

Guidance is provided to assist in clarifying the standard. The laboratory director may determine if it there are instances where verification of reagents and controls would occur concurrently with patient testing.

Document Control

Only comments and responses to the Document Control Standards are included here

Document Control	
Proposed Standard	***Proposed Guidance***
Document Control Standard of Practice 1 (DC S1): Availability All standard operating procedures, policies, instructions, programs, plans and manuals, and any other documents as indicated in any part of the New York State Clinical Laboratory Standards of Practice must be: a) under document control; b) in a standardized format with a system of numbering and/or titling of each procedure~~, as determined by the director~~; c) current and accurate; and d) available and accessible at all times in applicable work area(s). ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	Electronic procedures must be accessible to all relevant staff at all times. Backup systems are required to ensure accessibility if electronic procedures are not available.

Document Control Standard of Practice 1 (DC S1): Availability

COMMENT:

Our laboratory has existing procedures for the numbering and developing of documents organization wide. The numbering of documents is determined through our automated Document Management System and titling is determined by the author of the procedure. Our Laboratory suggests that the standard not include “as determined by the director” or should be clarified further to

indicate that the format for the numbering and titling of the documents can be determined by other means with laboratory director oversight.

RESPONSE:

The language of the standard has been revised based on the comment received.

Document Control	
Proposed Standard	***Proposed Guidance***
Document Control Standard of Practice 3 (DC S3): Manufacturer Instruction Manuals Current manufacturer's instructions, operator manuals, package inserts, or textbooks may be used in total or in part to meet Test Procedure Content Standards of Practice 1 and 2 or other document content requirements, provided that all relevant content requirements in any part of the New York State Clinical Laboratory Standards of Practice are fulfilled. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	All Document Control Standards of Practice apply to manufacturer instructions, operator manuals, package inserts, and/or or textbooks, etc., used in total or in part of the Test Procedure, including director approval.

Document Control Standard of Practice 3 (DC S3): Manufacturer Instruction Manuals

COMMENT:

We ask that instead of "director" it state: laboratory director or assistant director(s) holding an appropriate certificate of qualification.

RESPONSE:

According to interpretive guidelines for CLIA 493.1251 (d), test procedure approval responsibility cannot be delegated by the laboratory director. Any manufacturer's instructions, operator manuals, package inserts, or textbooks used in total or in part as the test procedure must be approved by the laboratory director or sole assistant director for New York State Clinical Laboratory Permit holders. In instances where there is no sole assistant director or there are multiple assistant directors, the responsibility must be fulfilled by the laboratory director. There is no change to the standard based on the comment received.

Document Control	
Proposed Standard and Guidance	***Revised Standard and Guidance***
Document Control Standard of Practice 4 (DC S4): Procedure Excerpts In addition to complete standard operating procedures, policies, instructions, programs, plans and/or manuals, excerpts that summarize key information may be used by laboratory staff, provided: a) the director, assistant director(s) or supervisor qualified staff reviews ~~and signs~~ the excerpts at least ~~annually~~ every two (2) years and this review is documented; and b) the content provided by the excerpt does not contradict the corresponding document. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	Procedure excerpts may also be referred to as job aides, training notes, and/or procedural subsections.

Document Control Standard of Practice 4 (DC S4): Procedure Excerpts

COMMENT 1:

We suggest the following change: the laboratory director, assistant director(s) holding an appropriate certificate of qualification or supervisor reviews and signs the excerpts at the same time the standard operating procedure is reviewed.
Rationale: Standard Operating Procedures (SOP) review requirements should coincide with the review of the procedure excerpts. The "annual" review requirement for procedure excerpts causes inconsistencies with the Document Management process.
NYS Document Control Standard of Practice 5 (CD S5): Director Approval states: Test procedure review, at a minimum every two (2) years, is required by the director.

RESPONSE 1:

The requirements in the standard for staff review and review timeframe have been changed based on the comment received.

COMMENT 2:
Why do these excerpts need to be reviewed annually if the SOP they are excerpted from only require review every 2 years? Do you mean they literally need to sign the excerpt or can there be an electronic review signature of revision controlled copy in document control system?

RESPONSE 2:
The requirements in the standard for review timeframe and documentation of review have been changed based on the comment received.

COMMENT 3:
This standard requires annual review and signing of procedure excerpts. With the updated guidance in DC S5 requiring a review at least every two years, the requirement for procedure excerpts should be updated to indicate review at least every two years or when the corresponding document is revised (if less than two years).

RESPONSE 3:
The requirements in the standard for review timeframe has been changed based on the comment received.

COMMENT 4:
The standard states that the director or supervisor must review and sign the excerpts annually.
We suggest that the wording of the standard be less prescriptive to allow for variations of acceptable documentation. Our suggestion would be to change the wording to "the director or supervisor reviews the excepts at least annually and this review is documented".

RESPONSE 4:
The requirements in the standard for review timeframe and documentation of review have been changed based on the comment received.

Document Control	
Proposed Standard and Guidance	***Revised Standard and Guidance***
Document Control Standard of Practice 5 (DC S5): Director Approval The director or sole assistant director~~(s)~~ designated for a category must sign and date each new or revised test procedure before it is used for reporting patient test results. Approval of new and revised test procedures, as indicated by signature and date, may not be delegated by the director or sole assistant director. Test procedure review, at a minimum every two (2) years, is required by the director. This duty may be delegated in writing to an ~~designated~~ assistant director holding an appropriate certificate of qualification or an individual qualified as a laboratory supervisor. For controlled documents not related to testing, an individual may be delegated by the laboratory director, as specified in writing and by job title, to approve, sign and review documents as indicated in the New York State Clinical Laboratory Standards of Practice. ***Regulatory authority: 10 NYCRR subdivisions 58-1.2(c) and 58-1.10(g)***	Non-testing documents may include safety policies and procedures, computer system specifications and/or maintenance instructions. This standard is applicable to laboratory developed tests (LDTs), as well as manufacturer instruction manuals adopted in lieu of laboratory-specific test procedures, standard operating procedures and/or excerpts. In the case of a change in the laboratory director or sole assistant director, all test procedures should be reviewed and signed by the new director and/or sole assistant director as soon as possible. If not done immediately, the laboratory should have a plan for having the review completed and documented within an appropriate timeframe, not to exceed six months. Electronic signature, or an alternative system, may be substituted for hard copy, as long as it is a password protected signature. Blood banks are required to follow the requirements in 10 NYCRR section 58-2.8 for annual review by the director or authorized supervisor.

Document Control Standard of Practice 5 (DC S5): Director Approval

COMMENT 1:

We ask that instead of "director or sole assistant director" it state: laboratory director, sole assistant director or assistant director(s) holding an appropriate certificate gf qualification.

RESPONSE 1:

According to interpretive guidelines for CLIA 493.1251 (d), approval of test procedures and changes to test procedures is the responsibility of the laboratory director and this responsibility cannot be delegated. For New York State Clinical Laboratory Permit holders, this responsibility must be fulfilled by the laboratory director or sole assistant director and cannot be delegated.

COMMENT 2:

Question/Comment: What are the qualifications of who this task can be delegated to? Will this be at the discretion of the facility?

RESPONSE 2:

According to the standard, review of test procedures may be delegated in writing by the laboratory director to an assistant director holding an appropriate CQ in the category or a supervisor qualified individual. For documents that are not a test procedure (e.g., quality documents, safety, LIS, etc.), the laboratory director may delegate approval and review to an individual deemed qualified by the director. 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.

COMMENT 3:

Question – Test procedure review may be delegated to a laboratory supervisor – if review finds the need for a revision of the Test Procedure – then the director or sole assistant director(s) designated for a category must sign and date each revised test procedure. Can the revised function be delegated to a director-designated assistant director holding an appropriate certificate of qualification or must all revised document be signed by the Medical Director or Sole assistant director?

RESPONSE 3:

According to interpretive guidelines for CLIA 493.1251 (d), approval of test procedures and changes to test procedures is the responsibility of the laboratory director and this responsibility cannot be delegated. Review of test procedures may be delegated in writing by the laboratory director to assistant directors holding a CQ in the category or individuals qualified as a supervisor. There is no change to the standard based on the comment received.

COMMENT 4:

- Electronic signature, or an alternative system, may be substituted for hard copy, as long as it is a password protected signature.

- Please clarify if electronic signatures, as long as they are password protected, can be applied to all reports requiring the lab director/assistant director's approval.

RESPONSE 4:

Password protected electronic signature(s) are acceptable to demonstrate approval for all documents. There is no change to the standard based on the comment received.

COMMENT 5:

Why does NYS require annual review for blood banks and every two years for other laboratories? Almost all other agencies now allow for every 2 years in blood banks.

RESPONSE 5:

Annual review is required under 10 NYCRR section 58-2.8. Laboratories holding or applying for a New York State Clinical Laboratory permit must comply with all applicable New York State regulations and statutes. The suggestion will be considered when future regulation revisions are deliberated. There is no change to the standard based on the comment received.

COMMENT 6:

The proposed language "For controlled documents not related to testing, an individual may be delegated by the laboratory director, as specified in writing and by job title," should be changed to "as specified in writing and by job title OR NAME". In many instances job titles alone do not link to all activities that may be delegated by the laboratory director and individuals with the same job title are not delegated the same responsibilities. Recommend allowing delegation to be assigned by name or job title because of the lack of correlation between job title and activities.

RESPONSE 6:

This standard does not require delegation by job title. There is no change to the standard based on the comment received.

COMMENT 7:

Our laboratory suggests clarification regarding whether the proposed change means that a new laboratory director does not need to meet a timeline for review of existing SOPs.

Our laboratory agrees with the proposed requirement to review procedures at least every two years as this requirement would align with College of American Pathologists (CAP) requirements.

RESPONSE 7:

Information regarding timeframes for test procedure approval and review for a new laboratory director or sole assistant director has been added to the guidance based on the comment received.

