

New York State Department of Health
Clinical Laboratory Standards of Practice
Response to Comments on Proposed Standards

We thank all who reviewed the proposed Clinical Laboratory Standards of Practice and provided comment. We received more than 150 comments from 100+ laboratories. Those comments and our response are presented here.

GENERAL COMMENTS

Comment: The fundamental standards of practice state that the laboratory must be in substantial compliance with the associated sustaining practice standards. What is meant by substantial compliance?

Response: *The General Systems requirements are built around a hierarchy of eleven Fundamental Standards; for each Fundamental Standard there is a set of Sustaining Standards that will be used to evaluate whether a laboratory is in compliance with the Department's minimum requirements for operation. Beginning March 2008, laboratories will receive, in addition to the standard Laboratory Evaluation Report or Deficiency Statement, a summary report that indicates the laboratory's degree of compliance: laboratories will be informed whether they fail to meet minimum requirements; meet minimum requirements; or exceed minimum requirements, for each of the Fundamental Standards. Laboratories found to meet minimum requirements for operation for the respective Fundamental Standards will be considered to be in substantial compliance.*

Comment: We received several comments about the fact that the document was too large for download and distribution, and a few requests from individuals who just wanted us to "tell them what was new."

Response: *The standards document is now divided into two parts: Part One-General Systems, and Part Two-Specialty Requirements, and are available at <http://www.wadsworth.org/labcert/clep/standards.htm>. Due to the extensive rewrite and context of standards as presented in December 2006, simple statements of 'what is new' would not have been effective: laboratory directors and personnel needed to read the document in its entirety to ascertain pertinent revisions to laboratory practice requirements. All revisions to the proposed standards that resulted from comments from the laboratory community are presented in a table on the standards web page.*

Comment: This is an excellent document and provides detailed and relevant information in a readable and useful format.

Response: *We are gratified by the number of individuals who acknowledged the utility of the standards document. A key objective in the rewrite was to align practice standards with advances in laboratory medicine and to facilitate an understanding of their intent.*

Comment: One commenter acknowledged that while some requirements in this revision are similar to those of other regulatory or accreditation agencies, others were different. There were comments expressing concern about the amount of effort it would take to review and update policies and procedures and expressed the opinion that some of the requirements would be onerous to implement in the current healthcare environment. One commenter went on to suggest that we trial the standards in a variety of settings as it might not be feasible for smaller laboratories to meet the same requirements as larger laboratories. This commenter and several others suggested a phased-in approach for the standards, particularly the Quality Management System or QMS Standards.

Response: *We acknowledge the challenges laboratories are facing, particularly in staffing and personnel and encourage laboratories to bring to our attention any requirements that are in conflict with those of other regulatory or accreditation agencies or impose an undue burden on laboratories so they can be evaluated and if justified, changes made. Based on field trials of survey tools that implement the updated standards and comment on the QMS Standards, we have revised standards for clarity of intent. We took the suggestion of the laboratory community and full compliance with the QMS Standards will be phased in over the next two years.*

Comment: Could you verify where and if Reproductive Laboratories fall under these standards - i.e., andrology laboratories and Assisted Reproductive Technology Laboratories (ART labs currently do not fall under CLIA'88).

Response: *Generally, andrology and ART facilities require a permit and would be held to these standards if they are doing tests on the reproductive products such as gametes or sperm, or performing tests on recipients or donors, for example, endocrinology or infectious disease testing. Storage, manipulation, washing, insemination etc. are not considered tests but facilities performing these procedures require a license from the Department's Blood and Tissue Resources Program (BTRP). Definitive requirements for when a license or laboratory permit is required can be obtained by contacting BTRP at (518) 485-5341.*

Comment: There were requests for clarification on the process to be followed when there is a change in director or other change (location or owner) which voids the laboratory permit.

Response: *The process to be followed is described in detail in our Program Guide, available on our website. One commenter requested clarification on the definition of an owner, as used in this document. Public Health Law states that both the owner and director are responsible for laboratory operations. However, the commenter pointed out that in a large public company the laboratory owner "does not exist," meaning, we assume, that the owner per se is not on the premises of the laboratory or involved in day-to-day operations. In this context, senior management personnel would be considered appropriate representatives of the owner.*

QUALITY MANAGEMENT SYSTEMS

Comment: It would be helpful to sponsor training seminars in Quality Systems Management.

