The Proposed General Systems Standards were circulated for comment on March 7, 2014. The announcement and copies of the proposed standards with a crosswalk were sent to NYS-permitted facilities that held or were in application for a permit (facilities). This distribution was by e-mail to the facility and laboratory contact person’s e-mail address. The documents were also posted to the CLEP website.

The comment period ended April 25, 2014. There were 26 commenters from regulated parties and coalitions with 58 comments. Modifications and clarifications to the General Systems Standards have been made based on the comments received. We appreciate your comments and recommendations. The standards with the changes described below will be adopted with an effective date of June 13, 2014.

<table>
<thead>
<tr>
<th>Proposed Standard</th>
<th>Proposed Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Director Fundamental Standard of Practice1 (DIR F1): Director and Assistant Director Oversight</td>
<td>As required in Subpart 58-1.1 of 10 NYCRR, when a director does not hold a certificate of qualification in all categories in which the laboratory tests, an assistant director with a certificate of qualification in the category must be designated in the laboratory permit or category addition application materials. In this instance the assistant director is considered the ‘sole director’ for that category and assumes all responsibilities and liabilities as if he or she were the director of the laboratory. The fulfillment of director and/or assistant director oversight stands alone as a fundamental standard of practice, and if the standard is not met, places laboratory permit and director/assistant director’s Certification of Qualification approvals at risk. Compliance with this Fundamental Standard of Practice is evaluated through assessment of director and assistant director fulfillment of responsibilities specified under the Director Sustaining Standard of Practice 1 and Director Sustaining Standard of Practice 3. The regulatory framework for director credentials and responsibilities is as specified at 10NYCRR Part 19. A person should not be designated as an assistant director if they do not hold responsibilities as described in 10NYCRR Parts 19 or 58-1 or these standards. The Clinical Laboratory Evaluation Program should be contacted by the director or assistant director or owner whenever they find themselves in a position where they are unable to fulfill their duties. Circumstances that may contribute to this situation include impediments created by laboratory management or owners.</td>
</tr>
</tbody>
</table>

**Comment 1:**
This standard guidance is somewhat vague and ambiguous as “impediments” can be perceived or actual. The guidance wording could create opportunity for a disgruntled employee to complain to the CLEP with little or no evidence to support the complaint. The Department should clarify this standard guidance before implementation to ensure it includes specific examples, and the associated supporting documentation, that would warrant CLEP notification.

**RESPONSE:** The standard has been revised to remove the statement regarding impediments created by laboratory management or owners.
Proposed Standard

**Director Sustaining Standard of Practice 1 (DIR S1): Director and Assistant Director Involvement and Time Commitment**

The director and designated assistant director(s) shall spend an adequate amount of time on-site, in the laboratory, to direct and supervise the technical performance of the staff and be readily available for personal or telephone (or electronic) consultation to the laboratory’s staff and clients. The amount of time a director/assistant director spends on site must be specified in their job description and shall be consistent with responsibilities described in Director Sustaining Standard of Practice 3.

**Proposed Guidance**

Designated assistant director is defined in **Director Fundamental Standard of Practice 1**.

The director must spend sufficient time on-site to effectively discharge the responsibilities described in Director Sustaining Standard of Practice 3 (DIR S3). Subpart 58-1.2 of 10 NYCRR describes full-time or regular part-time hours are required. Regular part-time hours are defined as a minimum of 20 hours per week. Time commitments of less than 20 hours per week will be considered based on the number of categories the director and assistant director is responsible for, the volume and complexity of testing performed at the laboratory, the laboratory’s performance as demonstrated by proficiency testing and on-site survey, the qualifications of other personnel on site, and time commitments at other laboratories.

The circumstances requiring the director/assistant director(s) presence and the amount of time each are to spend on site must be specified in the job description required in DIR S3. There must be documented evidence that the director/assistant director is actively involved in laboratory operations.

Measures used to evaluate the effectiveness of the director/assistant director’s oversight include, but are not limited to, active participation in the quality management system as described in Quality Management System Fundamental Standard of Practice 1, management of adverse outcomes and non-conformities; participation in the on-site survey; appropriate management of the results of the on-site survey, and performance in proficiency testing.

Previous approvals for time commitments of less than full-time may be rescinded if the evaluation of director or assistant director effectiveness demonstrates that his or her involvement is not acceptable.

Notifications submitted to add a director or assistant director that list hours ‘as needed’ or having overlapping hours between positions, will not be accepted.

**Comment 1:** The standard on Time commitment by the Laboratory Director (Standard of Practice 1) appears arbitrary. How was the 20 hours per week arrived at?

**Comment 2:** Members are very concerned about the definition of ‘regular part time’ as 20 hours per week. I was unable to find any specified number of hours in the regulations, and request clarification on how the number of 20 hours per week was selected as defining regular part time hours, and to share with us any data that supports the use of 20 hours in this context.

**Comment 3:** I am writing …to express concern regarding t Director sustaining Standard of Practice 1 (DIR S1): Director and Assistant Director Involvement and Time Commitment, one of the proposed general standards for the New York State Department of Health Clinical Laboratory Evaluation Program. We strongly recommend either that the standard remain unchanged as it pertains to on-site time commitments or that consideration be given to creating an exemption for or a standard specific to integrated laboratory medicine services provided by Article 28 licensed facilities.

[We] are committed to exceptional patient care and leading-edge research in cancer treatment, both of which rely significantly on laboratory services. [We] ensure high quality laboratory services, through the implementation of appropriate supervisions by the laboratory director, education and training of staff, and migration towards uniform instrumentation across all sites. Director and assistant directors are always available by phone and email to provide site support to clinicians and staff. While [we] recognize the importance of universal standards that ensure
quality of laboratory services, the proposed requirement that directors be on-site for a minimum of 20 hours per week would be overly prescriptive and would not positively impact the quality of laboratory services or overall patient health outcomes.

[We have] a large network of facilities, both within and outside of New York City, that have on-site laboratories. [We] provide appropriate supervision of these laboratories through assignment of lab directors who, as required by New York State regulations, spend a portion of their time on-site, and through staff training and education. The availability of on-site laboratory services allows laboratory results to be readily available for health care practitioners. This timeliness is critical for many cancer treatments, such as chemotherapy, which rely on laboratory results to determine how to proceed. Additionally, on-site laboratories eliminate concerns associated with specimen transportation. The proposed 20 hour minimum requirement could result in networked, separate laboratories having to centralize laboratory services, which will require all specimens to be transported to the central laboratory, significantly delaying chemotherapy for patients and increasing the risk of compromising specimen quality and integrity.

The proposed guidance indicates exceptions will be considered for time commitments of less than 20 hours per week. However, the guidance lacks specific criteria regarding specimen volume, complexity and performance on proficiency testing that will lead to exceptions being granted. Without specific guidance on exception criteria as it pertains to on-site time commitments, our laboratories will be unable to identify staffing needs associated with future growth in services and sites and we will be unable to engage in the strategic planning, including the expansion of effective an innovative laboratory services, which are essential to our ability to further improve patient access to care and health outcomes. Additionally, detailed job descriptions, as required by the proposed standard, cannot be developed and thus applicant recruitment cannot be conducted without knowledge of the number of hours a lab director is expected to be on-site.

[We] strongly support the need for appropriate on-site supervision to ensure provision of high quality laboratory medicine services, especially for independent laboratories not also subject to Article 28 licensure. Compared to independent and commercial laboratories, integrated laboratory medicine services provided at Article 28 licensed facilities have unique infrastructures and resources, as well as additional safeguards of Department of Health oversight. The proposed standard is highly prescriptive and, in our view, an unnecessarily burdensome means of ensuring quality for laboratory facilities that are also regulated under Article 28. The proposal does not consider the significant infrastructure and resource differences between independent and Article 28 facilities and would, we fear, inadvertently negatively impact upon our ability to provide high quality, efficient and innovative laboratory services.

Accordingly, we strongly recommend that standard remain unchanged as it pertains to on-site time commitments. In the alternative, we urge consideration to be given to including explicit exemptions for – or a standard specific to – integrated laboratory medicine services provided by Article 28 licensed facilities.

Comment 4: The thought of requiring laboratory directors and assistant directors to document a minimum of 20 hours per week at their respective labs may have merit for large community hospitals and tertiary care and specialty hospitals but it has little virtue if applied to critical access hospitals and outpatient labs. If this becomes policy we will have small hospitals being required, effectively, to maintain approximately .5 FTE of a pathologist with appropriate C of Q, a requirement that puts further financial pressure on already struggling health care organizations. As a director of a small facility and two outpatient labs I maintain that 10 hours
per week is not necessary. If I reviewed all calibration and quality control data, looked at all outlier clinical data, reviewed policies and procedures much more frequently, and attended meetings that I had little constructive input to offer I could fill up this time. I think I would be more efficient and of more value to the organization if I utilized my laboratory manager and supervisors. I would be tempted during underutilized time to do work from other venues, this would keep me busy but, honestly, goes against the spirit of the contemplated changes. I would rather criticize what I think is a potential miss-step rather than devise methods of circumventing it. When I directed the laboratory at Rome Memorial Hospital the menu of laboratory tests, the volume of material, and oversight of surgical pathology, cytopathology, and autopsy services were of a magnitude that a rule requiring 20 hours per week of direct residence by a director or assistant director seems quite reasonable to me. But in critical access hospitals and relatively small outpatient labs such a requirement is, in my opinion, misguided and counter-productive to efficiency and quality.

Comment 5: We wish to provide comment on the proposed interpretive guidance regarding: Director Sustaining Standard of Practice 1 (DIR S1): Director Involvement. The proposed guidance is understood to define required laboratory director or assistant director on-site presence at each laboratory site as a minimum of 20 hours per week. Many hospitals, especially those that are part of systems, operate multiple laboratory sites. The level and complexity of testing can range widely at the various laboratory sites. With the continuing shift in care from the inpatient setting to the outpatient setting, it is likely that more satellite laboratory sites will develop. It is not practical and may in fact be wasteful to dictate a minimum director presence that amounts to a minimum of half time for each laboratory site. While the proposed interpretive guidance would define part-time presence as a minimum of half time, there is also a caveat in the language indicating that consideration of time commitments of less than 20 hours per week would be made for certain circumstances. However, the circumstances under which this consideration will be applied are not defined in the proposed guidance. That caveat includes a range of variables to be considered, but does not define how any of them will be applied.

This proposed combination of an apparently arbitrary and prescriptive “one size fits all” half time minimum on-site director presence combined with an undefined exception is certainly problematic and could lead to confusion, variability and inconsistency. Therefore, it would seem to be more appropriate to require laboratory directors to define the amount of on-site presence necessary to ensure high quality performance at each of the various sites for which they are responsible and for the state to measure the effectiveness of that oversight through the quality of laboratory performance. Thus, we urge reconsideration and appropriate modification of this specific proposed revision in interpretive guidance.