Document Control	
Proposed Standard and Guidance	***Revised Standard and Guidance***
Document Control Standard of Practice 6 (DC S6): Controlled Document Archival The laboratory must have a system to: a) maintain and archive a copy of each revised document under document control, with the dates of use and discontinuation; and b) retain these records, if required, according to Document and Specimen Retention Standards of Practice. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	This activity is a critical element of document control whereby test reports can be readily associated with test procedures in place at the time a specific specimen was analyzed. ~~All test procedures must be readily associated with testing and reporting for all specimens.~~

Document Control Standard of Practice 6 (DC S6): Controlled Document Archival

COMMENT:

Require Clarification – Guidance “All test procedures must be readily associated with testing and reporting for all specimens”. How is this documented?

RESPONSE:

This requirement is related to traceability. The laboratory must have the ability to know which version of a test procedure is in use at the time of testing for each specimen. Guidance has been added based on the comment received.

Pre-Analytic Systems

Only comments and responses to the Pre-Analytic Systems Standards are included here

Pre-Analytic Systems	
Proposed Standard	***Proposed Guidance***
Specimen Processing	
Specimen Processing Standard of Practice 2 (SP S2): Monitoring Specimen Submissions The laboratory director, or individual that is delegated in writing by the director, ~~as specified by job title,~~ must monitor, document and take appropriate action when specimens received do not comply with the laboratory's specimen submission instructions. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	Examples of actions to be taken by the laboratory may include notification to submitters detailing problems observed, clarification of submission instructions, and/or training for submitters.

Specimen Processing Standard of Practice 2 (SP S2): Monitoring Specimen Submissions

COMMENT 1:

Question/Comment: What are the qualifications of who this task can be delegated to? Will this be at the discretion of the facility?

RESPONSE 1:

Responsibilities may be delegated in writing to an individual deemed qualified by the laboratory director. 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.

COMMENT 2:

This activity should not require a delegation as it is already covered under the authorization for testing. This is an activity which would be conducted by multiple individuals who have been trained on the processes and undergo competency assessment. Recommend not adding this as a separate standard.

RESPONSE 2:

The laboratory director or individuals delegated responsibility in witting by the director must have oversight of these activities and be responsible for ensuring compliance. There is no change to the standard based on the comment received.

Pre-Examination Procedures	
Former Standard and Guidance	***Proposed Standard and Guidance***
Specimen Processing	
Specimen Processing Sustaining Standard of Practice 3 (Processing S3): Order Entry Verification If the laboratory transcribes or enters test requisitions or authorization information into a record system or laboratory information system, the laboratory must ensure the information is transcribed or entered accurately. ***Regulatory authority: 10 NYCRR subdivision 58-1.2(c)*** **Guidance –** The laboratory must have an ongoing mechanism to ensure the accuracy of manual entries by personnel, both technical and non-technical, into the LIS.	**Standard deleted** **Required under Laboratory Information System Standard of Practice 4 (LIS S4): Transcription Accuracy**

Former Standard (deleted) Specimen Processing Sustaining Standard of Practice 3 (Processing S3): Order Entry Verification

COMMENT:

This requirement should remain as there is no other means of checking request verification. You require result verification, the same must be required for patient entry information. Having done review of patient data entry, many mistakes were found and corrected. Some are still missed and the submitter contacts the lab which then needs to send a corrected report.

RESPONSE:

Former Processing S3 (Order Entry Verification) was redundant with former LIMS S10 (Transcription Accuracy). These two standards have been replaced with a new standard, LIS S4 (Transcription Accuracy). Under requirements for LIS S4, the laboratory must ensure that any manually transcribed test request information and/or test results, or electronically interfaced request information and/or results, are accurately transcribed. There is no change to the standard based on the comment received.

Pre-Analytic Systems	
Proposed Standard	***Proposed Guidance***
Reference and Contract Laboratories	
Reference and Contract Laboratory Standard of Practice 1 (RCL S1): Reference Laboratory Selection and Use The laboratory must have a standard operating procedure for selecting and using reference and/or contract laboratories, including any secondary reference laboratories used by a primary reference laboratory. It is the responsibility of the director and owner to select and use only reference and/or contract laboratories that: a) hold valid New York State permit(s) in the category of testing and any required test approvals;	

b) use appropriate methods for the requested testing; and c) have the capacity and resources to meet clinical and/or contractual requirements. ***Regulatory authority: 10 NYCRR subdivisions 58-1.1(b) and 58-1.10(g)***	

Reference and Contract Laboratory Standard of Practice 1 (RCL S1): Reference Laboratory Selection and Use

COMMENT:

In the standard it is stated that the reference laboratory must be a NYS permitted laboratory, CDC is not NYS permitted laboratory. Does this mean the CDC cannot be used as a reference laboratory?

RESPONSE:

Clinical laboratories and blood banks operated by the federal government are exempt under Article 5, Title 5 of New York State Public Health Law Section 579. There is no change to the standard based on the comment received.

Analytic Systems

Only comments and responses to the Analytic Systems Standards are included here

Analytic Systems	
Proposed Standard	***Proposed Guidance***
Test Procedure Content	
Test Procedure Content Standard of Practice 1 (TPC S1): Test Procedure Content For test procedures, required standard operating procedure content must include: a) implementation date for the current version of the test procedure; b) test purpose and intended use; c) analytic principle of the test; d) biological, chemical and/or radiological safety; e) specimen type, acceptable container(s), and if applicable, minimum specimen quantity or volume and/or required preservative; f) requirements for patient preparation, specimen collection, labeling, storage, preservation, transportation, processing, and/or sending to a reference or contract laboratory; g) criteria for specimen acceptance and rejection that is consistent with requirements in Specimen Processing Standard of Practice 4;	

h) storage of residual specimens and time limits for requesting additional testing; i) required equipment, instruments and reagents; j) instrument and equipment function checks and preventive maintenance; k) test performance specifications for accuracy, precision, reportable range, and analytical sensitivity and specificity; l) environmental requirements, including as needed, the separation of incompatible activities and/or precautions to mitigate specimen contamination; m) actions to be taken if the laboratory is unable to perform any part of the testing procedure; n) steps required for testing, including, as appropriate: i. preparation of slides, solutions, calibrators, controls, reagents, stains and other materials used in testing; ii. microscopic examination, including the detection of inadequately prepared slides; iii. calibration and calibration verification procedures; iv. quality control procedures that specify acceptance and rejection criteria; v. corrective action to be taken when quality control or calibration verification fail to meet acceptability criteria; vi. calculations or evaluation criteria used to determine test results; vii. interpretation of test results; viii. confirmatory, supplemental or additional testing,	m) The test procedure may refer to separate policy documents. n) ix. Panic or alert value summary lists may be posted if under document control and referenced ~~where these values are reflected~~ in the clinical test procedure. For results that are communicated verbally, a read back requirement should be implemented to verify results.

if required; ix. reporting results, including imminently life-threatening results, or panic or alert values; and o) reportable range for quantitative tests; p) reference ranges, therapeutic or toxic concentrations, or other interpretive criteria as appropriate to the test; q) limitations of the test, including interfering substances when applicable; r) references to pertinent literature; and s) any laboratory policy, service or additional requirements as indicated in the New York State Clinical Laboratory Standards of Practice. Testing procedures must be retained according to Document and Specimen Retention Standard of Practice 3. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	

Test Procedure Content Standard of Practice 1 (TPC S1): Test Procedure Content

COMMENT 1:

Change must to shall be required a testing procedure. This allows for appropriateness of content in different procedures.
Strike section m) It is a generic statement that would be part of basic training when learning to set up a test. It should not be included in every test procedure, unless it would be test specific. This is what do I do if scenarios like the sample cannot be used due to clots, hemolysis, no/low volume, the instrument is down, etc. There are too many scenarios to cover and it would make the test procedure extremely long. There are also times when it is best to talk to the supervisor about what to do.
By making a testing procedure extremely long, bench excerpts are needed so all of the excess doesn't get in the way of how to "extract" a run and put it on an instrument. By having a separate, small excerpt for the analyst to follow, it increases the odds that there may be a difference between the large and bulky testing procedure and the small easy to read bench excerpt. By keeping the test procedure only having appropriate and test specific information, that would not include generic information that is used in all testing procedures, it lessens the chance for having discrepancies between the two documents.

RESPONSE 1:

New York State Clinical Laboratory Standards must demonstrate substantial equivalence to CLIA regulation. The requirement under (m) to describe actions to be taken if the laboratory is unable to perform any part of the testing procedure provides consistency with CLIA 493.1251 (b)(14). Guidance has been added based on the comment received to indicate that the test procedure may refer to a general policy or procedure dictating actions to be taken for common scenarios.

COMMENT 2:

Implementation date – does this mean the first time this procedure is put in use, or does it include each revision as an initial use. I think this could cause some confusion and should be clarified to as to how revisions should be handled.

RESPONSE 2:

The requirement in the standard has been revised based on the comment received.

Analytic Systems	
Proposed Standard	***Proposed Guidance***
Test Performance Specifications	
Test Performance Specification Standard of Practice 3 (TPS S3): Documentation Method performance documentation must be available and accessible and include: a) the conclusion of the outcome of the performance specification studies, including: i. summary(ies) of data and performance specifications as determined for Test Performance Specification Standards of Practice 1 or 2;	Information on Departmental approval of a laboratory developed test (LDT) is available at: https://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/test-approval.

ii. an attestation that the director, or ~~sole assistant director~~ individual delegated in writing by the director, has approved the test, including a signature and the approval date; and b) a letter of Department approval, if required. Documentation must be retained according to Document and Specimen Retention Standard of Practice 8. ***Regulatory authority: 10 NYCRR subdivision 58-1.11(c)(3)***	

Test Performance Specification Standard of Practice 3 (TPS S3): Documentation

COMMENT:

We ask that instead of "director or sole assistant director" it state: laboratory director, sole assistant director or delegated assistant director(s) holding an appropriate certificate of qualification.
Please clarify
b) a letter of Department approval. Is the letter of approval a NYS CLEP approval?

RESPONSE:

Approval of test performance specifications may be delegated in writing by the laboratory director. The laboratory director is responsible for ensuring that delegated responsibilities are performed by staff (CLIA 493.1407(b) and 10NYCRR 19.3(c)). For the purposes of the Clinical Laboratory Standards of Practice, Departmental approval is equivalent to CLEP approval.