Response: *Our requirements under the Quality Management Systems Fundamental Standard of Practice are grounded in consensus guidelines published by the Clinical and Laboratory Standards Institute (CLSI). Pertinent CLSI documents should be among primary resources used by laboratory personnel. Nonetheless, we will soon provide a handbook of survey practices for laboratory quality assessment, which is intended to describe minimum requirements in the design and implementation of quality systems, and survey tools used to assess the effectiveness of the quality system. We will also seek or create opportunities for quality systems seminars based on knowledge of the “state-of-practice” gained through laboratory survey.*

Comment: Item q (now s) of QMS SSP1 (now QMS S1) should state specifically that vendors and contractors are also required to receive pertinent communications relating to the support and/or resources for laboratory operations. The following revision is suggested: q) Communications with patients, health professionals, vendors, contractors, referral laboratories, and any applicable accreditation and regulatory agencies;

Response: *We agree that laboratories must clearly define and describe requirements for purchased products and services. The standard was revised as recommended.*

Comment: Changing policies, procedures and processes into a true document control system would be a very large undertaking requiring dedicated staff to complete this requirement in a timely manner. We suggest a 3-5 year plan to phase this new approach in laboratories. Under document control, do you expect all of the involved documents to be numbered in some fashion? If so, it would be almost impossible to attain in our laboratory.

Response: *Although there are many resources that address protocols for management of documents, including guidelines from CLSI (GP-2-A5 Laboratory Documents: Development and Control), the DOH standards for document control (QMS S1, Retention S1) are not prescriptive. ISO 15189: Medical Laboratories – Particular Requirements for Quality and Competence; 4.3 Document control, states that the laboratory defines, documents and maintains procedures to control all documents and information. The intent is that procedures exist to ensure version-sensitive documents - including policy statements, procedures, specifications, calibration tables, biological reference intervals and their origins – are approved and are made available for use at all relevant locations. We have revised (Retention S1): Document Control to clarify the intent of the document control standard.*

Comment: Several individuals commented that our use of the term document control is not consistent with common usage.

Response: *We presented at several outreach sessions around the state a survey tool titled: Document Control: Specimen Processing & Process Verification. The survey tool is designed to evaluate laboratory capability to substantiate patient test reports. The laboratory is asked to provide the policies and procedures that were in place at the time a selected patient specimen was processed, and the records that were produced under those policies and procedures. Using these documents, the surveyor will determine whether: 1) specimens were processed in accordance with pertinent laboratory policies and procedures; 2) the laboratory’s policies and procedures meet minimum requirements specified by NYSDOH standards of practice; and 3) the records substantiate the reliability of reported test findings. We use the phrase Document Control: Specimen Processing & Process Verification to denote an outcomes-based evaluation of document control and suitability of laboratory practices.*

Comment: Joint Commission PPR must be completed annually. Perhaps NYSDOH could align this audit process with Joint Commission PPR requirement process and request that targeted audits be done in areas identified as partial or non-compliance.

Response: *It is our understanding that the Joint Commission Periodic Performance Review (PPR) is a process whereby the laboratory assesses its compliance with Joint Commission standards. We encourage laboratories to conduct similar self-evaluations of compliance with NYSDOH standards; however, this is not the intent of (QMS S3): Quality System Audits (formerly QMS SSP2: Internal Audits). Under this standard, the laboratory is required to establish quality indicators (monitors) for its processes, and to determine whether process quality goals as established by leadership are being achieved. Minimally, the laboratory is to describe quality goals and objectives for each of the quality system elements listed under (QMS S1): Establishment of Specifications and Requirements. The policies and procedures that are developed to achieve quality goals must meet minimum requirements set forth by the Department in its sustaining standards of practice. Guidance to QMS S1 now includes references to pertinent sustaining standards for the respective quality system elements.*

Comment: Several laboratories commented that carrying out planned audits annually, as described in the standard QMS SSP2: *Internal Audits* (now QMS S3: *Quality System Audits*), would be extremely difficult given current staffing levels within laboratories across the state for both small and large laboratories. Better definition of internal audits and/or examples is needed.