Comment 6: This proposed revision places an unnecessary regulatory burden on laboratory directors and assistant directors that have oversight of busy main laboratories and small satellite laboratories that provide limited but essential services to more remote or specific patient populations. The required oversight is already sufficiently specified in section 58-1 of 10NYCRR which states in part that “commensurate with the laboratory workload, scope and complexity of the testing procedures carried out, qualifications of on-site personnel, proximity to another laboratory under identical directorship, and availability of alternate monitoring and communication capabilities, the director shall spend an adequate amount of time in the laboratory to direct and supervise the technical performance of the staff and shall be readily
available for personal or telephone consultation. The adequacy of the amount of time a laboratory director is present and in active direction shall be determined by the department based on the factors enumerated above, results of on-site inspections and proficiency testing and documentation of the director's full responsibility for direction and technical operation.” While it may be necessary to required underperforming laboratories to define the minimum number of on-site hours of the laboratory director and assistant director, the universal application of this guidance to all laboratories is unnecessary and may result in the closure of satellite laboratories, thus restricting patient access to health care services, or result in increased health care costs as laboratories recruit additional physicians to comply with the regulatory mandates.

Comment 7: Many laboratory Directors are responsible for two laboratories. In our situation, we oversee a larger hospital laboratory with several test categories including the categories of Cytopathology and Histopathology. The secondary laboratories we oversee are smaller satellite laboratories in close proximity to the larger hospital laboratory and have a limited number of categories which do not include Cytopathology and Histopathology. For efficiency, continuity of oversight practices, coordination, and hence overall quality, these smaller laboratories are closely integrated and managed along with our larger hospital laboratory. We propose that CLEP provide separate laboratory Director on-site and oversight requirements for these smaller satellite laboratories that have these limited menus.

Proposal:

- Remove the minimum requirement of 20 hours per week on-site presence by Director and/or Assistant Director (DIR S1 & DIR S2).
- Remove “regular part-time hours are defined as a minimum of 20 hours per week of on-site presence” (DIR S1 & DIR S2).
- We agree that standards should require documentation of site visits and contact with sites, but the time and frequency commitment for on-site presence should be determined by the laboratory Director and be based upon the size of the lab, test volume, quality of work, and outcomes as measured by proficiency scores, medical staff satisfaction with the laboratory, and other performance measures.
- Standards for smaller satellite laboratories in close proximity to a main laboratory should require different Director/Assistant Director oversight and time on-site standards than those for full service laboratories.
- We support the intent of improving quality and recognize there are some places where laboratory directors are not spending enough time in the laboratory. We think that the current regulations are dealing with this already and that these proposed regulations impose an extraordinary burden upon the majority of Directors who are doing a good job already. We are willing to work closely with the State to assist in developing practical regulations to assist in ensuring adequate laboratory coverage by laboratory Directors.
- We propose a delay in implementation of these two standards to allow time for NYS pathologist laboratory Directors to work closely with the State in determining appropriate measures to determine laboratory performance derived on-site time commitment and oversight requirements for the laboratory Director and Assistant Director.

Justification for Proposal:

- In this day and age where costs are increasing and we are attempting to decrease cost to the healthcare system, these standards would create a huge financial burden for hospitals. Many satellite labs are small with insufficient space for a pathologist Director...
to work effectively. Space and additional resources such as microscopes, computers, and dictation equipment would need to be provided for each of these laboratories. Additionally, courier services would be needed to transport slides and other materials from the main lab to the satellite lab. This increased financial burden could prove too much for some institutions and could lead to closure of some of the satellite labs which could significantly impact patient care.

- Community hospitals, such as ours, often have smaller limited service outreach satellite laboratories within a short distance of the main hospital laboratory where the pathologist laboratory Directors of both the main laboratory and the satellite laboratories are stationed. When presence on-site is required outside of regular visits, the Director can be there in a moment’s notice. The peripheral laboratories typically function at a high level and have a close working relationship with the main hospital laboratory. Requiring laboratory Directors to spend significant time away from the main laboratory risks adverse impact on the quality of services provided to the community.

- In our setting, time constraints required by the standards would limit the time the pathologist laboratory Directors are able to spend at the main facility where the bulk of the workload exists. This potentially puts quality of care at risk by moving the focus of pathologists and work volume off site. For example, with fewer pathologists on site at the main hospital there will be less pathologist expertise available to collaborate on urgent, highly time sensitive intra-operative consults. There would be an increase in turn-around-time for diagnoses and response time for both anatomic pathology and clinical laboratory matters requiring the type of efficient close collaboration which is already our standard of care, again with potential erosion of the quality of care we already provide.

- The laboratory testing services provided on-site by the smaller satellite laboratories are performed by trained NYS certified expert laboratory personnel with supervisor or supervisor qualified technical staff on-site. These services are not performed by pathologist laboratory Directors, and thus these physicians will be required to provide on-site presence and will have virtually nothing to do for 20 hours per week. Thus, with the exception of proficiency testing which requires on-site presence of the laboratory Director, most laboratory Director oversight functions can be performed remotely for these smaller nearby laboratories. Pathologist laboratory Directors are easily accessible to our off-site technical staff and providers by land-line phone, cell phone, or even video conference, as matters arise. This approach serves the community much better than using valuable physician time to be on-site which provides little effective practical advantage.

- Diagnostic responsibility is typically a large part of pathologist laboratory Director and Assistant Director jobs and it cannot easily be separated from the laboratory oversight responsibilities of the pathologist laboratory Director.

- Patient care may be put at risk by transporting slides to alternative sites so that the pathologists can continue their work.

- This standard could create a shortage of available qualified laboratory Directors. With the proposed time limitations and the serious challenges they would create for pathologist Directors, this could result in pathologists with little or no experience taking over as lab Directors without the guidance of an experienced laboratory Director. This lack of experience could potentially lead to closure of the lab, or worse, patient harm.

- The requirement to designate the number of hours spent in an off-site limited service satellite laboratory in close geographic proximity to the main laboratory by an Assistant Director has discouraged appointment of Assistant Directors for these sites. This
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hampers the ability to maintain continuity of high quality laboratory Director services when the Director is unavailable.

- New York State regulations are in place to monitor the quality of laboratories by proficiency testing, mandatory continuing education and on-site inspections, and the majority of problems are identified promptly. The proposed standards will jeopardize a system that is working.

Comment 8:
My comments are directed at the proposed guidance. Laboratories are diverse; each laboratory and section of each laboratory has inherent requirements for directorship. All directorships are full time, as medical care should be, and as the standards note - our job definitions should define the required on-site hours to fit the needs of the laboratory. I don't know the reference for the phrase in the guidance "regular part-time is considered 20 hours per week"; but I would be interested to know.

I would also hope that every laboratory should have a plan for interim directorship, as we do for emergencies, and just as clinicians provide coverage for their patients. I am a patient as well as a doctor and I would not appreciate it if my lab work was subjected to a "transition plan" and that my laboratory was "nominating an individual" to be my covering laboratory physician.

My last comment is concerning the title "Assistant Director". If the Assistant Director is the "sole director", would it be easier to designated that individual as an "Associate Director"? Just a thought.

Comment 9:
The particularly disruptive part begins on page 66 where the phrase "Regular Part-Time work is considered 20 hours per week of on site presence". This will be very disruptive in New York because there simply are not enough Directors to cover the laboratories in this state if one day a week is required of each of them. There are small hospitals which will not be able to obtain Directors and there will be a bidding war. The entities most at risk by this change in policy will be small hospitals that don't have enough volume to be able to afford a full time Pathologist. This will restrict their ability to find Directors because people willing to contract at the increased part-time time requirement will be going to the highest bidders.

We are deeply concerned about quality as well, but we do not think one size fits all. We would prefer to see an outcomes based standard: if the lab is functioning well, is not an outlier on PT results or NYS inspection results, does not have repeat deficiencies, and if lab staff and physicians who use the lab say that the lab director is accessible and responds in a timely way to all issues raised, then whatever amount of time the Director spends at that lab is obviously enough.

If the lab director spends 20 hours a week at the lab, but the converse is true (multiple problems on PT and NYS inspection, repeat deficiencies, lab staff or physicians state that the Director is not readily available (or worse, don't even know who the lab director is!) then even 20 hours is obviously not enough time.
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This outcomes based standard would allow flexibility based on the status of other factors that impact the amount of time needed to adequately direct a lab, including:

1. The number and complexity of tests performed on site, including the degree of automation and the number of manually performed tasks
2. The management skills and experience of other members of the lab management team (lab manager, supervisors, lead techs etc.)
3. Technological capability (telepathology for peripheral smear or other slide review, use of teleconferencing for lab tech continuing education etc.)

Comment 10:
Recommendation:
Designated assistant director is defined in Director Fundamental Standard of Practice1. The director must spend sufficient time on-site to effectively discharge the responsibilities described in Director Sustaining Standard of Practice 3 (DIR S3). Subpart 58-1.2 of 10 NYCRR describes full-time or regular part-time hours are required. Regular part-time hours are defined as a minimum of 20 hours per week. Time commitments of less than 20 hours per week will be considered based on the number of categories the director and assistant director is responsible for, the volume and complexity of testing performed at the laboratory, the laboratory’s performance as demonstrated by proficiency testing and on-site survey, the qualifications of other personnel on site, and time commitments at other laboratories. Comment:
Effective oversight can be achieved with a combination of on-site and remote presence. Technology allows Directors to effectively discharge their responsibilities described in DIR S3. For example, conference calls, Electronic Document Management Systems, document scanning, and e-mail.

Comment 11:
If the State counters that this is a misinterpretation of the 20 hour a week standard, I would add that this misinterpretation is exactly how it will be seen by Laboratory Directors and is exactly what will fuel the shortage of Directors and bidding war that will follow!

Comment 12:
The proposed revision gives a new definition of part-time hours on site as 20 hours per week. We disagree. Currently the director or assistant director determines the amount of time spent on site, and they take into account multiple factors: types and complexity of testing, frequency of testing, proficiency testing results, New York State and credentialing agency inspection results, ongoing quality measures, patient safety metrics, feedback from clinician users, performance improvement initiatives, and demonstration of an effective overall Quality Management System. We believe the stipulation of 20 hours is arbitrary. Has this time amount been determined by studies of Lab directors/assistant directors functioning as labs? Has it been validated by running a pilot study of the correlation of a 20 hour requirement with recognized laboratory quality measures?
This new requirement is potentially crippling in many areas of New York State where shortages of qualified medical personnel already exist. Lab directors/ assistant directors, will simply not be
able to meet the 20 hour time requirement at multiple locations separated by long travel times. This will affect patient care.