Analytic Systems	
Proposed Standard	***Proposed Guidance***
Test Performance Specifications	
Test Performance Specification Standard of Practice 5 (TPS S5): Comparability of Test Results A laboratory that performs the same test using different methods or instruments, and/or performs the same test at multiple test sites under the same Permanent Facility Identifier (PFI) must: ~~The laboratory must:~~ a) perform comparability studies as ~~determined by the director and~~ specified as part of the Quality Management System (QMS); ~~b) compare tests for a given analyte that use different methods or instruments and/or are performed at any location under the same Permanent Facility Identifier (PFI);~~ c) establish acceptability criteria for comparing test results and document the outcome of the comparison; and d) compare test results semiannually at a minimum. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	Analysis of samples from ~~primary~~ patient specimens is preferred for defining the relationship between test results. Specimens should be selected to provide full-range assessment of comparability. a) The comparability study acceptability criteria may be detailed in the QMS or standard operating procedures.

Test Performance Specification Standard of Practice 5 (TPS S5): Comparability of Test Results

COMMENT 1:

Our laboratory recommends changing the language from "The laboratory must:" to "A laboratory that performs the same test using different methods or instruments, and/or performs the same test at multiple test sites under the same Permanent Facility Identifier (PFI) must:" and then remove item b.

RESPONSE 1:
As suggested, the standard has been revised.

COMMENT 2:
a. After the initial method validation, do all subsequent comparability studies need to be signed off by the Laboratory Director? This task should be delegated at the Laboratory Director's discretion.
b. In the guidance, it says "analysis of samples from primary specimens is preferred for defining the relationship between test results". Is a primary specimen a patient specimen? If so, for multi-compound assays, it is almost impossible to find patient specimens that is positive for all compounds. Laboratories should be able to use spiked materials in these studies.

RESPONSE 2:
Responsibility for the approval of comparability studies may be delegated in writing by the laboratory director. According to DR S4, testing responsibilities must be delegated to personnel that are an assistant director or qualified as a supervisor. The laboratory director is responsible for ensuring that delegated responsibilities are performed by staff (CLIA 493.1407(b) and 10NYCRR 19.3(c)). As stated in the guidance, analysis of patient specimens is preferred for comparability studies. There is no change to the standard based on the comment received.

COMMENT 3:
We ask that instead of "director" it state: laboratory director or delegated assistant director(s) holding an appropriate certificate of qualification.

RESPONSE 3:
The requirements of the standard have been revised and no longer refer to the laboratory director.

Analytic Systems	
Proposed Standard	***Proposed Guidance***
Quality Control	
Quality Control Standard of Practice 1 (QC S1): Minimum Quality Control Requirements Unless an individualized quality control plan (IQCP) is established as described in Quality Control Standards of Practice 2, 3 and 4, at least once each day specimens are tested, the laboratory must test quality controls as follows: a) for qualitative tests, include a positive and negative control; b) for quantitative tests, include two (2) control materials of different concentration suitable for error detection throughout the reportable range; c) for tests producing graded or titered results, include a negative control material and a control material with graded or titered reactivity, respectively; d) for tests that include an extraction phase, include at least one (1) control sample or material that is subjected to the same extraction process as specimens and that is capable of detecting errors in the extraction process; or e) for nucleic acid amplification methods: i. include one (1) control capable of detecting amplification inhibition by patient specimens unless the Department approved laboratory developed test (LDT) exempts the requirement;	Information on Departmental approval of a laboratory developed test (LDT) is available at: https://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/test-approval. For tests, such as certain staining procedures, for which no controls are available, the laboratory should describe in their standard operating procedure how to determine when the expected reaction is not achieved. Although a run may be defined as up to twenty-four (24) hours, a laboratory that elects to perform all quality control at a fixed time (e.g., start of the day shift) should demonstrate that the system is stable throughout the twenty-four (24) hour period. c) For semiquantitative tests: anti-streptolysin O titer and antihyaluronidase titer tests do not require a negative control; cold agglutination tests do not require a positive control; radial immuno-diffusion tests require one control or standard on each plate. ~~d) Extraction control: A co-amplified housekeeping gene meets the intent of this standard. Housekeeping gene refers to a gene whose expression is unlikely to be altered.~~ e) Inhibition controls may be excluded if there are sufficient data showing that the inhibition rate is less than one (1) percent for a specimen type for the assay. It is possible to extend inhibition data to other analytes when applying the same extraction procedure and specimen matrix and utilizing the same amplification methodology. Inhibition

ii. when more than one (1) outcome is possible at a locus, include a control that represents each outcome periodically; and f) according to manufacturer instructions and all category specific New York State Clinical Laboratory Standards of Practice if more stringent than above. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	controls are not required if the run includes isolates only and not patient specimens. Negative controls, including template-free mastermix controls, not only serve to identify technical and/or reagent issues, but also help identify amplicon contamination. The negative controls may include a reagent processing control that serves as both a template-free mastermix reagent control as well as a processing/extraction negative control. For laboratories preparing mastermix to be used on multiple instruments, the template-free mastermix control should be utilized for each run of each instrument. For infectious diseases molecular amplification procedures, the positive control should be of a low but detectable amount. A low-range positive is defined as having a value of not more than ten (10) fold above the assay detection limit. For multiplex assays, a low range control is required for each target. These may be run on a rotating basis and may include pools of three (3) to four (4) targets.

Quality Control Standard of Practice 1 (QC S1): Minimum Quality Control Requirements

COMMENT 1:
Recommend including the following reference to the Guidance section:
httgs://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Individualized Quality Control Plan IQCP

RESPONSE 1:
The recommended reference to the CMS website has been added to the guidance of QC S2, QC S3 and QC S4. There is no change to QC S1 based on the comment received.

COMMENT 2:
QC Design 2a>QC S1: Although no change from current, Our laboratory requests clarification added to Guidance regarding item d) on extraction phase controls and specifically extracting nucleic acids from specimen as part of the preparation for analysis. Our

laboratory also requests clarification added to the General requirement regarding positive controls for Next Generation Sequencing germline tests versus infectious disease molecular methods, as indicated in the NYS NGS Guidance.

RESPONSE 2:

Based on the comment received, the requirement in the standard for (d) has been changed to indicate that an extraction control is a control that is capable of detecting errors in the extraction process and the guidance for (d) has been deleted. Questions regarding LDT requirements can be directed to clep@health.ny.gov.

Analytic Systems	
Proposed Standard	***Proposed Guidance***
Quality Control	
Quality Control Standard of Practice 2 (QC S2): Individualized Quality Control Risk Assessment If the laboratory does not follow minimum quality control requirements in Quality Control Standard of Practice 1, then a risk assessment must be performed to determine if an Individualized Quality Control Plan (IQCP) may be implemented. The documented risk assessment must, at a minimum: a) identify and evaluate potential sources of error associated with the test process based on testing performed by a representative sampling of staff; b) evaluate the frequency and impact of identified errors; c) consider the potential errors that might be attributable to the following components of the test process: i. specimen (e.g., labeling, transportation, storage, etc.);	Additional information on IQCP requirements is available on the CMS website. The laboratory should refer to the following to conduct the risk assessment: regulatory requirements; manufacturer package insert, operator's manual, troubleshooting guide, and bulletins; laboratory-performed verification and establishment of performance specifications data; testing personnel qualifications, training and competency records; historical quality ~~C~~control (QC) data; proficiency testing data; historical quality assurance (QA) data; and scientific publications. In laboratories with multiple numbers of identical devices (same make and model), a single risk assessment may be performed for the test system. When identical devices are utilized in different environments/locations, the risk assessment must consider this factor and the potential need for a customized IQCP for the different sites. a) to include historical testing data or validation data performed by bona fide employees of the laboratory.

ii. test system (e.g., interfering substances, equipment failure/errors, etc.); iii. reagent, quality control materials and calibrators (e.g., shipment, storage, expired materials, etc.); iv. environment (e.g., temperature, ventilation, dust, etc.); and v. staff (e.g., training, competency, staffing levels, etc.). ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	c) i. the following must be considered for the specimen: patient preparation, specimen collection, labeling, storage, preservation, stability, transportation, processing, acceptability, rejection and referral. c) ii. to include function and maintenance checks, inadequate sampling, detection of interfering substances, mechanical or electronic failures, system control and function checks failures, software and/or hardware issues, transmission of data to electronic systems including the laboratory information system (LIS) or electronic health records (EHR), and results reporting. c) iii. to include preparation, stability, variability between lots, intermixing of reagents from different lots. c) iv. to include temperature, ventilation, light intensity, noise and vibration, humidity, altitude, dust, water, utilities failure, and adequate space. c) v. to include education, licensure where required, training, competency and adequate staffing levels.

Quality Control Standard of Practice 2 (QC S2): Individualized Quality Control Risk Assessment

COMMENT:

The numbering of bullets under guidance repeats c) several times.

RESPONSE:

Guidance is provided for each requirement under (c). There is no change to the guidance based on the comment received.

Analytic Systems	
Proposed Standard	***Proposed Guidance***
Quality Control	
Quality Control Standard of Practice 3 (QC S3): Design of an Individualized Quality Control Plan If the laboratory chooses to perform quality control (QC) less frequently than specified in Quality Control Sustaining Standard of Practice 1, the laboratory must implement an Individualized Quality Control Plan (IQCP) based on the risk assessment performed according to Quality Control Standard of Practice 2. The laboratory must establish and maintain an IQCP, as described below, for any assay chosen by the laboratory in all categories, excluding histopathology and cytopathology, that verifies the intended quality of results is achieved prior to reporting results. The IQCP must include: a) approval ~~and~~, including signature and date, by the laboratory director or ~~sole assistant director for the category~~ individual delegated in writing by the director before implementation~~ng~~ and following any revisions; b) the process for performing QC, including: i. the number, type and frequency of control materials that must at least meet manufacturer's quality control instructions, when provided; ii. the criteria for acceptable control results and reporting of specimen data; and c) data from the laboratory to support the process for	Additional information on IQCP requirements is available on the CMS website at: Information on Departmental approval of a laboratory developed test (LDT) is available at: https://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit/test-approval. External QC refers to the use of control materials that are not integrated into the design of the assay. This would include control material purchased from a commercial vendor or derived in-house. This is distinct from internal QC, such as would be encountered in a single-use device like an immunochromatographic cassette.

testing QC in (a) above; d) requirements for testing external QC materials with each: i. change of reagent lot number; ii. new shipment; iii. change in storage conditions; iv. replacement of a critical part; or v. following any major preventive maintenance; and e) for a laboratory developed test (LDT), the laboratory must submit quality control plans to the Department for approval: i. as part of a validation package for the addition of a non-FDA-approved assay to the laboratory's test menu; or ii. when the QC procedure is changed for an LDT already approved by the Department; and f) a process that ensures annual review and documentation of review for effectiveness by the director or an individual delegated in writing by the director, as specified by job title. ***Regulatory authority: 10 NYCRR paragraph 19.3(c)(3) and subdivision 58-1.10(g)***	

Quality Control Standard of Practice 3 (QC S3): Design of an Individualized Quality Control Plan

COMMENT 1:

We ask that instead of "laboratory director or sole assistant director" it state: laboratory director, sole assistant director(s) or delegated assistant director(s) holding an appropriate certificate of qualification.