Response: *The Department has long-standing requirements for laboratory quality assurance programs that include procedures for monitoring and evaluating the quality of laboratory services (existing Quality Assurance Standard 2). The new Clinical Laboratory Standards of Practice for Quality Management Systems are intended to facilitate compliance with quality assessment requirements by providing a quality systems framework. The Handbook for Laboratory Quality Assessment, currently in development, will provide examples of quality system structures for elements listed under QMS S1: Establishment of Specifications and Requirements*

Comment: If external regulating bodies are able to view our internal findings, we believe it will have a negative impact on the effectiveness of the internal audit program. We recommend that NYS use the same professional discretion as allowed by the FDA, whereby they only look at internal audit results when there is other strong evidence to indicate a need to do so.

Response: *We have clarified (QMS S3): Quality System Audits (formerly QMS SSP2: Internal Audits) to reinforce the standard's intent that laboratories are to audit systems for attainment of its quality goals rather than for compliance with regulatory agency requirements. Quality goals, policies and procedures to achieve goals, and quality indicators are subject to review by the Department.*

Comment: The Clinical and Laboratory Standards Institute's Quality Management System Model (HS1-A2; A Quality Management System Model for Health Care; Approved Guideline-Second Edition) specifies twelve quality system essentials (QSEs); the NYSDOH lists twenty one QSEs under its Quality Management System Sustaining Standard of Practice 1 (QMS S1): *Establishment of Specifications and Requirements*. Why the difference?

Response: *CLSI describes its QSEs as foundational building blocks that must be in place and functioning effectively to direct and control the organization (laboratory) with regard to quality. Technical requirements pertinent to the healthcare organization must be developed to implement the respective QSEs. The NYSDOH QMS S1 standard lists the laboratory functions that must be described fully, including process specifications,*

quality goals and quality indicators. The alignment of NYSDOH quality system essential elements with CLSI QSEs is as follows:

CLSI Quality System Essentials	NYSDOH Quality System Essential Elements	Applicable Standards Establishing Minimum QSE Requirements
Documents and Records	QMS S1 (f), (t)	SOPM S2, S6; Retention S1, Retention S3
Organization	QMS S1 (a)	HR S1, S3, S4, S5; DIR S3(f)
Personnel	QMS S1 (b), (c)	HR S6, S7, S8; DIR S3
Equipment	QMS S1 (i)	Validation S1; LE S1(a)
Purchasing and Inventory	QMS S1 (i)	Validation S1; LE S1(a)
Process Control	QMS S1 (g), (h), (j), (k), (l), (m)	Requisition S3, Validation S5, Processing S4, QC S1-S6, Reporting S1-S6, Process Review S2
Information Management	QMS S1 (e)	LIMS S2, S4
Occurrence Management	QMS S1 (p), (q)	Control of Non-Conformities S1, Complaint Resolution S1
Assessment: External and Internal	QMS S1 (n), (o)	PT S1-S8; QA S3 (c)(d)
Process Improvement	QMS S1 (u)	QA S1, QA S2
Customer Service	QMS S1 (r), (s)	Referral S1
Facilities and Safety	QMS S1 (d)	GF S1

HUMAN RESOURCES

The Human Resource section was revised extensively based on feedback from the laboratory community as well as input from laboratory survey staff and the experiences during our site visits and outreach events. While most of the revisions involved reordering the standards and providing additional guidance to clarify their meaning, several additional standards were added. HR S7 was added to clarify that the requirement for competency assessment applies to supervisory as well as technical staff. As a result of our review for recognition as an exempt State under the federal CLIA regulations, additional standards (HR S3 and HR S4) were added to specify duties for supervisors and technical personnel consistent with those provided in the CLIA regulations.

Comment: The standards and guidance related to the role of the laboratory director do not seem realistic based on historical experience.