Comment 13:
We appreciate the opportunity to participate in the process of maintaining the highest standards for laboratory services.

While we understand that the intent is to ensure effective oversight by the laboratory Director, we do not feel that the requirements being proposed would accomplish that goal. Laboratory Directors have processes in place through their quality programs to ensure adequate oversight and support of the laboratories they are responsible for.

Many hospitals, especially those that are part of systems, operate multiple laboratory sites. The level and complexity of testing can range widely at the various laboratory sites. With the continuing shift in care from the inpatient setting to the outpatient setting, it is likely that more satellite laboratory sites will develop. It is not practical and may in fact be wasteful to dictate a minimum director presence that amounts to a minimum of half time for each laboratory site. NYS validates this through their bi-annual inspection of our laboratories.

Many laboratory Directors are responsible for two laboratories. In our situation, we oversee a larger hospital laboratory with several test categories including the categories of Cytopathology and Histopathology. The secondary laboratories we oversee are small satellite laboratories in close proximity to the larger hospital laboratory and have a limited number of categories which do not include Cytopathology and Histopathology. For efficiency, continuity of oversight practices, and hence overall quality, these smaller laboratories are closely integrated and managed along with our larger hospital laboratory.

We propose that CLEP consider separate laboratory Director on site and oversight requirements for these small satellite laboratories that have limited menus due to cross coverage from associated laboratories.

We have outlined our concerns and proposals in this review which now follows.

Proposal:

- Remove the minimum requirement of 20 hours per week on-site presence by Director and/or Assistant Director (DIR S1 & DIR S2).
- Remove “regular part-time hours are defined as a minimum of 20 hours per week of on-site presence” (DIR S1 & DIR S2).
- We agree that standards should require documentation of site visits and contact with sites, but the time and frequency commitment for on-site presence should be determined by the Director and be based upon the size of the lab, test volume, quality of work, and outcomes as measured by proficiency scores, medical staff satisfaction with the laboratory, and other performance measures.
- Standards for small satellite labs in close proximity to a main laboratory should require different Director/Assistant Director oversight and time on-site standards than those for full service laboratories.
- We support the intent of improving quality and recognize there are some places where laboratory directors are not spending enough time in the laboratory. We think that the current regulations are dealing with this already and that these proposed regulations impose an extraordinary burden upon the majority of Directors who are doing a good job already.
We are willing to work closely with the State to assist in developing practical regulations to assist in ensuring adequate laboratory coverage by laboratory Directors.

- We propose a delay in implementation of these two standards to allow time for NYS pathologist laboratory Directors to work closely with the State in determining appropriate measures to determine laboratory performance derived on-site time commitment and oversight requirements for the laboratory Director and Assistant Director.

**Justification for Proposal:**

- These standards may create an unsustainable financial burden for hospitals with a one-size-fits-all model.
- Many satellite labs are not designed to support full time or significant part-time pathologist’s activities as this was not their original intended use, i.e. that of providing local and expedient patient care where and when necessary to serve the patient community.
- This increased financial burden could prove too much for some institutions and has already resulted in closure of at least one small laboratory and will likely lead to more closures which could significantly impact patient care.
- The peripheral laboratories typically function at a high level and have a close working relationship with the main hospital laboratory.
- Requiring laboratory Directors to spend significant time away from the main laboratory risks adverse impact on the quality of services provided to the community.
- In settings with a large laboratory and related satellite laboratories, time constraints required by the standards would limit the time the pathologist laboratory Directors are able to spend at the main facility where the bulk of the workload exists.
- The laboratory testing services provided on-site by smaller satellite laboratories are performed by trained NYS certified expert laboratory personnel with supervisor or supervisor qualified technical staff on-site.
- Director oversight functions can be performed remotely for many small nearby laboratories.
- The requirement to designate the number of hours spent in an off-site limited service satellite laboratory in close geographic proximity to the main laboratory by an Assistant Director has discouraged appointment of Assistant Directors for these satellite sites since they would be required to be off-site with little functional work responsibility.
- Consideration of less than 20 hours in undefined circumstances is problematic and could lead to confusion, variability and inconsistency.

In closing, we ask that you hear our concerns and give careful consideration before proceeding with changing the General Systems Standards DIR S1, DIR S2. We believe it would be more appropriate to require laboratory directors to define the amount of on-site presence necessary to ensure high quality performance at each of the various sites for which they are responsible. Implementation of these revisions would erode and severely adversely impact oversight and management practices which are already working well as evidenced by current monitors substantiating the quality of our practices.

**Comment 14:** In the proposed revision to “General Systems Standards” governing clinical laboratory operations, the Clinical Laboratory Evaluation Program (CLEP) has proposed guidance to interpret an “adequate amount of time on-site” standard requirement for Directors and Assistant Directors. This guidance, in an extraordinary precedent, delineates the time that must be devoted to on-site activity for Directors and Assistant Directors, including “a minimum of 20 hours per week.” The use of a facile, stipulated time threshold, even in the guidance portion of the standard, is of great concern to [us]. In general, our concern is predicated on the belief
that an arbitrary, on-site time threshold for evaluating laboratory director compliance is both potentially counter-productive to quality and deleterious to the practice of laboratory medicine.

[We] believe that a laboratory director with multiple facility oversight, who is compelled to expend “20 hours a week” on-site at an otherwise well-functioning, high-quality facility, is potentially diverting attention from another facility that may be in need of more direct supervision and on-site presence. In addition, the diversion may also be away from direct patient diagnostic activity. Thus, the inflexible, depreciation and constraint of medical discretion in this area is not in the best interest of patient care. Moreover, the potentially extensive travel time that may be required for pathologist medical directors commuting to a facility to, in essence, punch an on-site time clock for meeting an arbitrary state contrived standard does not yield optimal use of physician laboratory directors. Pathologists as physicians must exercise their medical judgment in ensuring high quality laboratory performance, which is our professional, ethical and legal duty. We believe that the role of the laboratory director is of paramount importance and fundamental to achieve and maintain laboratory quality. Furthermore, the quality of laboratory director performance is amenable for appropriate state assessment in the context of laboratory quality; however, on-site time does not equate to necessary supervision, nor consistently correlate with optimal laboratory performance. Furthermore, state authority ought to recognize in the practice of medicine, the directorship of the clinical laboratory, dictates that on-site presence must be highly flexible and able to accommodate patient exigencies, and other vagaries associated with routine, high volume diagnostic medical practice.

While much of the CLEP narrative in the 2014 guidance as it relates to this issue provides state administrative discretion and flexibility, we still strongly urge deletion of the stipulated 20 hours per week time standard as we believe that in practical application it will become an inflexible rule of operation. We appreciate your consideration of our comments.

RESPONSE: Subpart 58-1.2 of the New York State Codes, Rules and Regulations (10 NYCRR) states that the laboratory director shall serve the laboratory full time, or on a regular part-time basis. Regular part-time was defined by the Attorney General’s Office during recent administrative actions as 20 hours per week. Furthermore, Subpart 58-1.2 states that the laboratory director shall not service as director of more than two clinical laboratories, within or outside of New York State. The laboratory director may be eligible for an exception from this requirement if it is determined that directorship of more than two laboratories is needed to serve the needs of the geographic area.

The guidance in the proposed standard is grounded on Subpart 58-1.2 (b) which describes the parameters to determine the adequacy of the time spent on-site by the director to meet the director responsibilities defined in Subpart 19.3(c). Although 20 hours per week is the baseline for regular part-time, the guidance provides criteria which are used to evaluate proposals for less than 20 hours per week. These criteria are currently utilized and will continue to be utilized to evaluate the acceptability of proposed on-site availability.
**NEW YORK STATE DEPARTMENT OF HEALTH**  
**CLINICAL LABORATORY EVALUATION PROGRAM**  

**COMMENTS and RESPONSES to PROPOSED GENERAL SYSTEMS STANDARDS**

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<tr>
<td><strong>Director Sustaining Standard of Practice 3 (DIR S3): Director Responsibilities</strong></td>
<td>The director remains responsible for all delegated activities and must provide evidence of ongoing monitors for the competent management of those delegations.</td>
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<td>A determination as to whether the director has adequately fulfilled the responsibilities indicated in a-n of this standard will be based on an assessment of laboratory compliance with department requirements. While certain of these responsibilities may be delegated to qualified individuals, such delegation must be in writing. Notwithstanding such delegation, the director remains ultimately responsible for monitoring that these responsibilities have been met and for the oversight of all laboratory operations. The director shall:</td>
<td>The director may not delegate the following quality management system activities: definition of quality goals and process objectives for each of the quality system essentials listed under Quality Management System Sustaining Standard of Practice 1; approval of specifications and requirements established to achieve stated goals and objectives; review of quality assessment reports; and, approval of process improvement initiatives.</td>
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<tr>
<td>a) provide oversight of all aspects of the laboratory’s quality management system to ensure conformance to requirements described in the Quality Management System chapter of these Clinical Laboratory Practice Standards;</td>
<td>Directors who also function as supervisors must also follow Standard HR S3b.</td>
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<td>b) provide effective and efficient administrative direction of the laboratory, including budget planning and controls in conjunction with the individual(s) responsible for financial management of the laboratory;</td>
<td>d) Education can be provided by a variety of methods including attendance at outside venues, even at other laboratories. The laboratory management needs to have documentation on-site for each technical staff member.</td>
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<tr>
<td>c) ensure that qualified personnel are employed; by defining the qualifications and responsibilities of all laboratory technical staff and documenting training and/or competency;</td>
<td>f) Permit application materials include the initial and annual permit application and Notification Forms to Add/Delete an Assistant Director and Add/Delete Permit Category forms. The description of the responsibilities and tasks for the assistant directors should include the specific technical and administrative areas of responsibility noted on these forms.</td>
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<td>d) provide continuing educational to laboratory technical staff that is relevant to laboratory medicine;</td>
<td>f) The technical supervisor for cytopathology should perform workload assessment of cytotechnologists twice per year, according to CYPA S10.</td>
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<td>e) ensure that policies and procedures are established for monitoring staff to assess competency, and whenever necessary, provide remedial training or continuing education to improve skill;</td>
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<tr>
<td>f) specify in writing the technical and administrative responsibilities and duties of all laboratory personnel, including assistant directors designated in the permit application(s) materials submitted to the Clinical Laboratory Evaluation Program. The director is responsible for competency assessment of assistant directors and direct-report supervisors. Documentation of assessments must be performed annually and whenever new systems are introduced. Remedial steps must be documented when staff do not perform as expected;</td>
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<tr>
<td>g) promote a safe laboratory environment for personnel and the public;</td>
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<tr>
<td>h) ensure that an approved procedure manual is available to all personnel;</td>
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<tr>
<td>i) monitor all work performed in the laboratory to ensure that medically reliable data are generated;</td>
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<tr>
<td>j) assure that the laboratory participates in monitoring and evaluating the quality and appropriateness of services rendered, within the context of the Quality Management System, regardless of where the testing is performed;</td>
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<tr>
<td>k) provide advice to referring physicians regarding the significance of laboratory findings and ensure that reports of test results include pertinent information required for specific patient interpretation;</td>
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<tr>
<td>l) ensure that the laboratory is enrolled in the Department’s proficiency testing program for the testing performed and that the laboratory adheres to the program’s administrative and technical requirements and for all tests with no available New</td>
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</table>
Comment 1: The standards indicate that the Medical Director will give continuing education to staff. I would like the addition of something like this. "The Medical Director may delegate training and education to competent staff, but retains responsibility." The purpose of the proposed change is to recognize that there will be areas outside the competence of the Director, or that there are times when the Director's schedule does not fit the requirements for training.