RESPONSE 1:

Design of an IQCP may be delegated in writing by the laboratory director. The laboratory director is responsible for ensuring that delegated responsibilities are performed by staff (CLIA 493.1407(b) and 10NYCRR 19.3(c)).

COMMENT 2:

The proposed language “review for effectiveness by the director or an individual delegated in writing by the director, as specified by job title,” should be changed to “as specified job title OR NAME". In many instances job titles alone do not link to all activities that may be delegated by the laboratory director and individuals with the same job title are not delegated the same responsibilities. Recommend allowing delegation to be assigned by name or job title because of the lack of correlation between job title and activities.

RESPONSE 2:

Based on the comment received, the language in the standard has been changed to indicate that the laboratory director may delegate responsibilities in writing. The requirement for specification by job title has been deleted.

Analytic Systems	
Proposed Standard	***Proposed Guidance***
Quality Control	
Quality Control Standard of Practice 4 (QC S4): Quality Assessment Plan for Individualized Quality Control Plan If an Individualized Quality Control Plan (IQCP) is developed according to Quality Control Standard of Practice 3, the laboratory must establish and maintain an IQCP Quality Assessment Plan. The IQCP Quality Assessment Plan must include: a) approval ~~and~~, including signature and date, by the laboratory director or ~~sole assistant director for the~~	Additional information on IQCP requirements is available on the CMS website.

~~category~~ individual delegated in writing by the director before implementation ~~initiated~~ and following any revisions; b) a system to monitor overall quality performance, to include an assessment of the accuracy and precision of test performance that may be influenced by changes in test system stability, environmental conditions, or variance in operator performance; c) a process that defines the review and revision of the quality control plan, as appropriate, when non-conformances are identified; and d) a process that ensures annual review and documentation of review for effectiveness by the director or an individual delegated in writing by the director, as specified by job title. ***Regulatory authority: 10 NYCRR paragraph 19.3(c)(3) and subdivision 58-1.10(g)***	

Quality Control Standard of Practice 4 (QC S4): Quality Assessment Plan for Individualized Quality Control Plan

COMMENT 1:

We ask that instead of "laboratory director or sole assistant director" it state: laboratory director, sole assistant director(s) or delegated assistant director(s) holding an appropriate certificate of qualification.

RESPONSE 1:

The quality assessment plan for an IQCP may be delegated in writing by the laboratory director. The laboratory director is responsible for ensuring that delegated responsibilities are performed by staff (CLIA 493.1407(b) and 10NYCRR 19.3(c)).

COMMENT 2:

The proposed language “review for effectiveness by the director or an individual delegated in writing by the director, as specified by job title,” should be changed to “as specified job title OR NAME". In many instances job titles alone do not link to all activities that may be delegated by the laboratory director and individuals with the same job title are not delegated the same responsibilities. Recommend allowing delegation to be assigned by name or job title because of the lack of correlation between job title and activities.

RESPONSE 2:

The laboratory director may delegate this responsibility in writing according to the Clinical Laboratory Standards of Practice. The requirement of the standard has been revised based on the comment received.

Analytic Systems	
Proposed Standard	***Proposed Guidance***
Quality Control	
Quality Control Standard of Practice 10 (QC S10): Control Routine Analysis Quality control materials must be rotated among all testing personnel, and to the extent possible, tested in the same manner as patient specimens. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	If a laboratory operates on multiple shifts, quality control material shall be incorporated on other shifts on a regular basis. Rotation among testing personnel may be conducted, for example, during annual competency assessments or after calibration, or with the verification of new lots of materials.

Quality Control Standard of Practice 10 (QC S10): Control Routine Analysis

COMMENT:

Would you please clarify what this policy means? Does the previous standard/guidance (Process QC S6) meet this proposed standard?

RESPONSE:

Guidance from former Process QC S6 has been added based on the comment received.

Analytic Systems	
Proposed Standard	***Proposed Guidance***
Quality Control	
Quality Control Standard of Practice 13 (QC S13): Control Records Records of actual results for each quality control must be maintained by the laboratory, including: a) quality control charts; and/or b) other records which identify the controls by date and lot. Actual measurements taken, reactions and /or observations must be recorded, including if the results are acceptable. "Check" marks are not sufficient to record acceptability unless the definition of the checkmark is established in writing. For tests in which results are reported in terms of graded reactions (e.g., 1+, 2+, minimally reactive), the reaction grade must be recorded. Control records must be available for recreation of the test process and when requested by the Department. ***Regulatory authority: 10 NYCRR paragraph 58-1.11(c)(3)***	

Quality Control Standard of Practice 13 (QC S13): Control Records

COMMENT:

a. Do we need to document when a QC is acceptable and does not have any issues or outliers?
b. Quality control records should include Levey-Jennings charts.

RESPONSE:

The outcome of QC must be documented, including acceptable results. Levey-Jennings charts may be used to document QC data. Acceptability of QC may also be accomplished through LIS programming to flag results outside of the acceptable range or documented on a log sheet that states the acceptable range and indicates if the results were acceptable or not. There is no change to the standard based on the comment received.

Post-Analytic Systems

Only comments and responses to the Post-Analytic Systems Standards are included here

Post-Analytic Systems	
Proposed Standard	***Proposed Guidance***
Result Review	
Result Review Standard of Practice 1 (RR S1): Result Review Criteria The laboratory must have standard operating procedures for the review of test results for accuracy and reliability. Staff that are responsible for result review must be specified in writing ~~by job title~~. The laboratory must document the review of test results and testing adherence to acceptability criteria. Autoverification and subsequent release of examination results is acceptable, provided the conditions and algorithms used have been approved and signed by the director or an individual delegated in writing by the director. Review of all test results must verify that: a) test results were produced with the required calibration and/or quality control materials; b) calibration and/or quality control data are acceptable based on manufacturer requirements or laboratory developed acceptability criteria; c) test results are determined and/or calculated correctly; d) dilution and other correction factors have been applied, if needed;	

e) specimen identification and associated results are accurately linked and transcribed to the test report; f) patient test results that are consistent with relevant patient information such as age, gender, diagnosis, and relationship are identified; g) reference ranges are appropriate; h) reporting interpretations are appropriate for the test results; and i) abnormal results are flagged, and alert or panic values are communicated according to the laboratory's established standard operating procedures, protocols or policies. ***Regulatory authority: 10 NYCRR paragraph 19.3(c)(4) and subdivision 58-1.10(g)***	

Result Review Standard of Practice 1 (RR S1): Result Review Criteria

COMMENT 1:

We ask that instead of "director" it state: laboratory director or assistant director(s) holding an appropriate certificate of qualification.

RESPONSE 1:

Responsibilities may be delegated in writing by the laboratory director. The laboratory director is responsible for ensuring that delegated responsibilities are performed by staff (CLIA 493.1407(b) and 10NYCRR 19.3(c)).

COMMENT 2:

The proposed standard requires "Staff that are responsible for result review must be specified in writing by job title". There are numerous job titles which may apply to individuals who are competent and authorized to review results. Having sufficient documented training for an individual as required in **Human Resources Sustaining Standard of Practice 6 (HRS6)**: **Training for Testing and Non-technical Personnel** should suffice as evidence that an individual may perform that job function, including result review regardless of job title. It is therefore redundant to require separate documentation for this specific function. Recommend the

language proposed be changed to “staff that are responsible for result review must have documented training of result review requirements”.

RESPONSE 2:

The laboratory director must specify in writing the technical and administrative responsibilities and duties of all laboratory personnel (DR S4, 10NYCRR subdivision 19.3(c)). Testing responsibilities must be delegated to an assistant director or a supervisor qualified individual. There is no change to the standard based on the comment received.

Post-Analytic Systems	
Proposed Standard	***Proposed Guidance***
Result Review	
Result Review Standard of Practice 3 (RR S3): Nonconformance Identification During result review, any nonconformities identified as not following the laboratory’s established standard operating procedures or policies must be investigated. Actions taken by the laboratory must include, but are not limited to: a) performing root cause analysis when a nonconformance in the test process is identified and implement corrective action(s), if required; b) evaluating test results obtained since the last acceptable testing to determine if results are inaccurate or unreliable; c) retesting specimens and notifying clients for any reported results that are determined to be inaccurate or unreliable; d) releasing test reports only after corrective action has	The requirements of this standard are intended to be assessed in concert with Investigation and Corrective Action Standards of Practice 3, 4 and 5.

been taken and documented to be effective; and e) taking appropriate preventive action to ensure that non-conformance does not recur. The laboratory director or ~~assistant director~~ individual delegated in writing by the director ~~responsible for the category~~ must document review of the investigation and approval of any corrective action taken. ***Regulatory authority: 10 NYCRR paragraph 19.3(c)(4) and subdivision 58-1.10(g)***	

Result Review Standard of Practice 3 (RR S3): Nonconformance Identification

COMMENT 1:
Our laboratory recommends that the standard allow delegation of this review to other qualified management staff.