Response: *The requirements for the role and responsibilities of a laboratory director are not new; they are derived from existing regulations in Part 58 and Part 19 of NYCRR. This comment is very general and we would be interested in learning more about how the requirements for laboratory directors are unrealistic.*

Comment: It is possible that one Laboratory Director can be responsible for two or more geographically different locations within the same business organization – these are not different labs per se but simply not on the same premises—please clarify this requirement.

Response: *Under regulations at Subpart 58-1.2, an individual is limited to two directorships; this limit has also been applied to assistant directorships when the individual is the only certificate of qualification holder for a permit category. The regulations allow that a blood bank and a laboratory on the same premises (even if operating under separate permits) can be counted as one directorship; however, under all other circumstances the limit applies to the number of separately permitted laboratories (and statute requires a separate permit for*

laboratories that are not on the same premises). Part 58 does allow the Department to authorize additional directorships when it can be demonstrated that “more than two laboratories are required to serve the needs of an area and the total volume and the types of laboratory service provided by the several laboratories are not such as to require the services of more than one director.” Additional directorships are authorized (up to the CLIA limit of five) when it can be demonstrated that these criteria are met and the director is able to maintain active oversight and satisfactory compliance of the laboratories under his or her direction.

Comment: There were several comments regarding HR SSP1 (now renumbered as DIR S1) regarding the requirement for the hours the director spends on-site in the laboratory. One commenter remarked that it is less relevant to include the hours a director spends on site; more relevant is a description of the nature of the director’s involvement, including how others such as assistant directors and other management staff are utilized to help fulfill the director’s role. There were several requests that a minimum number of hours be established for the on-site presence of the director. One commenter asked if the intention of the standard is for the director to “clock-in” or otherwise physically document his or her time on-site. Another asked if the amount of time a director is expected to spend on-site as documented in a contract for services would meet this requirement.

Response: *We recognize that the amount of time the director spends on site is not to be used as the only criterion for his or her effectiveness; however, the requirement for a director to document his or her hours is derived from regulation at Subpart 58-1.2(a) of NYCRR, which states that a director shall serve a laboratory on a full-time or **regular part-time basis** (emphasis added). This requirement is included in the Standards documents as DIR S2. Thus the laboratory must document the actual hours the director will spend on-site so we can confirm that there is a director who serves the laboratory on a regular part-time basis. As such, we discourage submissions for director or assistant director appointments that list hours as “as-needed” or “variable;” there must be an established schedule or number of hours a director or assistant director is expected to spend on-site.*

We do not set a minimum number of hours because the adequacy of the time a director spends onsite must be evaluated in the context of the size of the laboratory, scope of testing, and availability of other qualified staff and documentation that if delegated, the director’s duties are assigned appropriately and there are mechanisms in place for the director to monitor that duties delegated to others are being discharged as required. Guidance to this standard does provide examples of how a director’s involvement will be evaluated; guidance regarding delegation of duties has been provided. While documentation of director involvement in required activities would substantiate compliance with this standard, and it is not required that the director “clock-in” or otherwise record his or her hours on-site, such a system would provide assurance that this requirement has been met, as would a contractual agreement. The requirement to implement a system to record hours spent onsite has been imposed as part of several recent enforcement actions, when there has been evidence that the director is not actively involved in laboratory operations.

Comment: Could California State CLS licensure be presumed adequate to meet the requirement for out-of-state laboratories to employ personnel with credentials equivalent to the licensure required by the New York State Education Department (SED), for laboratory personnel employed in New York State.

Response: *It is our understanding that SED cannot accept licenses granted by other States; however, there is a system to endorse out-of-state licensure as meeting some of the prerequisites for New York State licensure. We will consult with SED and develop consistent policies with regard to the equivalency of out-of-state licenses with the requirements for licensure under the SED Clinical Technology Practice Act.*

Comment: There was one comment in favor of holding personnel employed in laboratories located outside of New York State to standards equivalent to those of SED and another comment that all personnel employed in New York State permit-holding laboratories should instead be required to be licensed through SED. There were additional comments expressing concern about how far we would take the requirement for equivalency with SED.