Comment 2: Our members have also been very concerned about the requirement for competency assessment of the assistant director by the director. Again, I could not find any requirement for this in 42 CFR 493 currently. I would be grateful if you could share any information you have as a CLIA deemed organization that this will be a CLIA requirement in the future (per our phone conversation today).

Comment 3: “The director is responsible for competency assessment of assistant directors.” Anatomic pathology laboratories typically employ a number of pathologists, some of whom are delegated assistant (technical) directors responsibilities under NYS current standards. By the very nature and necessity of this delegation (i.e. that the medical director does not hold a NYS CQ for a particular laboratory area), it is unclear from the published material what the competency assessment for a technical director would consist of. Specific guidance should be provide on how these individuals will be evaluated so as to meet the standard. Will the elements detailed as part of a supervisory competency assessment (HR S7) be applied or will competency be measured similar to that detailed for the oversight standard (DIR S1)? Will an annual documented performance review fulfill this requirement? The revision seems redundant as NYS currently requires a CQ holder for each category of testing and clearly permits delegating responsibilities for which the CQ holder is accountable under the standards.

Comment 4: Assistance laboratory directors are AP/CP trained, board certified, licensed and registered with the New York State Education Department and issued a Certificate of Qualification for their areas of responsibility making the requirement for an annual competency assessment a redundant and unnecessary layer of credentialing.

Comment 5:
Proposal:
• Remove the necessity for competency assessments of assistant directors.

Justification for Proposal:
• Assistant Directors are trained in both anatomical and clinical pathology.
• Most, if not all, are board certified in both anatomical and clinical pathology and are required by the American Board of Pathology to perform a significant amount of CME/SAM credits in order to maintain our certification.
• All Assistant Directors hold a NYS issued certificate of qualification.
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- Duties performed by the Assistant Director are under the supervision of a laboratory Director. In addition, NYS regulations are already in place to monitor the quality of the lab by proficiency testing, on-site inspections, and other measures.
- Most Assistant Directors have the same qualifications as the laboratory Director. Further, many Assistant Directors are themselves Directors of other laboratories.
- Assistant Directors that are working in a hospital based environment are required to obtain credentialing privileges and must maintain good standing with the hospital.
- Assistant Directors work in close collaboration with the Director who monitors their performance.
- In summary, we think that adding an additional layer of competency is unnecessary.

Comment 6:
We would like clarification on the use of the terms “direct-report” and “new systems” in this standard. Recommendation: We propose using terminology consistent with the CLIA Brochure, “What Do I Need to Do to Assess Personnel Competency?” Perform a competency assessment of the individual serving as the technical consultant (TC), technical supervisor (TS) or general supervisor (GS) based on their regulatory responsibilities.

Note: Clinical consultants, technical consultants, technical supervisors, and general supervisors who are performing testing on patient specimens are also required to have a competency assessment as outlined in Human Resources Sustaining Standard of Practice 8 (HR S8): Competency Assessment – Technical Staff.

Comment 7:
Another new requirement is the proposed revision, annual competency assessment for assistant directors, is also troubling, assistant directors function as the certificate of qualification holders for their areas of expertise. All are doctoral level and board certified in the area of specialty. Additionally, they are already required to have recent lab director experience and to hold a New York State issued certificate of qualification, assistant directors are usually hired for their expertise in a particular specialty. It is unclear how a requirement for annual competency assessment performed by the director would add to laboratory safety or quality.

RESPONSE: In January 2013, CMS provided a webinar regarding its expectations for competency assessment and developed a brochure titled “What Do I Need to Do to Assess Personnel Competency?” CMS requires that competency assessment be performed and documented for clinical consultants, technical consultants, technical supervisors, general supervisors and testing personnel. Please be reminded that an assistant director is comparable to a technical supervisor. As an exempt state, New York State must be at least as stringent as CLIA. In addition, please note that the CLIA brochure states that if a laboratory director is performing laboratory testing, then he or she must also be competency assessed to ensure that the required competency for reliable testing and reporting is maintained.
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<tr>
<td><strong>Human Resources Sustaining Standard of Practice 2 (HR S2): Personnel Records</strong></td>
<td>Duties and qualifications for laboratory supervisors and cytology supervisors are described 10NYCRR Part 58. Requirements for licensure through the New York State Education Department are available at <a href="http://www.op.nysed.gov">www.op.nysed.gov</a>. Licensure is not required for individuals performing testing for non-medical purposes, such as parentage/identity testing or forensic toxicology, or for individuals employed as technicians, technologists or cytotechnologists in out-of-state laboratories; however, these individuals must continue to meet the education and experience requirements in 10NYCRR Subpart 58-1. Laboratories located in New York State must maintain copies of the registration or limited permit issued by the New York State Education Department for all technical personnel. Documentation required for directors and assistant directors is a copy of their New York State Certificate of Qualification. For out-of-state laboratories, diplomas, resumes, transcripts, and/or official letters from an institution of higher education indicating board eligibility or attesting to the highest level of learning achieved; letters from former employers; or other records should be maintained to establish that education and experience requirements have been met. Individuals educated in a college or university outside the United States should refer to the CLEP Program Guide for a description of acceptable credentials evaluation policies.</td>
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</table>

**Comment 1:**
With the number of employees and the cross training of staff in different areas, maintaining the competency records for such a long period of time is burdensome and can be costly to the organization. We would like to see the competency assessments remain at two years. The timeframe for the remaining documents listed in the proposed standard would be manageable.

**Comment 2:**
We propose a record retention of 5 years. This is consistent with AABB and CLIA requirements.

**Comment 3:**
“... competence of all personnel for 1 year after be replaced with the new competencies are yearly. “

**RESPONSE:** Although there are many resources that address retention of documents, including AABB and other accrediting agencies, the DOH standard is comparable to the Federal Record Retention Requirements which describe that retention of personnel records including training and competency should be retained for 7 years after termination of the employee.
Proposed Standard

Human Resources Sustaining Standard of Practice 6 (HR S6):

Training

Laboratory management shall have procedures for the training for all staff. Training must be documented for all individuals, 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, as well as supervisory and management staff. Personnel must be trained and their competence assessed in the performance of all tasks for which they are responsible. Training by test system manufacturers or through industry sponsored workshops, while a valuable component of a laboratory training program, cannot be substituted for training programs based on an assessment of the individual’s duties, background and skills. Training programs should include the following elements:

- objectives for the training;
- identification of the methods to be used in training;
- identification of the materials to be used in the training;
- criteria to assess the effectiveness of training.

Proposed Guidance

Training on safety protocols as required under Facility Design and Resource Management, Safety Standards, should include use of a biosafety cabinet, when present in the laboratory. Laboratories are encouraged to include a training video prepared by the Wadsworth Center’s Laboratory Response Network entitled, Essentials in Biosafety, in its training program for use of biosafety cabinets.

Training should also be provided on ensuring data integrity. Data integrity is defined as: generating, transforming, maintaining and assuring the accuracy, completeness and consistency of data over its entire life cycle in compliance with applicable regulations.

Comment 1:
Added guidance statement on training on ensuring data integrity. Data integrity is defined as: generating, transforming, maintaining and assuring the accuracy, completeness and consistency of data over its entire life cycle in compliance with applicable regulations. Need clarification on this requirement. Is this relative to IT systems?

Comment 2:
We would like clarification on the use of the terms “data integrity”, “entire life cycle”, and “regulations” in the guidance. What type of data? Is the life cycle related to retention requirements? Which regulations correspond with ensuring data integrity?

RESPONSE: Additional guidance has been added to HR S6 to further define data integrity: “The intent of training in data integrity is to ensure that there are no intended or unintended changes to the data that resulted during processing, storage or retrieval. This is for the entire lifecycle (i.e., all phases of sample analysis from collection to reporting and including quality assessment and improvement) of the data. This relates to all data generated when producing a test result.”
Proposed Standard

Human Resources Sustaining Standard of Practice 8 (HR S8): Competency Assessment – Technical Staff

Laboratory management shall:

a) have written procedures for performing and documenting competency assessment for all staff to include, at a minimum:
   i. direct observation of employee’s duties by supervisory staff;
   ii. observation of compliance with safety protocols;
   iii. review of intermediate test results or worksheets, quality control records, proficiency testing results and preventive maintenance records;
   iv. monitoring the recording and reporting of test results;
   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; and
   vii. assessment of problem solving skills;
   viii. assessment of competency of any delegated supervisory functions;

b) document the actual date of observation or be able to recreate the test performance event as applicable; and,

c) evaluate the competency of staff for all tasks for which they are responsible at least semiannually during the first year the individual tests patient specimens and thereafter annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual’s performance must be re-evaluated to include the use of the new test methodology or instrumentation.

Proposed Guidance

Competency assessment must be documented for all individuals who perform technical functions, including healthcare providers performing testing at the point-of-care, and supervisory and management staff performing testing.

Documentation of the event used for the assessment of the staff’s test performance must contain enough specific detail so that the evaluation can be substantiated. For example, for external proficiency testing, the date of the event, the score and analytes that the staff member tested needs to be retrievable. Documentation of the event when using previously analyzed specimens must indicate the date and the result of both the original testing and the testing performed by the staff member.

Internal samples should be aliquots of previously analyzed specimens that are reintroduced into the work load in a blinded fashion.

Comment 1:

In an effort to utilize electronic systems, it is an unreasonable burden to document specific detail and recreate the events. We have written procedures for performing and documenting competency assessment for all staff. We find that a summary documenting the assessment of the staff’s test performance by a qualified trainer is adequate.