RESPONSE 1:
Responsibilities may be delegated in writing by the laboratory director. The laboratory director is responsible for ensuring that delegated responsibilities are performed by staff (CLIA 493.1407(b) and 10NYCRR 19.3(c)). The standard has been revised based on the comment received.

COMMENT 2:
Question/Comment: It is not possible for all of our nonconformities to be reviewed by our Director. We currently document all incidents regardless of how minor, into our quality management system. Can the review by the Director be based on the severity of the issue or other factors to streamline the process and ensure the Director is focusing on the more critical issues or trends?

RESPONSE 2:
Responsibilities may be delegated in writing by the laboratory director. The laboratory director is responsible for ensuring that delegated responsibilities are performed by staff (CLIA 493.1407(b) and 10NYCRR 19.3(c)). The standard has been revised based on the comment received.

COMMENT 3:

Why does this have to be signed off by the lab director? Some nonconformances may be very minor in nature. Lab director should only need to approve if it's a critical error or process failure that impacts patient care and requires full CAPA.

RESPONSE 3:

Responsibilities may be delegated in writing by the laboratory director. The laboratory director is responsible for ensuring that delegated responsibilities are performed by staff (CLIA 493.1407(b) and 10NYCRR 19.3(c)). The Standard has been revised based on the comment received.

Post-Analytic Systems	
Proposed Standard	***Proposed Guidance***
Reporting	
Reporting Standard of Practice 1 (REP S1): Authorized Release of Test Results The requirements to authorize release of test results must be described in a standard operating procedure. The procedure must define staff ~~by job title~~ that are authorized to release test results, as delegated in writing by the director. Standard operating procedures for automated verification and release of results must be approved by the director or individual delegated as responsible in writing by the director. In the categories of cytopathology and histopathology, only a licensed pathologist, practicing in the state where they are licensed, is authorized to release pathology reports, with the exception of negative gynecological cytopathology reports which may be released by a cytotechnologist. ***Regulatory authority: 10 NYCRR section 58-1.3 and subdivision 58-1.10(b) and (g)***	Supervisor~~y~~ qualified staff must verify that approved protocols are routinely followed by technologists who have been authorized to release results. Electronic signatures must be password protected.

Reporting Standard of Practice 1 (REP S1): Authorized Release of Test Results

COMMENT 1:
We ask that instead of "director" it state: laboratory director, or delegated assistant director(s) holding an appropriate certificate of qualification.
Please confirm the following: Cytopathology and Histopathology are the only categories that require a licensed pathologist to release reports. If this statement is correct, suggest adding this to the Guidance section. Such as statement in current standard.

RESPONSE 1:
Responsibilities for result review may be delegated in writing by the laboratory director. The laboratory director is responsible for ensuring that delegated responsibilities are performed by staff (CLIA 493.1407(b) and 10NYCRR 19.3(c)). Pathology reports must be reviewed by a licensed pathologist. The standard has been revised based on the comment received.

COMMENT 2:
Authorized release of test results- revised standard says an SOP must define those by job title who are able to release results, as delegated in writing by the director. Our SOP's are approved by the Director, does this qualify as being delegated in writing? Or is an actual delegation of duties stating that personnel by title may release results needed?

RESPONSE 2:
Delegation by the director must be in writing. A standard operating procedure approved by the director is evidence of delegation. 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.

COMMENT 3:
The proposed standard requires a procedure with the requirements for release of test results and further states "the procedure must define staff by job title that are authorized to release test results as authorized by the director". There are numerous job titles which may apply to individuals who are competent and authorized to release test results. Having sufficient documented training for an individual as required in **Human Resources Sustaining Standard of Practice 6 (HRS6)**: **Training for Testing and Non-technical Personnel** should suffice as evidence that an individual may perform that job function, including release of test results regardless of job title. It is therefore redundant to require separate documentation for this specific function. Recommend the language proposed be changed to "staff that are responsible for release of test results must have documented training of result release requirements".

RESPONSE 3:

The laboratory director must specify in writing the technical and administrative responsibilities and duties of all laboratory personnel (DR S4 based on 10NYCRR subdivision 19.3(c)). A job description that has a line item that requires this of the individual would be acceptable if director approval is documented. There is no change to the standard based on the comment received.

Post-Analytic Systems	
Proposed Standard and Guidance	***Revised Standard and Guidance***
Reporting	
Reporting Standard of Practice 2 (REP S2): Test Report Content Test results must be available in a timely manner to the authorized ordering source or client. Laboratories must be capable of producing a hard copy of a laboratory report. Test results, whether transmitted electronically or by hard copy, must include all required report information, including: a) patient name or other identification; b) the name and address under which the reporting laboratory has been issued a permit, unless the laboratory has reported to the Department an alternative name (e.g., "doing business as"); c) the date, and hour if required, when the specimen was collected; ~~d) the date the specimen was received in the laboratory;~~ e) the test report date ~~that the result is first available~~; f) specimen type and/or source (i.e., anatomic location), when appropriate;	~~e) the test report date should be indicated for each test included on the report, therefore, there may be multiple test report dates if some tests are completed and reported before others included on the requisition. The test report date is the date that the test result is available to the provider.~~

g) test results, and if applicable, units of measure, reference ranges, or a similar method for identifying abnormal values; h) signature of the qualified person who reviewed, approved and/or diagnosed the case, as required under Reporting Standard of Practice 1; or i. a record of the cytotechnologist releasing the report is required for negative gynecological cytopathology reports; and i) a statement on the report if compromised specimens are tested, the nature of the problem and, if applicable, any impact on result interpretation; j) if applicable, the name and address of the reference or contract laboratory and the date the specimen was tested or the date the result was reported ~~by the reference or contract laboratory~~; and k) any disclaimers or limitations to testing where required by the Department for an approved laboratory developed test (LDT); l) any additional information required for the interpretation of results; and m) any other information as required in any part of the New York State Clinical Laboratory Standards of Practice. ***Regulatory authority: 10 NYCRR paragraph 58-1.11(b)(2)***	

Reporting Standard of Practice 2 (REP S2): Test Report Content

COMMENT 1:

The guidance for standard REP S2 (e) "the test report date should be indicated for each test included on the report, therefore, there may be multiple test report dates" conflicts with NYCRRs and CLIA standards as described as follows:
NYCRR 58-1.11(b)(2)(vii) requires that each laboratory report contain the following information regarding the result report: if the specimen is received from another laboratory, either the date the specimen was tested or the date the result was reported, provided

that the testing date or dates are available upon request of the originating physician or forwarding laboratory for the same period of time specified in subdivision (c) of this section.
NYCRR 58-1.11(b)(1)(viii)(a-b) further provides that a laboratory must have records indicating the daily accession of specimens and that if the specimen is not received from another laboratory either: (a) the date the specimen was tested; or (b) the date the result was reported, provided that the testing date or dates are available upon the request of the originating physician for the same period of time specified in subdivision (c) of this section for the retention of the report, unless the information required by clause (a) or (b) is recorded in the laboratory report required by paragraph (2) of this subdivision.
A laboratory fulfills the NYCRR requirements listed above by having the testing date or dates available in the LIS system for the appropriate period of time to be provided upon request by the originating physician whether or not the test report date is indicated on the report for each test.
Additionally, the CLIA Standard §493.1291(c)(3), does not specify that a test report date be reported for each individual test result on the patient report. Rather, the Interpretive Guidelines define the following, " The date of the test report is the date results were generated as a final report and must not change on copies generated at a later date." Finally, Reporting Standard of Practice 2 (REP S2): Test Report
Content states simply that "e) the test report date that the result is first available" is a require report element. This is consistent with the State regulations and CLIA standard referenced above. However, the Guidance goes on to state "the test report date should be indicated for each test included on the report, therefore, there may be multiple test report dates if some tests are completed and reported before others included on the requisition. The test report date is the date the test result is available to the provider." It is respectfully submitted that this Guidance conflicts with the New York Regulation and CLIA Standard discussed above, and therefore should not be offered as guidance. Recommend that the guidance for REP S2(e) align with the standard and the NY CRR.

RESPONSE 1:

The standard has been revised and the guidance removed based on the comment received. Laboratory receipt date is required under TR S3 and SP S5.

COMMENT 2:

Our laboratory does not agree with the proposed requirement to include the report date for each test on the report. It is our understanding that LCLS reports cannot meet this requirement and neither can MedTox LIS reports

RESPONSE 2:

The standard has been revised and the guidance removed based on the comment received.

COMMENT 3:

Question/Comment: There are limitations of most electronic systems in that a signature cannot be captured on the test report. We do have traceability as to who performed testing and released results. Would this be acceptable?

RESPONSE 3:

Under REP S1, in the categories of cytopathology and histopathology, only a licensed pathologist is authorized to release pathology reports (10NYCRR 58-1.10(b)). Password protected electronic signature is acceptable for pathology reports. There is no change to the standard based on the comment received.

COMMENT 4:

Comment regarding (d) the date the specimen was received in the laboratory, is to provide the following guidance as part of the standard for multi-site health system laboratories that share the same LIS:
d) For multi-site health system laboratories that utilize the same laboratory information system (LIS) the received date is the date the specimen is initially received to create a specimen case number. The material from one location to another within the same health system must be tracked and available for review.

RESPONSE 4:

The requirement in the standard has been deleted.

Post-Analytic Systems	
Proposed Standard	***Proposed Guidance***
Public Health Reporting	
Public Health Reporting Standard of Practice 2 (PHR S2): Communicable Disease Confirmation	For specific communicable diseases and additional information, see Communicable Disease Reporting Guidelines at: https://www.wadsworth.org/regulatory/clep/laws.

New York State Public Health Law Section 576-c (4) and Article 11 of the New York City Health Code require confirmatory testing of isolates for communicable diseases. For specimens that are suspected or reported as confirmed positive for communicable diseases, the testing laboratory must submit isolates for confirmatory testing in accordance with the Communicable Disease Reporting Guidelines. ***Statutory authority: as noted***	

Public Health Reporting Standard of Practice 2 (PHR S2): Communicable Disease Confirmation

COMMENT 1:
PHR S2. References 2016 Communicable Disease Reporting Guidelines. Suggest this guideline be updated to include handling of organisms identified by NAAT and cannot be isolated – no need to send specimen as per email from Wadsworth staff. Even as a footnote to the guidelines would be helpful.