Response: *SED has sought a legal opinion with regard to the scope of the Clinical Laboratory Practice Act and has taken the position that law cannot be applied to individuals employed outside the State without a statutory amendment. Thus the existing law would have to be amended or a new law passed to extend the jurisdiction of licensure requirements to individuals employed in other States. We will be working on revisions to Part 58 to recognize SED licensure, adopt equivalent requirements for those working in out-of-state laboratories and specify requirements for individuals employed in specialties not subject to SED licensure such as forensic identity, paternity, and forensic toxicology. The laboratory community will have an opportunity to comment and provide input to these revisions.*

Comment: The titles for laboratory personnel used throughout the document should be consistent, i.e., the terms medical technologist and clinical laboratory technologist seem to be used interchangeably, and the titles should be defined.

Response: *The term medical technologist is used in our regulations at Part 58 of NYCRR, while the terms clinical laboratory technologist and clinical laboratory technician are used in the SED Clinical Laboratory Practice Act. The standards have been edited to ensure that the titles are used consistently and definitions for the titles used will be incorporated.*

Comment: There was a request for clarification on record-keeping requirements for technical personnel. Our standards indicate that a copy of technical personnel licenses must be maintained by the laboratory; however, as pointed out by the commenter, the actual registration certificates issued by SED bear the statements “Do Not Copy” and “This document is valid only if it has not expired, name and address are correct, it has not been tampered with and is an original, not a copy.” The commenter asked whether the laboratory must keep original licenses on file for technical personnel or would there be other acceptable alternatives.

Response: *It is our understanding that the registration certificates issued by SED’s Office of the Professions (OPC) are typically posted at the individual’s worksite, hence, the emphasis on the original document. It is acknowledged that this requirement is impractical for individuals who may be employed at several different laboratories, and unrealistic for laboratories employing hundreds of employees to post an original certificate for each individual. We will accept copies, which may be kept in a central binder or incorporated into the individual’s personnel file, provided there is an acknowledgement that the original certificate has been seen. There must be a mechanism to ensure that certificates are kept current. Employers should utilize OPC’s web-based utility to verify the licensure status of each employee and maintain a copy of this verification on file in addition to a copy of the current certificate. We do understand that SED prefers employers retain original certificates and advises individuals to obtain multiple certificates as needed for each site of employment. Any inquiries about the proper use of certificates should be directed to SED to ensure that the laboratory is in compliance.*

Comment: Rather than registering individual out-of- state techs, it may be more efficient for NYS to require that the individual laboratories monitor workload for each cytotechnologist; then inspect this monitoring during when on-site.

Response: *Registration of all cytotechnologists and monitoring of their workload are statutory and regulatory requirements, and registration is a proven mechanism for documenting multiple sites of employment.*

Comment: One commenter asked whether the requirements for competency testing for supervisory personnel applied only to supervisors engaged in testing.

Response: *The intent is that the laboratory develops a mechanism to ensure that supervisors are competent in fulfilling both their technical and supervisory responsibilities. Duties of a supervisor consistent with those required under the CLIA regulations were added to standard HR S3.*

Comment: We recommend that the guidance indicate the functions of a Quality Systems Manager. The method to accomplish this may or may not be effective to be the responsibility of one manager depending on the size and scope of services of the laboratory.

Response: *Guidance clarifying that a Quality Systems Manager, limiting his/her scope of activity to oversight of quality system activities, does not have to be licensed. It is understood that in a large facility several individuals may fulfill this role as appropriate for the specialty of testing.*

Facility Design and Resource Management

Comment: Several individuals asked whether GF SSP2 (now GF S2) required laboratories to use temperature recorders for all refrigerators or freezers in order to meet the requirement for “continuous monitoring of temperatures.” One commenter pointed out that this would be expensive to achieve and not easily achieved on older equipment.

Response: *This standard does not require temperature recorders; it only states (under guidance) that continuous monitoring by automated temperature recorders, if used, would be acceptable.*

Comment: There was one comment regarding Laboratory Equipment Standard LE SSP2 (now LE S2). The commenter asked whether a laboratory is required to exceed manufacturer recommendations for preventive maintenance.