RESPONSE: The intent of the standard is to ensure that all components of competency assessment are documented and available for review. Guidance from the Centers for Medicare and Medicaid Services describes that documentation of competency for each employee must match the laboratory’s actual procedures performed by its personnel. The CLIA guidance is consistent with the intent of this standard.
Proposed Standard

Human Resources Sustaining Standard of Practice 9 (HR S9): Competency Assessment – Non-technical Staff

Laboratory management shall:

a) have written procedures for performing and documenting competency assessment for all staff to include, at a minimum:
   i. direct observation of employee’s duties by supervisory staff;
   ii. observation of compliance with safety protocols;
   iii. periodic review of work product for compliance with standard operating procedures and applicable workload limits;
   iv. monitoring the recording and reporting of test results;
   v. assessment of problem solving skills;

b) document the actual date of observation or be able to recreate the test performance event as applicable; and,

c) evaluate the competency of staff for all tasks for which they are responsible at least annually.

Regulatory authority: 10 NYCRR Subpart 58-1.2(d)

Proposed Guidance

Competency assessment must be documented for all individuals who perform supportive tasks, such as data entry or accessioning, that are not technical in nature.

Comment 1:
My question is in regard to this proposed standard that indicates Non-Technical Staff require competency assessment. At a large reference laboratory, any non-testing individuals could be categorized as non-technical and supportive. This could be IT, engineering, or varied departments and titles. How broad is the proposed guidance and the definition of supportive tasks?

Comment 2:
Requirements for competency assessment of support staff may be difficult to enforce as these employees may not be part of the laboratory.

Comment 3:
While we agree that non–technical individuals who perform supportive tasks should have some type of competency assessment, we believe that the assessment elements proposed as minimum requirements may not be appropriate for all types of positions that could be covered under the new standard. The current CLIA regulations (November 2012) for What Do I need to Do to Assess Personal Competency? States “…competency assessment is not required by LICA for non-testing personnel (e.g., phlebotomists, accessioning personnel, etc.). However, this would be considered good practice and a good quality assurance measure.” Appreciating New York State’s goal to ensure good quality practices are applied at our laboratories, we offer the following alternative wording for your consideration:

“Laboratory management shall:
a) have written procedures for performing and documenting competency assessment for all staff to include, at a minimum:
   i. assessment of knowledge and skills required to perform critical duties as defined in job description;
   ii. observation of compliance with safety protocols;
   iii. periodic review of work product for compliance with standard operating procedures and applicable workload limits;
b) document the date(s) of that assessments were actually performed; and ,
c) evaluate the competency of staff for all critical tasks for which they are responsible at least annually."

RESPONSE: We acknowledge challenges the laboratories are facing particularly in staffing and personnel. Therefore, it becomes a matter of particular importance to assure that all staff whose responsibilities impact the testing process are adequately trained and competent to perform their assigned job tasks. CLIA and other accrediting agencies recommend competency assessment for all staff involved in the testing process (i.e. phlebotomists, specimen processing staff, clerks/customer service staff who call laboratory results to the providers offices or notify the providers that there is a problem with a specimen). Competency assessment of non-technical staff is good laboratory practice and a good quality assurance measure. The standard has been revised to provide additional clarification.
Human Resources Sustaining Standard of Practice 10 (HR S10): Continuing Education

The laboratory director shall provide continuing education to laboratory staff commensurate with the scope of their duties and such training and continuing education shall be documented. A minimum of twelve hours of continuing education must be performed by laboratory staff on an annual basis and staff participation must be documented.

Acceptable forms of continuing education include in-service, professional meetings or industry sponsored training/workshop programs.

Cytotechnologists must follow the continuing education requirements of 10 NYCRR Part 58-1.12(c).

Comment 1:
Define 'lab staff'. Does this refer to technical staff as defined in HR S8? It is difficult to have 12 hours of CE as mandatory. Employers can offer it, but it is another issue to get employees to attend.

RESPONSE: The standard has been modified to indicate that the staff referred to in the standard is technical staff.
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<td><strong>Human Resources Sustaining Standard of Practice 11 (HR S11): Supervisor Staffing</strong>&lt;br&gt;The clinical laboratory shall have a supervisor on the laboratory premises during all hours in which tests are performed. An exception to the on-premises requirement shall be considered when performance of testing is required for emergency purposes, provided the person performing the test qualifies as a clinical laboratory technologist, the results of his or her work are reviewed by the supervisor or director during his or her next duty period, and a record is maintained to reflect the actual review.</td>
<td><strong>For testing performed without a supervisor on-site, the director should establish the maximum time period between reporting of test results and the review. This time period should consider the implications of incorrect results on patient care. The director should describe the elements of testing that need supervisor review, including quality control.</strong></td>
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Comment 1:<br>I am writing to express my very deep concerns with your proposed new standard, Human Resources Sustaining Standard of Practice 11 (HRS11): Supervisor Staffing. I see several significant issues with this proposal.<br>• First, there continues to be a medical technologist shortage that is not likely to be ameliorated in the near future. Even with the increased numbers of students currently studying medical technology, it will be six years before graduates could even qualify as supervisors, and, as we well know, the tendency has been for med techs to take jobs in related areas with more monetary reward, such as in pharmaceutical companies.<br>• Second, supervising requires a distinct set of skills which don’t always correlate with technical ability. I’m afraid we may actually dilute the quality of our laboratory performance by requiring us to have more personnel with a “supervisor’s” title.<br>• Third, and related to the thoughts above, when a supervisor is sick or on vacation, this rule would cause much difficulty in switching coverage, which many hospitals and relatively smaller labs would have great difficulty in overcoming.<br>• Fourth, as so often happens when a new regulation is proposed, you will immediately increase the costs of running a laboratory, as a supervisory title mandates compensation. In order for hospitals to maintain cost neutrality in an otherwise difficult environment, some other staffing (laboratory or otherwise) may be cut.<br>The current system, whereby qualified personnel must be on site and a supervisor could be reached by phone in an emergency, works, in my opinion, quite well! Before instituting this regulation, you should ask, “what problem are we trying to solve,” and, “will this proposal actually solve the issue?” I believe the proposal actually has the potential to decrease quality, rather than increase it!

Comment 2:<br>Does this apply to the total TESTING process or the final reporting of results to client?

Comment 3:<br>“The clinical laboratory shall have a supervisor or personnel qualifying as a supervisor on the laboratory premises during all hours in which tests are performed. …..”

RESPONSE: This standard remains unchanged from the 2008 standard currently in use (see current HR S3). Subdivision 58-1.3(e) of the New York State Codes, Rules and Regulations (10 NYCRR) requires that the supervisor shall be on-site during all hours in which tests are performed. The intent of the regulation and standard is to ensure that laboratory has adequate oversight to provide an accurate
and reliable test result. An individual who qualifies to as a supervisor would be acceptable if he or she was delegated in writing supervisory responsibilities.
Comment 1:
The proposed standard requires that the lab must “employ a sufficient number of qualified technical personnel to ensure that there are no gaps in laboratory staffing.” While the intent of the proposed standard is recognized, this wording is by its very nature vague and ambiguous. What is the measure of staffing that creates a “gap” according the Department? Laboratories continuously look to create leaner, more efficient processes and utilize staff to the fullest extent possible while maintaining quality. This is why a robust QMS is imperative – it monitors all the processes that are affected by staff input to ensure they produce expected levels of quality. The standards that currently exist evaluate the QMS in all these processes. Lack of evidence for supervisory oversight (fulfilled responsibilities) can be attributed to many things – including poor performance and misrepresentation of qualifications – and should not, be default, imply that the lab is understaffed. Supervisory oversight gaps would be evidence during the Department’s on-site survey, and it would be incumbent on the laboratory to investigate and determine why they occurred.

RESPONSE: Subdivision 19.3(c) of Chapter 10 of the New York State Codes, Rules and Regulations (10 NYCRR) requires laboratory directors to ensure that sufficient qualified personnel are employed with documented training and/or experience to supervise and perform the work of the laboratory are require. This standard is an extension of the regulation. The guidance has been modified as suggested.
### General Facilities Sustaining Standard of Practice 1 (GF S1): Design and Environment

The laboratory design and environment shall be suitable for the tasks performed and have:

- **a)** sufficient space allocated so that its workload can be performed without compromising the quality of work and safety of personnel;
- **b)** energy sources, lighting, ventilation, water, waste and refuse disposal, and environmental controls commensurate with task requirements;
- **c)** protection from fluctuations and interruptions in electrical current that would pose risk to the reliability of test systems;
- **d)** backup power so that critical systems be maintained or controlled as recovery procedures are followed;
- **e)** controlled access to and use of areas affecting the quality of the examinations, safeguarding specimens and resources from unauthorized access; and
- **f)** relevant storage space and conditions, consistent with Quality Management System specifications and manufacturer’s instructions, if provided, to ensure the continuing integrity of specimens, slides, histology blocks, retained micro-organisms, documents, files, manuals, equipment, reagents, laboratory supplies, records, and results as specified in the Records and Specimen Retention sections of these Standards.

### Proposed Guidance

Notification of changes in laboratory location that may void the laboratory permit must be made as indicated in the Quality Management System Fundamental Standard of Practice (QMS F1).

### Comment:

It is unclear what is meant by sufficient space to perform tasks and whether there is a requirement for a number of square feet per employee or, will this be subjectively determined.

**RESPONSE:** This standard remains substantially unchanged from the 2008 standard currently in use (see current GF S1). There are many consensus guidelines published to assist laboratories handling and managing space allocation including the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC) and the Occupational Safety and Health Administration (OSHA). Work spaces must be uncluttered and clear to be able to perform work tasks safely. Aisles, doors and access to equipment must be unobstructed. Since some instruments require a specified amount of space for appropriate ventilation, this must also be included in the laboratory’s determination of square footage required.
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| **Reagents Sustaining Standard of Practice 7 (REAG S7): Expiration**  
Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded the manufacturer’s stated expiration date, have deteriorated, or are of substandard quality. | Laboratories may use reagents beyond the expiration date only if the manufacturer has provided written authorization to do so. The laboratory may not conduct its own validation studies to extend the shelf life of reagents.  
Outdated items may be used for training or student use. They should, in this case, be stored separately from in date reagents and be clearly labeled “Educational use only” or similar wording.  
For reagents provided without a manufacturer expiration date, the laboratory director shall determine the expiration date based on test development and validation data. The expiration date should be based on viability, obvious contamination or deterioration, or problems with quality control. Laboratory-determined expiration dates should be re-evaluated periodically, and revised as needed, based on historical data review, lot-to-lot verification, and/or test calibration. |

**Comment 1:**  
In regard to Reagents Sustaining Standard of Practice 7 (REAG S7): Expiration, the guidance states: “….may use reagents beyond expiration date if the manufacturer has provided written authorization to do so.”  
Red Cross proposes the following modification: “….may use reagents beyond expiration date if the manufacturer or another governing entity has provided written authorization to do so.”  
The rationale for this modification is in regard to reagent panel cells for antibody identification when, due to the rarity of the red cell phenotype, in-date reagents may be unavailable. A governing entity such as NYSDOH, or AABB, could grant authorization to continue to use reagent panel cells beyond their expiration date.