RESPONSE 1:
Currently, the 2016 Communicable Disease Guidelines are available on the website. This comment will be incorporated in a future version of the Guidelines when they are available. There is no change to the standard based on the comment received.

COMMENT 2:
Question/Comment: Can we have further clarification on what this means for out of state labs?

RESPONSE 2:
Specimens from New York State residents that are suspected or reported as confirmed positive for communicable diseases must be submitted by the testing laboratory for confirmatory testing according to the Communicable Disease Reporting Guidelines including out of state laboratories. Please refer to the website in the guidance which points to the Communicable Disease Reporting Guidelines. There is no change to the standard based on the comment received.

COMMENT 3:

Post Analytic Systems: Clarify that: *specimens that are suspected of reported as confirmed positive for* "certain" *communicable diseases*. Do specimens have to be submitted or only if asked?

RESPONSE 3:

Specimens from New York State residents that are suspected or reported as confirmed positive for communicable diseases must be submitted by the testing laboratory for confirmatory testing. The Communicable Disease Reporting Guidelines provide specific information on applicable communicable diseases. It is the responsibility of the testing laboratory to submit specimens that are specified in the guidelines. Please refer to the website in the guidance which points to the Communicable Disease Reporting Guidelines. There is no change to the standard based on the comment received.

COMMENT 4:

- Please clarify how and who specimens are to be submitted.

RESPONSE 4:

The Communicable Disease Reporting Guidelines provide specific information on applicable communicable diseases, as well as specimen and submission requirements. Please refer to the website in the guidance which points to the Communicable Disease Reporting Guidelines. There is no change to the standard based on the comment received.

Post-Analytic Systems	
Proposed Standard	***Proposed Guidance***
Confidentiality	
Confidentiality Standard of Practice 2 (CON S2): Confidentiality Protocol The laboratory must establish policies and protocols to ensure that protected health information remains confidential. The ~~laboratory confidentiality~~ policies and protocols must include:	~~Level of access should be defined for each job title.~~ Employees who may have contact with confidential information should sign an attestation statement, which documents training on the laboratory's confidentiality policy, applicable statutes

a) a prohibition of access or disclosure unless approved by the director to perform duties; and b) responsibilities of all employees and agents to ensure that: i. confidential information is accessible only to authorized persons; ii. confidential information, if stored, is secure; iii. only information necessary to fulfill authorized functions is maintained in the laboratory units; iv. confidential information is secured from casual observation; v. confidential information is released or transferred only as authorized by the director, subject to New York State and federal confidentiality requirements; vi. obsolete information is purged or destroyed in an appropriate manner; and vii. proper behavior is exhibited showing no discrimination, abuse or other adverse actions directed at any patient or client. ***Regulatory authority: 10 NYCRR subdivision 58-1.10(g)***	and regulations, and acknowledgment of the consequences of violation, which may include criminal prosecution.

COMMENT:

The guidance for the proposed standard indicates “Level of access should be defined for each job title”. There are many effective ways for the laboratory to ensure confidentiality and levels of access to the system without defining by job title. In many instances job titles alone do not link to all access level. Recommend allowing access level to be assigned by name or job title or other laboratory defined mechanism because of the lack of correlation between job title and activities.

RESPONSE:

The guidance has been removed based on the comment received.

Document and Specimen Retention

Only comments and responses to the Document and Specimen Retention Standards are included here

Document and Specimen Retention	
Proposed Standard	***Proposed Guidance***
Document and Specimen Retention Standard of Practice 8 (DSR S8): Analytic System Records Retention Analytic system records must be retained by the laboratory, as follows: a) performance specification data and records of acceptability criteria that the laboratory establishes or verifies under Test Performance Specification Standards of Practice 1 and 2 must be retained for as long as the laboratory uses the test process, plus two (2) years after discontinuation: b) testing records, including but not limited to worksheets containing instrument readings, the identity of staff who performed the test(s), and raw patient results, must be retained for two (2) years; c) result review records, including acceptability of quality control and calibration materials for two (2) years: d) histogram of an automated differential ~~that has~~ result~~s of "normal" or "negative"~~ for two (2) years; e) a record of the purity of all drug standard(s) for the period they are in use, and for two years thereafter for forensic toxicology; and	

f) cellular immunology electronic flow cytometer data in listmode or equivalent format for one (1) year. ***Regulatory authority: 10 NYCRR paragraphs 58-1.11(c)(2),(3),(4)***	

Document and Specimen Retention Standard of Practice 8 (DSR S8): Analytic System Records Retention

COMMENT:

d) What about abnormal differential histograms?

RESPONSE:

The requirement under (d) in the standard has been revised based on the comment received.

Document and Specimen Retention	
Proposed Standard	***Proposed Guidance***
Document and Specimen Retention Standard of Practice 9 (DSR S9): Report Retention All reports of tests performed, including the original or duplicates of original reports received from another laboratory, must be kept on the premises of both laboratories. Reports must be produced for the Department upon request and be retained by the laboratory for: a) tissue pathology including exfoliative cytology for twenty (20) years; b) syphilis serology negative report for two (2) years;	Off-site or electronic storage systems are acceptable, provided the laboratory can produce records within twenty-four (24) hours of a request. Original electronic data must be maintained as long as the case file and must be protected from loss or modification.

c) cytogenetics for twenty-five (25) years and according to Cytogenetics Standard of Practice 14; d) case files for forensic identity investigations and electronic data for fifteen (15) years and according to Forensic Identity Standard of Practice 19; and e) all others for seven (7) years. ***Regulatory authority: 10 NYCRR paragraph 58-1.11(c)(5)***	

Document and Specimen Retention Standard of Practice 9 (DSR S9): Report Retention

COMMENT:
b) What about positive syphilis serology?

RESPONSE:
Positive syphilis serology reports must be retained for 7 years, under the requirement in (e) of the standard. There is no change to the standard based on the comment received.

Document and Specimen Retention	
Proposed Standard	***Proposed Guidance***
Document and Specimen Retention Standard of Practice 10 (DSR S10): Specimen Retention Laboratories must be able to retrieve specimens within twenty-four (24) hours. Specimens must be retained, as follows: a) blood films: i. routine, for six (6) months; ii. other than routine, for one (1) year;	For specimens not addressed in this Standard, the laboratory director may determine an appropriate retention time. a) i and ii. A routine blood film is one where no abnormal cells or cell counts are observed, or where a blood disorder is not indicated. a) A routine histogram of an automated differential is one that results as “normal” or “negative” and does not imply the need for further analysis. Histograms are considered to be an instrument printout and must therefore be retained for

b) bacteriology slide on which a diagnosis depends, for one (1) year; c) cytology slide showing: i. no abnormality, for five (5) years; ii. any abnormality, for ten (10) years; d) tissue block for twenty (20) years; e) pathology tissue remnants, until a diagnosis is made; f) histopathology: i. block, for twenty (20) years; ii. slide, for twenty (20) years; g) bone marrow biopsy, for twenty (20) years; h) cytogenetic slide, for six (6) years; i) recipient blood specimens, for one (1) week stoppered at ~~two (2)~~ one (1) to six (6) degrees Celsius; j) samples of each unit of transfused blood, for seven (7) days for further testing in the event of a transfusion reaction; k) forensic toxicology specimens that were reported as positive, adulterated, substituted or invalid for a minimum of one (1) year and according to Forensic Toxicology Standard of Practice 34; and l) mycobacteriology: i. all original and subsequent *M. tuberculosis* complex isolates from all patients, for one (1) year and according to Mycobacteriology Standard of Practice 13; and ii. stained slides of direct smears from primary specimens, until the final culture report has been issued and according to Mycobacteriology	two (2) years, electronically or as hard copy, as required in Document and Specimen Retention Standard of Practice 8. It is not required for a laboratory to create or maintain routine blood films if such films are not routinely generated in accordance with the laboratory's approved procedures. c) i. and ii. include gynecological, non-gynecological, and fine needle aspirate (FNA) for ~~Cytology~~ cytopathology. f) i. and ii. Slides or electronic images that allow re-evaluation of the entire slide(s) used for reported results. i) Recipient refers to any person receiving blood or blood components.

Standard of Practice 9. ***Regulatory authority: 10 NYCRR paragraph 58-1.11(d)(1)***	

Document and Specimen Retention Standard of Practice 10 (DSR S10): Specimen Retention

COMMENT 1:
Specimen Retention- part i- Recipient blood specimen, for one week stoppered at 2-6 degrees Celsius? Can you please clarify "Recipient?" Is this anyone for blood transfusions, transplant of organs etc.?

RESPONSE 1:
Recipient in the context of the standard applies be any person receiving blood or blood components. Guidance has been added based on the comment received.

COMMENT 2:
Recommend that the proposed requirement for DSR S10(i) which requires recipient blood specimens be stored at 2 to 6 degrees C not be adopted. The previous requirement allowed 1 to 6 C degree storage which aligns with the industry standard as defined in the Circular of Information for the Use of Human Blood and Blood Components (https://www.aabb.org/tm/coi/Documents/coi1017.pdf)

RESPONSE 2:
The standard has been revised based on the comment received.

Proficiency Testing

Only comments and responses to the Proficiency Testing Standards are included here

Proficiency Testing	
Proposed Standard	***Proposed Guidance***
Proficiency Testing Standard of Practice 2 (PT S2): Authorized Release of Proficiency Testing Results The laboratory must authorize the proficiency test provider to release all proficiency testing grades and/or results to the Department, in a manner prescribed by the Department. ***Statutory authority: Article 5, Title 5 Public Health Law Section 576(3)***	Participation in proficiency testing is recommended for all tests not included in Subpart I, if a formally evaluated program is available.

Proficiency Testing Standard of Practice 2 (PT S2): Authorized Release of Proficiency Testing Results

COMMENT:
Is authorization to release all proficiency testing grades and/or results to the Department done at the time of registration?

RESPONSE:
Laboratories are responsible for contacting their PT provider and fulfilling the provider's requirements for authorizing the release of PT results to the Department. There is no change to the standard based on the comment received.