Response: *It is not required, but it is recommended that the laboratory have mechanisms to monitor whether the manufacturers recommended procedures and intervals for preventive maintenance are adequate (based on system performance) and implement more rigorous preventive maintenance procedures, if indicated.*

Comment: There were several comments regarding the requirements in standards LE S6 and LE S7 for the monitoring of CO₂ incubators and UV decontamination procedures.

Response: *These standards were revised based on this feedback.*

Comment: The intent of the standards REAG S4 and Retention S5 requiring inventory control of reagents and supplies is recognized; however, the specific approach for capturing the information is onerous and time-consuming. All elements detailed in the standard are monitored according to policy. Additionally, on each analyte worksheet for technologist review, lot numbers and expiration dates are recorded; expired lot numbers will not print on the worksheet. I believe our policy and practices achieve the intent of the standard.

Response: *The intent of the referenced standards is to ensure that validated resources are used in specimen processing, and that outdated resources are removed from use. We recognize that there are many possible designs for inventory control, and it is not our intent to prescribe a design. We do expect that in an exercise of recreating the test process for selected patient specimens, the laboratory will be able to readily identify the resources used (including lot numbers, where appropriate) and provide evidence of validation prior to use. The individual commenting appears to understand the intent of the inventory control standards, and the described practices are consistent with needs for documentation.*

Comment: Regarding inventory control systems for laboratory supplies, we currently list on the product the received date and the opened date. If this had to be recorded elsewhere for all supplies, it would create a tremendous amount of extra work for the staff which based on current staffing levels is impossible.

Response: *The intent of long existing records retention standards is to allow the credible review of analytical records as necessary to substantiate the reliability of test findings. The laboratory must be capable of identifying all resources, including reagent lot number, used for the analysis of selected patient specimens. Records retention is two years.*

Comment: One commenter asked if the New York Laboratory Safety Standards are applicable to out-of-state laboratories.

Response: *Requirements for handling regulated medical waste are not applied to out-of-state laboratories. Laboratories located out-of-state will be assessed for compliance against the remainder of the Safety Standards.*

Comment: The reference to the laboratory director in Safety Standards SSP7 and SSP8 (now S7 and S8) should be replaced by the term "laboratory director or designee."

Response: *Promoting a safe laboratory environment is one of the director responsibilities outlined in Part 19 and listed in Standard DIR S3. Like many other of the director responsibilities, it can be delegated, but the director remains ultimately responsible for the safety practices of the laboratory.*

Comment: One commenter asked whether the pest management plan required under LE SSP11 (now LE S11) should be written, and how the requirement for sufficient space to ensure adequate cleaning can be assessed objectively and uniformly.

Response: *Written evidence to document pest management would be recommended. One option to ensure an objective assessment would be to have an independent evaluation, or consult industry references.*

Comment: There was one comment suggesting that Safety Standard SSP6 (now S6) be revised to clarify that the requirement for New York State license for radioactive materials license applies only to laboratories located in New York State.

Response: *The standard has been revised as suggested.*

Comment: Please clarify if out of state labs are subject to LIMS S1, which requires test results generated by the LIS are reported, archived, and maintained in an accurate and reliable manner. 21 CFR Part 11 requires multiple technical and procedural controls and should be considered an acceptable alternate standard.

Response: *Out-of-state laboratories are held to all LIMS standards. If the technical and procedural controls specified under 21 CFR Part 11 are adequate to meet the intent of LIMS S1, then the CFR protocol is an acceptable standard.*

Comment: A new requirement has been added in LIMS SSP7 (now LIMS S7) that states that the REASON for the correction must print on the corrected report. The requirement to include a reason for the change on the report will not add clinical interpretive value to the result.