**RESPONSE:** Approval would be required from the FDA or the manufacturer in writing. Other entities would not have the authority to provide approval to use a reagent beyond its expiration date.
Safety Sustaining Standard of Practice 1 (Safety S1): Biohazard Risk Assessment and Biosafety Program

The laboratory shall conduct an infectious agent risk assessment for each permit category or designated area separate from the laboratory space and based on this review shall develop and implement an appropriate biosafety program that identifies the laboratory’s biosafety level(s) and incorporates the use of biosafety equipment, practices and procedures that shall:

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<td>a)  be described in the laboratory’s safety manual;</td>
<td>A five-step approach to infectious agent risk assessment:</td>
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<tr>
<td>b)  be revised as necessary;</td>
<td>a) Identify the biorisk characteristics (e.g. pathogenicity, route of infection) and doses (concentration/volume) of agents handled by the laboratory.</td>
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<tr>
<td>c)  minimally meet biosafety level 2 (BSL-2) criteria and incorporate, as</td>
<td>b) Identify laboratory practices that increase exposure risks such as aerosol-generating procedures (centrifuging, vortexing, etc.) and the use of sharps.</td>
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<td>appropriate, the use of a certified class II (or higher) biological safety</td>
<td>c) Determine the appropriate biosafety level (BSL) and develop a biosafety program that includes the appropriate precautions, practices, PPE, safety equipment and facility design and access.</td>
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<td>cabinet (BSC) and/or other containment equipment/devices and practices intended to</td>
<td>d) Review the risk assessment process and biosafety program with biosafety professionals.</td>
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<td>prevent release of infectious aerosols into the work environment; and,</td>
<td>e) Ensure staff knowledge and proficiency regarding the laboratory’s biosafety program, including the use of PPE and safety equipment.</td>
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<td>d)  incorporate the use of appropriate personal protective equipment (PPE)</td>
<td>A biosafety professional is a competent person who has a relevant qualification in the field of life sciences and additional recent working experience or training in the microbiological laboratory or in laboratory infection control procedures consistent with the type of work performed by the laboratory.</td>
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<td>such as lab coats or gowns, face shields and disposable gloves intended to protect</td>
<td>Diagnostic and health care laboratories must minimally meet BSL-2 criteria.</td>
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<td>the worker from splashes, spills or other direct contact with infectious specimens</td>
<td>Aerosol-generating specimen/culture procedures (e.g. vortexing, centrifuging,</td>
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<td>/materials; and,</td>
<td>pipetting, mixing) should incorporate the use of practices and equipment (e.g.</td>
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<td>e)  when applicable, include a written plan to be implemented in the event that</td>
<td>BSC) or devices (e.g. closed centrifuge cups/carriers) intended to prevent release of aerosols.</td>
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<td>an agent suspected of exceeding the laboratory’s biosafety level/practices is</td>
<td>A designated area separate from the laboratory space, as intended in this standard, means a single location where testing is performed under more than one permit category, means a patient service center, a limited service laboratory, or areas designated as point of care testing sites.</td>
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<td>encountered. The plan shall include provisions for:</td>
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<td>i.  immediate notification of the laboratory supervisor and/or director;</td>
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<td>ii. cessation of work with the material until appropriate safety practices and</td>
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<td>PPE can be put into place or the specimen referred to an appropriate laboratory;</td>
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<td>iii. implementation of the employee exposure plan, if applicable; and,</td>
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<td>a)  require that the biohazard risk assessment be revised as necessary and</td>
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<td>reviewed by the director at least annually.</td>
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Comment:
The requirement for Biosafety Cabinet containment states “where appropriate.” Please provide examples or better define what is meant by “where appropriate”?

RESPONSE: It is the responsibility of the laboratory director to perform a risk assessment to determine the potential hazards in that particular laboratory. It is only after the risk assessment has been performed that it is possible to identify what biosafety level is appropriate for the laboratory. For example, if the laboratory is performing microbiology culture where there is the potential for aerosol transmission, then use of a certified biosafety cabinet would be required. Additional guidance has been provided to define biosafety levels.
# Proposed Standard

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<th>Safety Sustaining Standard of Practice 3 (Safety S3): Facility Design</th>
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<td>Laboratory facilities shall be designed to ensure that infectious agents cannot be transmitted to health care workers or the general public and shall include:</td>
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<tr>
<td>a) a pest management plan which ensures that pests cannot act as a mechanical vector to spread infectious agents;</td>
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<tr>
<td>b) sufficient space between benches, cabinets and equipment to allow adequate cleaning;</td>
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<tr>
<td>c) flooring and furniture located in the testing laboratory must be impervious to liquids and capable of being easily cleaned and decontaminated. Carpets and rugs must not be used in the laboratory where specimens are processed and/or manipulated.</td>
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<td>d) work surfaces that are impervious to liquids and resistant to moderate heat and the chemicals used for cleaning and decontamination;</td>
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<td>e) adequate hand washing facilities within the laboratory work area;</td>
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<tr>
<td>f) properly maintained eye wash facilities;</td>
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<tr>
<td>g) emergency showers, if appropriate; and,</td>
</tr>
<tr>
<td>h) doors designed to facilitate access control.</td>
</tr>
</tbody>
</table>

## Proposed Guidance

| a) The pest management plan can include mechanical barriers such as screens on the windows to prevent flies from entering the laboratory or visual inspection of the structural integrity of the facility. |
| c) Chairs and other furniture used in the laboratory work area should be covered with a non-fabric material that can be easily decontaminated. Rugs and carpets may not be used in areas where open specimens are handled. They may be used in areas where stained, fixed and, when appropriate, coverslipped slides are examined. Rubber non-skid mats may be used in specimen processing areas provided they are easily decontaminated. |
| e) Minimally, laboratories should be designed so that hand washing facilities are located near each exit. Additional, hand washing facilities should be located so that there is easy access for use prior to handling communal objects (e.g. phone, keyboard, etc). Chemical disinfectants are not considered an acceptable alternative to soap-and-water hand washing in the BSL-2 or higher clinical laboratory setting. Patient Service Centers are under the auspices of the laboratory and must also follow this standard including the placement of hand washing facilities. When collecting urine specimens for chain of custody (forensic) purposes attempts should be made to provide hand washing facilities to the donor without compromising the integrity of sample. |
| f) Plumbed eye wash stations should be flushed weekly. Manufacturer’s maintenance instructions should be followed for free standing eye wash devices and discarded when outdated or appear contaminated. |
| g) OSHA rules for emergency showers when caustic or corrosive chemicals are used must be followed. See also Safety Sustaining Standard of Practice 15. |
| h) Preferably, self-closing doors should be used in the laboratory. |

### Comment:

When cleaning in and around benches, how will benches attached to the perimeter walls be managed?

### RESPONSE:

This standard remains substantially unchanged from the 2008 standard currently in use (see current Safety S3). The standard doesn’t apply to the securing of the bench to the wall but the cleaning of the bench. All benches must be cleaned regardless of how they are attached.
<table>
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<tbody>
<tr>
<td><strong>Safety Sustaining Standard of Practice 6 (Safety S6): Biological Safety Cabinets (BSC)</strong></td>
<td>The need for a class II or higher BSC should be determined based on the laboratory’s biohazard risk assessment (see Safety Sustaining Standard of Practice 1).</td>
</tr>
<tr>
<td>Laboratories utilizing a BSC shall:</td>
<td>Airflow monitoring may be accomplished by the use of a magnehelic or similar device, or a device built into the cabinet, with or without an alarm.</td>
</tr>
<tr>
<td>a) decontaminate the BSC with an appropriate disinfectant before and after each use and immediately following a spill or splash;</td>
<td>During installation it should be verified that fluctuations of the room supply and exhaust air do not cause the BSC to operate outside the parameters for containment. BSCs should be situated so as to avoid interference of airflow such as by opening of doors or personnel traffic. The BSC shall be certified according to the National Sanitation Foundation (2002), Standard 49, Class II (laminar flow) Biohazard Cabinetry, Ann Arbor, MI.</td>
</tr>
<tr>
<td>b) monitor and document the air flow while in use;</td>
<td></td>
</tr>
<tr>
<td>c) test and certify the BSC in situ at the time of installation within the laboratory, at any time the BSC is moved, and at least annually thereafter; and,</td>
<td></td>
</tr>
<tr>
<td>d) document that all users are trained in the proper use of the BSC and are periodically observed for compliance with defined practices.</td>
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</tbody>
</table>

**Comment:**
The language of the proposed standard is unclear. Is documentation of air flow required at the beginning of BSC use, the end of BSC use or are you looking for a record that shows continuous air flow throughout the use?

**RESPONSE:** The standard has been revised to provide further clarification. The purpose for this standard is to ensure that personnel are appropriately trained in the use of the biosafety cabinet (BSC) and that they can recognize a malfunction of the equipment. Personnel who are utilizing the BSC need to monitor the equipment visually or if the equipment has the capability, through the use of an audible alarm. Monitoring should be documented and can be done prior to BSC use. Continuous monitoring does not need to be documented unless a problem arises during use of a BSC. Any problem that occurs while using a BSC needs to be documented.
<table>
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<tr>
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</table>
| LIMS Sustaining Standard of Practice 10 (LIMS S10): Transcription Accuracy | If the laboratory manually transcribes or enters test requisitions, authorization information or test results into a LIS, the laboratory must ensure the information is accurately transcribed.  
  
  The laboratory must have ongoing mechanisms such as double-keying or supervisory review, to ensure the accuracy of manual entries by personnel, both technical and non-technical, into the LIS. Verification of accuracy is not required prior to release of the test result. Personnel performing data-entry must be subject to training and competency assessment as specified under the Human Resources section of these standards. Results must be released by qualified technical personnel. |

**Comment 1:**
We need clarification on what the statement in the Proposed Guidance means: “Verification of accuracy is not required prior to release of the test result. Results must be released by qualified technical personnel.”

**RESPONSE:** The guidance was revised to provide additional clarification regarding verification of manually entered results.
Proposed Standard

Operating Procedures Sustaining Standard of Practice 4 (SOPM S4): Bench Excerpts
Card files or similar systems that summarize key information are acceptable for use as a quick reference at the workbench, provided that a complete manual is available for reference. The card file or similar systems shall correspond to the complete manual. All procedure excerpts and notes used at the bench must be reviewed and approved by the director or supervisor at least annually.