Proficiency Testing	
Proposed Standard	***Proposed Guidance***
Proficiency Testing Standard of Practice 3 (PT S3): Alternative to Proficiency Testing Laboratories must have standard operating procedures to verify the reliability and accuracy of test results for: a) New York State mandated analytes for which there is no commercially-available proficiency testing; and b) tests/analytes that are not listed in 42 CFR 493 subpart I ~~non-Subpart I analytes~~ for which: i. the laboratory does not participate in commercially-available proficiency testing; or ii. proficiency testing is not available. Test reliability and accuracy assessment must be conducted at least semiannually and according to Proficiency Testing Standard of Practice 10.	Information on New York State PT requirements is available at: https://www.wadsworth.org/regulatory/clep/pt. The laboratory may evaluate the accuracy of testing through testing of: split-samples (specimens and/or quality control samples) with another validated method; blind testing of specimens with known results~~,~~; or other equivalent system.

Proficiency Testing Standard of Practice 3 (PT S3): Alternative to Proficiency Testing

COMMENT:

The proposed standard refers to “New York State mandated analytes”. Please include guidance with the standard that provides a reference to the published list of those analytes.

RESPONSE:

New York State requirements for PT, including New York State mandated analytes, are available on our website. The guidance has been revised based on the comment received, with a link to the website provided.

Proficiency Testing	
Proposed Standard	***Proposed Guidance***
Proficiency Testing Standard of Practice 4 (PT S4): Routine Analysis Unless instructed otherwise by the proficiency testing provider, laboratories must use the same test process for proficiency testing samples that is used for patient specimens. Proficiency testing samples must be: a) incorporated into the laboratory's routine workflow; and b) rotated among all operators that perform testing. ~~; and~~ c) ~~rotated through all shifts on a regular basis, if the test is performed on multiple shifts.~~ ***Statutory authority: Article 5, Title 5 Public Health Law Section 576(3)***	Proficiency test samples must be accessioned and handled as much like patient specimens as possible, with the exception of automatic reflex testing to another laboratory.

Proficiency Testing Standard of Practice 4 (PT S4): Routine Analysis

COMMENT 1:

The revised verbiage of this standard further enforces the rotation of proficiency testing (PT) samples among all operators that perform testing and throughout shifts. While our lab strives to rotate these samples through shifts and to keep the anonymity of PT samples, the personnel involved in PT is highly dependent on the time of sample arrival and high-volume automation in our lab. In order to mimic the patient testing process as closely as possible, it is difficult to run these proficiency testing samples with specific testing personnel without manual intervention and inadvertently hinting to personnel the manually assigned samples contain PT samples. Any guidance on how to fulfill this regulation will be greatly appreciated.

RESPONSE 1:

The standard has been revised based on the comment received.

Proficiency Testing	
Proposed Standard	***Proposed Guidance***
Proficiency Testing Standard of Practice 9 (PT S9): Attestation The proficiency test provider's attestation statement must be signed ~~before submission~~ by the: a) laboratory director or individual delegated in writing by the ~~assistant~~ director as responsible ~~for the permit category~~; and b) analyst(s) performing the test. The signed document must be kept on file in the laboratory for review by the Department during on-site survey. ***Statutory authority: Article 5, Title 5 Public Health Law Section 576(3)***	The summary page(s) generated by online results submission, signed by the required personnel, fulfills this requirement. These documents will be reviewed during the on-site survey.

Proficiency Testing Standard of Practice 9 (PT S9): Attestation

COMMENT 1:

Strike section b) that the analyst must complete before submission or amend it so that they must sign in a timely manner.
I ask for leniency in regards to the time frame around the analyst being required to sign before submission. All samples are blinded that enter the laboratory, so no analyst knows what patient sample they are handling. All proficiencies are treated like samples. Analysts know and understand that there are set procedures around how proficiencies are handled. With the complexity and time constraints of some proficiency samples and the workflow of larger laboratories, it makes it cumbersome to attain an analysts wet signature, when the analyst didn't even know that they had a proficiency sample in their run until they were told. The short timeframe surveys are for more critically monitored compounds of interest like Occupational exposures and blood alcohol surveys, where it is more critical to make sure that the laboratory is consistently performing within very stringent criteria.
It is still appropriate that the laboratory director or assistance director responsible for the permit category to sign before submission, since they approve of laboratory procedures which includes the process of treating proficiency samples the same as patient samples.

RESPONSE 1:
The standard has been revised based on the comment received.

COMMENT 2:
We request that "before submission" be removed. Rationale: see CLIA regulation below
CLIA 493.801 Condition: Enrollment and testing of samples
(b)Standard: Testing of Proficiency testing samples
(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event.
There is no requirement for signature prior to submission.

RESPONSE 2:
The standard has been revised based on the comment received.

COMMENT 3:
Our laboratory recommends retaining the original language “The laboratory director, or the assistant director responsible for the permit category, and analyst(s) must sign the proficiency test provider’s attestation statement indicating the routine integration of the samples in the patient workload using the laboratory’s routine method.”
The change to "attestation must be signed before submission" will create an undue burden on the labs and could cause proficiency testing to be submitted late if the director and/or assistant director responsible for the permit category is out of town, off-site, or otherwise unavailable to sign in person.
Other regulatory agencies do not require the attestation to be signed before submission.

RESPONSE 3:
The standard has been revised based on the comment received.

COMMENT 4:

The requirement that the director or assistant director and analyst(s) sign the attestation statement before submission is not always possible. There are cases where the director or assistant director may be away during the survey period. Recommend the language of this standard not be changed to require signatures prior to submission.

RESPONSE 4:

The standard has been revised based on the comment received.

COMMENT 5:

The proposed standard specifies that the proficiency test provider's attestation statement must be signed by both the laboratory director (or assistant director responsible for the permit category) and the analyst(s) performing the test prior to results submission. This requirement is problematic particularly in situations where the laboratory director or analyst is absent due to vacation, medical leave, or for other reasons and will be unable to sign until after the results submission deadline. In addition, note that the attestation requirement stated in PT S9 is contradictory to that found in proposed Proficiency Testing Standard of Practice 16 (PT S16). That standard states that the proficiency testing provider's attestation form should be "…completed in accordance with the provider's instructions and requirements..". We participate in the CAP proficiency test program, which does not require attestation statement signature before submission. In fact, the CAP's advice is as follows: "The form does not need to be signed prior to sending the results to PT provider. It can be completed after the event when the results are being reviewed." [CAP accreditation checklist requirement: COM.01400]. In consideration of the above, we request that PT S9 be revised to remove the requirement that the PT attestation statement must be signed prior to results submission.

RESPONSE 5:

The standard has been revised based on the comment received.

Proficiency Testing	
Proposed Standard	***Proposed Guidance***
Proficiency Testing Standard of Practice 10 (PT S10): Performance Review – All Results The laboratory director~~, sole assistant director,~~ or staff ~~specified by title and~~ delegated in writing by the director, must review and document evaluation: a) of all proficiency testing results; b) of any results produced as an alternative to proficiency testing to fulfill the requirements of Proficiency Testing Standard of Practice 3; and c) within two (2) weeks of proficiency testing results becoming available from the provider or completing the alternative assessment. For proficiency testing, an individual analyte score and, when applicable, overall event testing score, must be reviewed. ***Statutory authority: Article 5, Title 5 Public Health Law Section 576(3)***	This standard applies to all proficiency tests, alternatives to proficiency testing, and educational analytes/events.

Proficiency Testing Standard of Practice 10 (PT S10): Performance Review – All Results

COMMENT 1:

We ask that instead of "laboratory director or sole assistant director" it state: laboratory director, sole assistant director(s) or delegated assistant director(s) holding an appropriate certificate of qualification.

RESPONSE 1:

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)).

COMMENT 2:

The proposed standard allows that "… staff specified by title and delegated in writing by the director…" are permitted to perform the review and document the evaluation of proficiency test within two (2) weeks of results availability. Please provide guidance concerning the minimum qualifications required of the delegated staff member in order that they may perform this review.

RESPONSE 2:

Director responsibilities related to testing must be delegated to personnel that are an assistant director or individual that supervisor qualified according to DR S4. There is no change to the standard based on the comment received.

Proposed Standard	***Proposed Guidance***
Proficiency Testing Standard of Practice 12 (PT S12): Unsatisfactory and Unacceptable Performance – Remedial Action The laboratory must implement and document corrective action(s), if needed, when an unsatisfactory or unacceptable proficiency testing or alternative assessment result is identified. Laboratories that demonstrate unsatisfactory or unacceptable performance must: a) identify impacted patient results based on the root cause analysis of the unsuccessful or unsatisfactory PT performance investigation performed according to Proficiency Testing Standard of Practice 11; ~~evaluate test results obtained since the last acceptable run to~~	

~~determine if reported results are inaccurate or unreliable;~~ and b) notify clients and issue corrected reports for reported results that are determined to be inaccurate or unreliable. The laboratory director or ~~assistant director~~ staff delegated as responsible in writing by the director ~~for the category~~ must document review and approval of any corrective action taken. ***Statutory authority: Article 5, Title 5 Public Health Law Section 576(3)***	

Proficiency Testing Standard of Practice 12 (PT S12): Unsatisfactory and Unacceptable Performance – Remedial Action

COMMENT 1:
Under a) - last acceptable run- is this just an acceptable run based on QC and acceptable run criteria or the last acceptable PT run (because the run that the unacceptable PT result was on, could have been acceptable based on QC results and other acceptance criteria). I think this needs to be more clear.

RESPONSE 1:
The standard has been revised based on the comment received.

COMMENT 2:
The proposed standard requires that in the event of unsatisfactory or unacceptable PT performance, laboratories must "evaluate test results obtained since the last acceptable run". The intent of this requirement is unclear, as this action is more typical for corrections necessitated by a quality control failure rather than for a failure in proficiency testing where in most cases the analytical run was acceptable. Please clarify whether the standard should instead read, "evaluate test results obtained since the last acceptable proficiency testing".

RESPONSE 2:
The standard has been revised based on the comment received.