Response: *The individual misinterprets LIMS S7, which is not a new standard. The standard does not require that the reason for report correction be printed on the corrected report, only that the reason for change is captured and retained by the laboratory. The Reporting S4 standard addresses the requirement that the laboratory retain the basis for the correction, which is not necessarily done using the LIMS. Therefore, the reference to "reason for change" is removed from the LIMS S7 standard.*

STANDARD OPERATING PROCEDURE MANUALS

Comment: I am writing this out of complete frustration. I have been a Laboratory Technologist for almost 30 years both military and civilian. I feel that one of the biggest myths around is that SOPs must be written for inspectors not necessarily for the tech working the bench. I understand the requirement for standardization and the importance that certain things must be included in the SOP. But a Cross Match can not be written the same way as a serology test. Why include categories that do not pertain to the test, i.e., calibration when none is done do not just put in N/A or does not apply. Where I am presently employed SOPs are like text books, everyone skips over them and goes directly to package inserts, and when anyone says anything the response is always "the inspector likes it this way". Well I wish the inspector would try using one and see how great they are!

Response: *We concur with your sentiment that the SOPM must be written to benefit the technologist, serving as the reference document on proper performance of examination procedures. SOPM S4 describes requirements for the content of SOPM. Although CLSI and other organizations provide useful templates for manuals, we do not prescribe a format for the procedure manual; only that information essential to the reliable performance of examination procedures is provided and used. Inspectors review procedure manuals to verify that all pertinent requirements under SOPM S4 are addressed for the respective examination procedures.*

PRE-EXAMINATION PROCEDURES

Comment: Two laboratories recommended that the time to get a written order for the verbal orders be extended from 48 hours as required under Requisition S2: Oral Request. Physicians often have multiple office locations and thus are not always available to write up the order that day. Also, outreach laboratory services continue to grow, thus it is necessary for written orders to be completed and mailed in.

Response: *We concur that the requirement for obtaining a written test requisition should be extended; however, the 48 hour window is in regulation, Part 58-1.7. Part 58 is soon to be revised, but until then, the 48 hour window remains in effect.*

Comment: Guidance to Requisition S1 states: A healthcare provider or clinical laboratory may request approval to refer a sample to a clinical laboratory that does not hold a permit or specific test approval...by submitting a *Non-Permitted Laboratory Request...*". An exception policy should be applied when there is an urgent patient care matter, pediatric sample or unusual metabolic disorder. The exception policy would permit specimen referral concurrent with submission of the *Non-Permitted Laboratory Request* form.

Response: *The submission of a request to refer a specimen to a non-permitted laboratory **prior to** specimen referral allows program to determine whether a permitted laboratory is approved to provide the examination. Program staff responsible for management of the NPL approval process strives to provide immediate response to urgent requests for specimen referral, but acknowledges that 24/7 coverage cannot be provided to triage NPL requests. An exception to the requirement for prior approval is appropriate where staff is not available to respond to the urgent request. **Guidance Revision:** A healthcare provider or clinical laboratory may request approval to refer a sample to a clinical laboratory that does not hold a permit or specific test approval by submitting a *Non-Permitted Laboratory Request*, available at <http://www.wadsworth.org/labcert/regaffairs>. An exception to the requirement for prior approval is allowed in cases of urgent need for testing and program staff is not available to process the referral request.*

EXAMINATION PROCEDURES

Comment: Several laboratories expressed the sentiment that for FDA cleared single use devices, what is the value of more rigorous QC and function tests as opposed to following manufacturer guidelines? Additional QC requirements would increase the cost of performing the test(s). Adding requirements without value along with other unfunded mandates is burdensome to laboratories.

Response: *The NYSDOH standards, (QC Design S2): Design of QC Systems for Single-Use Test Devices and (Process QC S3): Single-Use Test Devices, do allow the use of device manufacturer guidelines or recommendations for quality control. The DOH standard simply requires that the laboratory director is informed of the design capabilities of integrated control systems to allow informed decision-making on needs for a total quality control process, including the use of external quality control materials. The FDA approves/clears test devices, but does not approve manufacturer recommendations for quality control. The laboratory director is solely responsible for assessing quality control requirements, taking into consideration the unique testing environment under which devices will be used.*

Comment: In the guidance to (Process QC S4): Electrophoresis, some comments may be added to reflect the situation with serum protein electrophoresis, where separation is based on both size and charge. In these instances, running a normal serum sample and an abnormal serum sample might be adequate.