Proposed Guidance

A process must be established to ensure the excerpts used as a quick reference at the workbench, including notes made by technical personnel, are updated to include all revisions to the procedure as approved by the laboratory director.

Comment 1:
“All procedure excerpts and notes used at the bench must be reviewed and approved by the director or supervisor at least annually.” This proposed standard will, by association, seem to require that all SOPM be reviewed annually. The approach here could instead be more process-oriented and require that the laboratory have a documented process to ensure that bench excerpts and notes are current and derived from a controlled procedure.

Comment 2:
Bench excerpts that are linked to a controlled document should be reviewed on the same cycle as the associated document; currently laboratory review cycles vary from either one year or two years. Reword the standard to allow for this variation:
“Card files or similar systems that summarize key information are acceptable for use as a quick reference at the workbench, provided that a complete manual is available for reference. The card file or similar systems shall correspond to the complete manual. All procedure excerpts and notes used at the bench must be reviewed and approved by the director or supervisor at least annually biennially.”

Comment 3:
Card files or similar systems that summarize key information are acceptable for use as a quick reference at the workbench, provided that a complete manual is available for reference. The card file or similar systems shall correspond to the complete manual. All procedure excerpts and notes used at the bench must be reviewed and approved by the director or designee at least annually every two years. No bench excerpt.

RESPONSE: The intent of the standard is to ensure that all procedures used in the laboratory, including bench excerpts, have been approved by the laboratory director or verified by the laboratory supervisor prior to implementation and are followed by laboratory personnel.
Operating Procedures Sustaining Standard of Practice 6 (SOPM S6): Director Approval

Each policy and procedure and subsequent revisions shall be signed and dated by the current director or director-designated assistant director holding an appropriate certificate of qualification.

Director-designated means the assistant director who has been delegated in writing by the laboratory director as responsible for the approval of procedures used in the assistant director's area(s) of expertise. In the case of a change in director or assistant director, all procedures should be reviewed and signed by the new director and/or director designated 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.

This standard is applicable to laboratory-derived procedures, as well as manufacturer instruction manuals adopted in lieu of laboratory-specific procedures and bench excerpts.

Each procedure requires a signature and review date, and revisions to an approved SOPM should be provided in a prologue to the procedure to facilitate notification of changes. The director may use a cover sheet to annotate approval of SOPM provided the document contains a list of all procedures, their implementation dates, all revisions and revision dates. The SOPM should be revised immediately once there has been a change in procedure. Memos notifying staff of changes will be accepted provided the SOPM is updated as soon as possible. All procedures should be reviewed and signed by a new director and/or director designated assistant director as soon as possible, if not done immediately (or underway) laboratory should have a plan for having the review completed and documented within an appropriate timeframe.

Blood banks need to follow the requirements in 10 NYCRR Part 58-2.8 concerning the annual review by the director or authorized supervisor.

Electronic signature or an alternative system may be substituted for hard copy as long as the system is secure and can verify the director or assistant director's oversight.

Comment 1:
“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. This standard is applicable to laboratory-derived procedures, as well as manufacturer instruction manuals adopted in lieu of laboratory-specific procedures and bench excerpts. All procedures should be reviewed and signed by a new director and/or director designated assistant director as soon as possible, if not done immediately (or underway) laboratory should have a plan for having the review completed and documented within an appropriate timeframe.”

The guidance appears to duplicate information. We agree with the second paragraph which does not have the timeframe defined as 6 months. We have found that a realistic plan for new directors performing real-time work in addition to review of thousands of procedures exceeds the 6 month timeframe.

Comment 2:
“Blood banks need to follow the requirements in 10 NYCRR Part 58-2.8 concerning the annual review by the director or authorized supervisor.”
Could the Department consider revising the standard to be consistent with the accrediting organization standard AABB 6.1.4 Review of each policy process, and procedure shall be performed by an authorized individual at a minimum every two years?

Comment 3:
“Each procedure requires a signature and review date, and revisions to an approved SOPM should be provided in a prologue to the procedure to facilitate notification of changes.”

We request that the location/method of facilitation for notification of changes be removed. Our facilities effectively utilize highlighting of changes and a revision history summary at the end of documents.

RESPONSE: The responsibilities of a laboratory director are not new and are derived from New York State Public Health Law and in Parts 58 and 19 of the New York State Codes, Rules and Regulations (10 NYCRR). The laboratory director is responsible for ensuring the proper operation of the laboratory and for monitoring all work performed in the laboratory to ensure that medically reliable data are generated. He or she must be familiar with the laboratory’s policies and procedures in order to perform the responsibilities of laboratory director. The SOPs can be used by the new laboratory director as one tool to familiarize him or herself with the laboratory’s operations for which he or she is now responsible. Please note that a revision of Subpart 58-2.8 would be required to revise the current requirement that Blood Bank policies and procedures must be reviewed annually. The issue will be brought to the Blood Council for consideration.
NEW YORK STATE DEPARTMENT OF HEALTH
CLINICAL LABORATORY EVALUATION PROGRAM

COMMENTS and RESPONSES to PROPOSED GENERAL SYSTEMS STANDARDS

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<tbody>
<tr>
<td><strong>Validation Sustaining Standard of Practice 5 (Validation S5): Performance Specifications</strong>&lt;br&gt;Method validation shall be performed before a test method is used to report results; and,</td>
<td>While the vendor may conduct initial on-site validation, active participation by the laboratory personnel should also be evident. Manufacturer verification of proper instrument operation is only one component of method validation.</td>
</tr>
<tr>
<td>a) for methods cleared or approved by the FDA as safe and effective for in vitro diagnostic use and used unmodified, (i.e., in a manner and for indications so approved), the laboratory shall:</td>
<td>The laboratory may not state that a specific test is capable of identifying or detecting a substance at a certain concentration (i.e., titer) unless it has the data to substantiate these and all other claims.</td>
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<tr>
<td>i. verify performance specifications for accuracy, precision, reportable range of test results established by the manufacturer; and,</td>
<td>For many commonly performed tests there is a large body of peer-reviewed data that may be provisionally accepted for use as a laboratory reference (normal) range. Results from the population served should be periodically reviewed in light of these ranges thereby confirming that these values are appropriate. If the population served represents specific sub-sets of overall population (e.g., geriatric, pediatric, obstetric population), special care may be needed in establishing reference intervals.</td>
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<tr>
<td>ii. verify that the manufacturer’s reference interval is appropriate for the laboratory’s population.</td>
<td>Analytical sensitivity is also referred to as the limit of detection (LOD).</td>
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<tr>
<td>b) for methods not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as textbook procedures); for commercialized methods where performance specifications are not provided by the manufacturer (e.g., IUO, RUO, FUO); and for modified FDA-cleared or approved test systems, the laboratory shall:</td>
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<tr>
<td>i. establish performance specifications for accuracy, precision, reportable range of test results, reference interval(s) (normal values), analytical sensitivity and specificity (to include interfering substances); and other applicable performance characteristics, including the clinical sensitivity and specificity of novel assays without comparative methods;</td>
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<tr>
<td>ii. assure that the established reference interval is appropriate for the laboratory’s population; and,</td>
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<td>iii. submit validation data and SOPM for review in accordance with guidelines established by the New York State Department of Health.</td>
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<tr>
<td>c) method validation shall be performed at the actual site where the method will be used; and,</td>
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<tr>
<td>d) if the instrument will be hand-carried or otherwise transported to the location of the patient, the laboratory shall document the portability of the system.</td>
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</table>

**Comment 1:**<br>We recommend that all abbreviations be defined before using the abbreviation alone in a requirement. For example, the addition of the undefined abbreviation FUO to this standard confused some reviewers who are not familiar with forensic testing. The standard should state *Forensic Use Only (FUO).*

**Comment 2:**<br>Please define FUO

**RESPONSE:** *The standard has been revised to define the abbreviations referred to including IUO (Investigational Use Only), RUO (Research Use Only) and FUO (Forensic Use Only).*
Quality Control Sustaining Standard of Practice 1 (QC Design S1):
Design of Individualized Quality Control Plan

Unless the laboratory follows the minimum requirements set forth in QC Design Sustaining Standard of Practice 2a, the laboratory shall establish and maintain an individualized quality control plan for each assay in all specialties and subspecialties, excluding histopathology and cytopathology, that verifies the intended quality of results is achieved prior to reporting of patient results for each test. Such plans shall include:

a) a risk assessment to identify and evaluate potential failures and sources of error in the entire testing process, as outlined in Quality Control Sustaining Standard S2b;

b) a quality control plan, approved by the laboratory director, to describe the procedure for performing quality control, including the number, type and frequency of testing control materials, and for determining the parameters of acceptability for the quality control results; at least in accordance with the FDA-cleared/approved test manufacturer’s quality control instructions, where provided, and with applicable specialty standards. The quality control plan must be supported by empirical data established by the laboratory;

c) a quality assessment plan 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.

d) a process or procedure that defines the review and revision of the quality control plan, as appropriate, when non-conformances are identified.

e) testing with external quality control 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;

f) the submission of quality control plans for non-FDA approved assays:
   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 quality control procedure is changed for a New York State approved assay.

It is important, for all types of laboratories, that the control system provides staff members with clear and easily understood information on which to base technical decisions.

b) Data to support the quality control plan may include verification or establishment of performance specifications and historical (existing) QC data. Published data or data from manufacturers may be used as guidance, but may not be used as the sole basis for decision - making.

b) For molecular amplification assays, the department recommends that one negative control be run for every eight samples. At a minimum, three negative controls should be run on every 96-well plate containing 25 or more samples.

References:
EP23-A Laboratory Quality Control Based on Risk Management;
CLSI-Approved Guideline
EP23-A Implementation Workbook; CLSI-Approved workbook

Comment 1: Define External QC testing? Many esoteric tests do not have external QC available (i.e. manufacturer produced).