Proficiency Testing	
Proposed Standard	***Proposed Guidance***
Proficiency Testing Standard of Practice 13 (PT S13): Unsuccessful Performance – Remedial Action and Continued Specimen Testing Laboratories that are notified by the Department of unsuccessful performance in proficiency testing must: a) identify a New York State permitted laboratory to refer patient specimens to for testing, in the event that patient testing is voluntarily stopped; b) immediately perform root cause analysis to identify the root or contributing cause(s) of the deficiency to include what happened, why and how the nonconformity occurred, when it began and who was involved; c) describe the impact of the nonconformity on results; d) notify clients and issue corrected reports for reported results that are determined to be inaccurate or unreliable; e) report findings to the Department within the specified time period of notification of unsuccessful performance: i. failure to report the results of the investigation and plan of correction to the Department within ten (10) business days, or when the plan of correction is deemed unacceptable by the Department, will result in a cease testing directive being issued by the Department; and f) demonstrate the effectiveness of the corrective action through successful performance in two (2) consecutive proficiency test events.	~~One (1) event may be an out-of-sequence event provided by the proficiency testing program designated by the laboratory to fulfill proficiency testing requirements for the calendar year.~~ Laboratories may perform one (1) out of sequence event per year if the out of sequence event is supplied by the PT provider designated by the laboratory.

The laboratory director or assistant director responsible for the category must document review of the investigation and approval of any corrective action taken. ***Statutory authority: Article 5, Title 5 Public Health Law Section 576(3)***	

Proficiency Testing Standard of Practice 13 (PT S13): Unsuccessful Performance – Remedial Action and Continued Specimen Testing

COMMENT:

Related to Unsuccessful PT- Remedial Action and Continued Specimen Testing - the guidance is unclear, one event may be an out-of-sequence event provided by the proficiency testing program designated by the laboratory to fulfill proficiency testing requirements for the calendar year, can you please provide clarification of this?

RESPONSE:

The guidance has been revised based on the comment received. The out-of-sequence event must be from the PT provider that the laboratory designated for the year.

Investigation and Corrective Action

Only comments and responses to the Investigation and Corrective Action Standards are included here

Investigation and Corrective Action	
Proposed Standard	***Proposed Guidance***
Investigation and Corrective Action Standard of Practice 2 (ICA S2): Procedure and Documentation for Control of Nonconformities The laboratory must have a standard operating procedure describing actions taken when laboratory services do not follow an established policy~~ies~~ and/or standard operating procedure, requirements of the Quality Management System (QMS) or client specifications. All nonconformities must be documented and ensure that: a) personnel responsible for problem resolution are designated; b) appropriate steps to be followed are defined; c) the clinical significance of the nonconforming laboratory service is considered, and where appropriate, the authorized ordering source or client is informed; d) testing is suspended, and reports withheld as necessary; e) corrective action and root cause analysis are initiated at the time the nonconformance is identified~~ and root cause analysis is performed initiated at the time that~~	

~~the nonconformance is identified and corrective action is taken as necessary~~; f) any released test results associated with nonconforming laboratory services are identified and recalled or corrected, if necessary; g) steps to be taken to resume testing and authorization for resumed testing are defined; and h) each episode of nonconformity is documented, recorded and reviewed at regular specified intervals as defined in the standard operating procedures to detect trends and initiate preventive action(s). ***Regulatory authority: 10 NYCRR paragraph 19.3(c)(5) and subdivision 58-1.2(c)***	

Investigation and Corrective Action Standard of Practice 2 (ICA S2): Procedure and Documentation for Control of Nonconformities

COMMENT:

Suggest that the statement "All nonconformities must be documented and ensure that: " be replaced with: Corrective action shall be appropriate to the magnitude of the problem and commensurate with the risks encountered and ensure that:
Suggest the following verbiage for e):
e. Immediate corrective action is taken at the time that the nonconformance is identified. Root cause analysis is initiated based upon risk of the nonconformance.

RESPONSE:

Based on the comment received, the requirement in the standard has been revised to indicate that corrective action and root cause analysis are initiated at the time that a nonconformance is identified.

Investigation and Corrective Action	
Proposed Standard	***Proposed Guidance***
Investigation and Corrective Action Standard of Practice 3 (ICA S3): Actionable Events The laboratory must define a nonconformity to include any aspect of the test process that does not follow the laboratory's established standard operating procedure and/or policies, requirements of the quality management system or client specifications including: a) when the criteria for proper storage of reagents and specimens are not met; or b) supplies are insufficient or not available for testing; or c) equipment, instruments or testing that perform outside of established operating parameters or performance specifications, as evidenced by: i. unacceptable results or performance; ii. unacceptable differences in test results between different instruments or with the same test performed at multiple testing sites; or d) when results of quality control and/or or calibration materials fail to meet the laboratory's established acceptability criteria; or e) specimen results ~~are~~ outside of the laboratory's reportable range for the test procedure indicate that the test is not performing according to the laboratory's defined performance specifications; or f) reference ranges for a test procedure are inappropriate for the laboratory's test population.	

Regulatory authority: 10 NYCRR paragraph 19.3(c)(5) and subdivision 58-1.2(c)	

Investigation and Corrective Action Standard of Practice 3 (ICA S3): Actionable Events

COMMENT 1:

Reword the two following sections for clarity. This is due to the inability to control test populations that are broad and may be out of the focus of the testing laboratory which may give rise to unnecessary nonconformities for laboratories.
e) an unusually large number of specimen results are outside of the laboratory's reportable range for the test procedure;
f) reword to make more clear what the expectation are. Reference ranges are usually made around the patient data that is derived in that laboratory or they could come from literature.
Strike section b. With the recent past months with Covid-19, we have seen that sometimes reagent supplies are out of our control. To have to explain this with a nonconformity would make no sense. If you are pointing that people do not know when to order supplies appropriately is more of conversation with a manager and the person in charge of keeping on top of the supply. This would be dealt with during their annual review and not in a nonconformity.

RESPONSE 1:

Language for (e) has been revised based on the comment received. If a laboratory determined that the reference range is inappropriate for their population, it must be considered a nonconformance according to (f) (CLIA 493.1282(b)(1)(iii)). If a laboratory does not have sufficient supplies to perform testing, it must be considered a nonconformance according to (b). There is no change to (b) or (f) based on the comment received.

COMMENT 2:

Our laboratory disagrees with proposed item (e) requiring that specimens outside the lab's reportable range should be treated as nonconforming events. Samples with results above the reporting range are routinely diluted into range based on validated dilution protocols or reported as greater than the upper reporting limit (e.g., >10,000 ng/mL). Samples with results below the reporting range are reported as Negative or below the lower reporting limit (e.g., <1.0 ng/mL). Values below or above the reporting range that are abnormal are flagged and reported as such. Existing requirements address the handling of any critical/panic values.

RESPONSE 2:

Language for (e) has been revised based on the comment received.

Investigation and Corrective Action	
Proposed Standard	***Proposed Guidance***
Investigation and Corrective Action Standard of Practice 4 (ICA S4): Corrective Action Procedure and Documentation The laboratory must have a standard operating procedure describing the process for initiating corrective actions that are appropriate to the magnitude of the problem and commiserate with the risks encountered. For ~~all~~ corrective actions, the laboratory must: a) perform root cause analysis to identify underlying cause(s) of a nonconformance; b) initiate and document corrective actions and, where appropriate, preventive actions; c) document and implement any policy and/or standard operating procedure changes required for corrective actions, if applicable; d) assess the results of any corrective actions taken to ensure that they have been effective; e) ensure that noncompliant practices are not occurring in other sections/categories of the laboratory; and f) submit the results of corrective actions to the laboratory director or individual designated in writing by the director for documentation of review. ***Regulatory authority: 10 NYCRR paragraph 19.3(c)(5) and subdivision 58-1.2(c)***	

Investigation and Corrective Action Standard of Practice 4 (ICA S4): Corrective Action Procedure and Documentation

COMMENT 1:

We suggest removing the word "all" corrective actions and use the laboratories risk assessment process for assessing the outcome of the nonconformity and its impact.
We suggest retaining the prior verbiage used in the Standard Corrective Action S1: Corrective action shall be appropriate to the magnitude of the problem and commensurate with the risks encountered. The laboratory must:
For e)
Suggest changing the word "sections" to "categories"
We ask that instead of laboratory director it state: laboratory director or delegated assistant director(s).

RESPONSE 1:

The standard has been revised based on the comment received.

COMMENT 2:

Our laboratory recommends modifying to "…laboratory director or designee…"

RESPONSE 2:

The standard has been changed based on the comment received.

Investigation and Corrective Action	
Proposed Standard	***Proposed Guidance***
Investigation and Corrective Action Standard of Practice 5 (ICA S5): Corrective Action Effectiveness After implementation of a corrective action, preventive action, or improvement, the laboratory must ~~perform~~ evaluate and document ~~an audit to evaluate~~ an assessment of effectiveness. ***Regulatory authority: 10 NYCRR paragraph 19.3(c)(5) and subdivision 58-1.2(c)***	

Investigation and Corrective Action Standard of Practice 5 (ICA S5): Corrective Action Effectiveness

COMMENT 1:
Suggest the following verbiage: After implementation of a corrective action, preventive action, or improvement, an effectiveness assessment must be performed by the laboratory and documented.
Rationale: There are numerous ways to perform an effectiveness assessment other than "an audit".

RESPONSE 1:
The standard has been revised based on the comment received.

COMMENT 2:
Reword to: After implementation of a corrective action, preventive action, or improvement, the laboratory must evaluate the risk of the improvement. If warranted, see if the improvement was effective and document the action taken. By phrasing it this way, it gives flexibility on how to best monitor the effectiveness of an action since no two actions are the same. Not all actions would require an audit to check the effectiveness of the action. Sometimes effectiveness can be seen with merely looking to see if the action did not occur again over a specific time period.

RESPONSE 2:
The standard has been revised. Based on the comment received, there are no additional changes to the standard.

COMMENT 3:
Question for NY: We perform an EC on issues of higher criticality. Is it acceptable to define which incidents required an EC as this is not performed on issues that are minor or neglible.

RESPONSE 3:
The assessment of effectiveness is required. This assessment can be performed in a number of different ways. There is no change to the standard based on the comment received.