Response: *Guidance has been added as recommended.*

Comment: Process Review S1 states that the director or supervisory staff must authorize release of test results. In practice, technologists release results all the time. Is this saying no lab results can be released until a Medical Director or supervisor reviews them? That is not practical. We have trained LICENSED staff who now are the only ones who can perform tests - they have to be able to release results.

Response: *The standard's intent is to ensure that all protocols used for the review and release of results, including auto verification, have been approved by the director, and that supervisory staff verify that approved protocols are routinely followed by technologists who have been authorized to release results.*

Comment: Please clarify (Reporting S1) (h): Report Content, as to whether the name of the laboratory's director is required to be on the laboratory report.

Response: *There is no requirement for the name of the laboratory director to appear on a report. The signature of the qualified person is required, for reports issued in the categories of cytogenetics, genetics, fetal defect markers, cellular immunology and oncology. A qualified person is defined in the standards for these specialties as a director or assistant director who holds a valid New York State certificate of qualification in the category. In the category of paternity, the laboratory director is required to sign the report. In pathology, reports must include the signature of the pathologist who examined, reviewed and/or diagnosed the case. Laboratories may use electronic signatures, but must have a procedure in place that ensures and documents the qualified person's authorization for each signature occurrence (such as access limited by password).*

Comment: Why is the worksheet retention requirement under (Retention S3): Test Request and Process Documents increased from one to two years?

Response: *CLIA rules now require two year retention requirements, as is appropriate given the two inspection cycle for records review.*

QUALITY ASSESSMENT AND IMPROVEMENT

Comment: Please clarify (QA S3): Ongoing Verification of Examination Accuracy regarding the frequency of examination procedure accuracy: twice each year or once every six months. In practice, the NYS surveyors are interpreting this to mean that the interval between PT must be 6 months.

Response: *The standard was revised to state that accuracy verification must be performed at least every six months.*

Proficiency Testing Sustaining Standard of Practice 2 (PT SS2): Routine Analysis

Comment: (PT S2): Routine Analysis states that “the laboratory shall examine, test, or analyze the PT samples it receives from New York State proficiency testing program and other provider programs in the same manner as patient samples...” To reflect clinical reality and avoid misinterpretation of this standard, it would be preferable to restate the standard to include the intent expressed in the guidance, e.g., that the PT material will be handled as much like a patient sample as possible.

Response: *Laboratories must make every effort to process PT specimens as routine patient specimens. Violations of this standard may carry severe penalties, and we believe that introducing qualifying statements in standard is inappropriate. Nonetheless, we recognize that PT specimens are typically not presented to the laboratory as patient specimens, and that the PT provider may specify requirements for reporting. The surveyor is aware of defensible PT handling and reporting anomalies, which will be addressed as stated in guidance to the standard.*

Comment: Please provide an example of an attestation statement as required under (PT S8): Attestation.

Response: *The laboratory does not prepare attestation statements. The Department and other PT providers supply the attestation statement that is to be signed by laboratory personnel.*

Comment: Several laboratories questioned the need to periodically review the services provided by referral laboratories as required under (Referral S2): *Periodic Review* because the referral laboratories have already been approved and licensed by the Department.

Response: *As required under quality systems standards (QMS S1 r), laboratories establish specifications and requirements for the selection of referral laboratories. Selection criteria likely include arrangements for pre-examination and post-examination procedures, timeliness of reporting and access to expertise for results interpretation. Although the referral laboratory is permitted by the Department to accept and process specimens, the referring laboratory is best positioned to evaluate whether the referral laboratory is meeting stated performance requirements. A referral laboratory's performance history dictates the frequency of performance reviews: semi-annual review is suggested for good performing referral laboratories; monthly or more frequently where services to clients are potentially compromised by referral laboratory practices.*

Part Two: Comments to Specialty Standards

We thank those who provided comment on the specialty standards of practice. The Compilation of Changes to Proposed Standards (available on the Standards of Practice webpage) includes revision to *Specialty Requirements* as was required by federal agency review. The *Specialty Requirements* will be revised further over the next year to incorporate technical updates with consideration of laboratory community comments, and will be reordered to conform to the hierarchy of the *General Systems* standards.