Comment 2: The current assays we run involve Sanger sequencing, Nextgen sequencing, fragmentation and RT-PCR. Both Sanger and Nextgen do not require a negative control as they are sequencing methodologies any contamination will result in high background. Fragmentation requires the use of one master mix in which a negative template control is incorporated to ensure no contamination occurs through-out the entire run. In our RT-PCR methods a no template control is used in both a wild-type and mutation master mix. The standard curve that is created on every run is a clear indicator of the analyst’s ability to pipette accurately. Thus the no template controls will indicate any contaminations.
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RESPONSE: Additional guidance has been provided to clarify the meaning of external quality control testing.
<table>
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<tbody>
<tr>
<td><strong>Process QC Sustaining Standard of Practice 7 (Process QC S7):</strong></td>
<td>Actual measurements taken, reactions and/or observations should be recorded. “Check” marks are not sufficient to appropriately record the acceptability of quality control. The laboratory is required to define the parameters of acceptability for quality control results.</td>
</tr>
<tr>
<td>Records</td>
<td>For tests in which results are reported in terms of graded reactions (e.g., 1+, 2+, minimally reactive), controls of graded reactivity should be used.</td>
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<tr>
<td>Records shall be kept of the actual results for each control determination,</td>
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<td>including quality control charts and/or other records which identify by date and</td>
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<td>lot the controls and/or calibrators used by the laboratory.</td>
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<tr>
<td>Records Retention Sustaining Standard of Practice 3 (Retention S3): Test Request</td>
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<td>and Process Documents</td>
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<td>The laboratory shall retain the following records for at least the period specified, except that where other New York State or Federal regulations or statutes require retention for different periods of time, the laboratory shall retain the appropriate record for the longest period applicable.</td>
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<tr>
<td>a) Test requisitions shall be retained for the same period of time as required for</td>
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<td>the test results or seven years, whichever is less, except that referral information for</td>
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<td>cytogenetic cases shall be retained for six years.</td>
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<td>b) Accession records shall be retained for seven years.</td>
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<td>c) Test procedures shall be retained for at least two years after a procedure</td>
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<td>has been discontinued, and all test procedures must include the dates of initial</td>
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<td>use and discontinuance.</td>
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<tr>
<td>d) Analytic system records, including worksheets containing instrument readings</td>
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<td>and/or personal observations upon which the outcome is based, the identity of personnel who performed the tests, quality control, patient results, and product recalls for reagents and consumables shall be</td>
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<tr>
<td>retained for at least two years.</td>
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<td>e) Preventive maintenance, service and repair records shall be retained for as</td>
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<td>long as the instrument remains in use, except that records of monitoring of</td>
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<td>temperature-controlled spaces shall be kept for two years.</td>
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<tr>
<td>f) Records of test system performance specifications that the laboratory</td>
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<td>establishes or verifies under Validation Sustaining Standard of Practice 5 and</td>
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<tr>
<td>product recalls for equipment parts shall be retained for the period of time the laboratory uses the test system plus two years after the system has been discontinued, but no less than two years.</td>
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<tr>
<td>Regulatory authority: 10 NYCRR Subpart 58-1.11(c)(2),(3),(4)</td>
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</table>

**Comment 1:**

While we agree that the laboratory is required to define the parameters of acceptability for quality control results, check marks can be defined to indicate that their use implies the results fall within the parameters. The definition of “check marks” can be defined in an SOP along with a requirement that the identity of the person making the check mark and date are clear. Some
instrument manufactures even design maintenance logs as “check lists” that needs to be signed and dated.

Comment 2:
“Check marks are not sufficient to appropriately record the acceptability of quality control.” There are “check mark” QC forms in use in laboratories for purposes of evaluating the acceptability of qualitative QC 9 (Acceptable/ not acceptable) that should continue to meet the requirements of this standard. In our laboratory, the QC of a slide staining process would fall into this category to a certain extent. When the quality of the stain is acceptable and sufficient we find that requiring comment would be redundant; a narrative description of acceptability seems inefficient and unnecessary. If the stained slide is found to be unacceptable, the pathologist is required to explain in more detail, by way of a comment, why the stain is not acceptable, in order to allow for appropriate corrective action.

RESPONSE:  Written evidence to document the actual quality control result is required. Guidance has been revised to address the comments.
### Proposed Standard

Reporting Sustaining Standard of Practice 1 (Reporting S1): Report Content  
Each clinical laboratory or blood bank shall produce a laboratory report and shall supply the original of said report to the physician or other authorized person submitting each specimen for analysis.  

Each report shall contain the following information:  

- **a)** patient name or other identification and the name of the person or institution referring the specimen;  
- **b)** the name under which the laboratory has been issued a permit and its address, except that a d/b/a may be used provided it has been reported to the Department;  
- **c)** the date, and hour if required, when the specimen was originally collected by the physician or other authorized person;  
- **d)** the date the specimen was received in the laboratory;  
- **e)** the test report date;  
- **f)** specimen source, when appropriate;  
- **g)** test results, and if applicable, units of measure, reference intervals, or a similar method for identifying abnormal values;  
- **h)** signature of the qualified person who reviewed, approved and/or diagnosed the case, where required in specialty areas of examination;  
- **i)** information regarding the condition and disposition of specimens that do not meet criteria for acceptability;  
- **j)** in the event a specimen is forwarded to another clinical laboratory for examination, the name and address of such laboratory, the date the specimen was tested and the date the result was reported; and  
- **k)** any disclaimers or limitations to testing where required by laboratory validation or NYS approval of test method.

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.

### Proposed Guidance

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Each report shall contain the following information:  

- **a)** patient name or other identification and the name of the person or institution referring the specimen;  
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- **c)** the date, and hour if required, when the specimen was originally collected by the physician or other authorized person;  
- **d)** the date the specimen was received in the laboratory;  
- **e)** the test report date;  
- **f)** specimen source, when appropriate;  
- **g)** test results, and if applicable, units of measure, reference intervals, or a similar method for identifying abnormal values;  
- **h)** signature of the qualified person who reviewed, approved and/or diagnosed the case, where required in specialty areas of examination;  
- **i)** information regarding the condition and disposition of specimens that do not meet criteria for acceptability;  
- **j)** in the event a specimen is forwarded to another clinical laboratory for examination, the name and address of such laboratory, the date the specimen was tested and the date the result was reported; and  
- **k)** any disclaimers or limitations to testing where required by laboratory validation or NYS approval of test method.  

Comment 1:  
Added requirement for test disclaimers and test limitations on test report; and for test report to include test date for each test included on the test report. Does this apply to panels with more than one test but reported at the same time? Is it acceptable to have the test date available in computer rather than including on the test report? The additional of multiple reporting dates may result in a confusing report.

**RESPONSE:** The Centers for Medicare and Medicaid Services requires that the test report date must be included on the report.
### Proposed Standard

**Proficiency Testing Sustaining Standard of Practice 9 (PT S9): Performance Review**

The laboratory director must document a review of proficiency testing performance evaluations within two weeks of notification of release and investigate results when:

- **a)** the score received in an external proficiency testing program is less than 100 percent;
- **b)** results do not meet the laboratory’s specified performance criteria; or
- **c)** shifts and trends are identified.

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### Proposed Guidance

This standard applies to New York State and all external proficiency tests.

This standard applies to education analytes/events.

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**Comment 1:**

I would like to suggest revision to part (a) or the addition of a part (d) to PTS9:

- **a)** the score received in an external proficiency testing program is less than 100 percent or the result(s) indicate review is required or unacceptable
- **d)** result(s) indicate review is required or unacceptable

**Comment 2:**

We had attempted to use the two week deadline to complete the review of proficiency test results. With our process, the quality/compliance supervisor triages all proficiency results. The section supervisor performs the preliminary review of all proficiency results. Once supervisory reviews are completed, the proficiency is forwarded to the laboratory director for his review and signature. If there are any issues detected with a survey, those surveys take priority since the section supervisor must investigate the problem and work with the laboratory director to determine appropriate follow-up. We used this method for many months. Due to the number of proficiency events we receive, (we also perform CAP proficiencies), and the amount of time required for an adequate review, the two week deadline proved to be very difficult to achieve and we changed it to within 30 days of result receipt. We would like to request a 30 day timeline from result release to ensure an effective review.

**RESPONSE:** *The standard has been revised as suggested.*
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<tr>
<td><strong>Proficiency Testing Sustaining Standard of Practice 11 (PT S11): Unsuccessful Performance – Cessation of Patient Testing</strong>&lt;br&gt; The laboratory must cease testing of clinical specimens for a minimum of six months upon unsuccessful performance in proficiency testing where the Department finds that any of the following conditions exist:</td>
<td>Unsuccessful proficiency testing performance is unsatisfactory performance for the category, subcategory or analyte in two consecutive or two out of three consecutive testing events, including events that are failed for non-technical reasons such as a late postmark, failure to submit proficiency test results electronically before test event closure, or failure to participate.</td>
</tr>
<tr>
<td>a. analytical errors suggestive of immediate jeopardy to patient care;</td>
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<tr>
<td>b. the laboratory has demonstrated an inability to make progress toward improvement of previously identified substandard performance following a reasonable opportunity to correct deficiencies;</td>
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<tr>
<td>c. the root causes of substandard performance are systemic to laboratory practices;</td>
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<tr>
<td>d. the laboratory has demonstrated a history of non-compliance with standards of good laboratory practice; or</td>
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<td>e. there have been other instances of unsuccessful performance in the category within the past two years that reflect a pattern of poor performance relevant to the current event, including repeated unsuccessful performance (unsatisfactory performance over 3 of 5 contiguous test events) for the same analyte, category or subcategory.</td>
<td></td>
</tr>
</tbody>
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Comment 1:<br> Proposed standard PT S11 that states that when 2 unsuccessful PT events occur and testing is suspended, the testing will be suspended for a minimum of 6 months. We feel that this is too long of a period to cease testing. I realize that this is a rare occurrence (2 of 3 event failures). If this does occur, investigation and analysis would generally not take 6 months. If this happened to occur with an analyte that could be critical to life and a hospital lab like ours was suspended for 6 months, it would be a grave patient safety issue.

RESPONSE: The requirement for a minimum of 6 month suspension of testing when a cease testing order is issued is required by federal regulations (42 CFR 493.807). To maintain our CLIA-exempt status, New York State standards must be as stringent as federal requirements. Therefore, we cannot remove this requirement from our standards.
## Referral Laboratories Sustaining Standard of Practice 1 (Referral S1): Performance Review

The laboratory shall have an effective documented procedure for evaluating, selecting and monitoring the quality of referral laboratories, including any secondary referral laboratories used by the primary referral laboratory. The policies and procedures for these reviews leading to arrangements for examinations or contracts shall ensure that the:

- **a)** requirements, including the methods used, are adequately defined and documented;
- **b)** laboratory has the capability and resources to meet the requirements;
- **c)** appropriate procedures are selected and capable of meeting the contract and clinical requirements; and,
- **d)** the referral laboratory holds a New York State permit in the required category of testing and any required test approvals.

**Proposed Guidance**

- **d)** It is the responsibility of the referring laboratory to ensure that the reference laboratory holds a permit for the appropriate category and test.

### Comment 1:

Will NY make an approved lab, category and testing list available?

**RESPONSE:** A list of clinical laboratories currently holding a New York State clinical laboratory permit in a specified category of testing is available at [http://www.wadsworth.org/labcert/clep/CategoryPermitLinks/CategoryListing.htm](http://www.wadsworth.org/labcert/clep/CategoryPermitLinks/CategoryListing.htm). The website currently does not contain a list of approved laboratory-developed or FDA-modified tests.