

NEW YORK STATE DEPARTMENT OF HEALTH

CLINICAL LABORATORY EVALUATION PROGRAM

COMMENTS and RESPONSES to PROPOSED GENERAL SYSTEMS STANDARDS

The Proposed revisions to the General Systems Standards were circulated for comment on October 21, 2016. 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 November 28, 2016. There was 4 comments received from regulated parties. A change was made to the guidance of one standard based on the comment received.

The standards are considered to be generally accepted and will be adopted as of January 1, 2017.

Proposed Standard	Proposed Guidance
<p>Quality Management System Sustaining Standard of Practice 1 (QMS S1): <i>Establishment of Specifications and Requirements</i></p> <p>The quality management system shall establish written specifications and requirements for the following quality system essential elements:</p> <ul style="list-style-type: none"> a) qualifications, responsibilities, authority and interrelationships of all personnel; b) adequate training and competency evaluation of all staff and supervision by competent persons conversant with the purpose, procedures, and assessment of results of the relevant examination procedures; c) management support of all laboratory personnel by providing them with the appropriate authority and resources to carry out their duties and by responding to their concerns and problems; d) provision and maintenance of facilities as necessary to support analytical systems and to promote safety and security practices; e) laboratory information system initial and periodic performance verification; f) development, updating, approval and implementation of standard operating procedures; g) protocols to ensure positive identification and optimum integrity of primary and subsamples from the time of collection or receipt through completion of testing and reporting of results, including written policies and procedures for test request, patient preparation, specimen type, collection, labeling, handling and processing; h) specimen acceptance and rejection criteria; i) selection of instruments and reagents; j) validation or verification, as appropriate, of examination procedures' performance characteristics; k) quality control practices that monitor the conformance of examination procedures to specified requirements; 	<p>Specifications and requirements established by laboratory management under Quality Management System Sustaining Standard of Practice 1 shall meet or exceed minimum requirements provided under applicable parts of these Clinical Laboratory Standards of Practice. In developing specifications and requirements for effective delivery of laboratory services, management should identify and seek input from stakeholders, i.e., those who have expectations and dependencies on the quality of services provided. Specifications and requirements developed by laboratory management and stakeholders should be clearly described and presented to vendors and contractors that provide support and resources for laboratory operations.</p> <p>References to applicable sustaining standards of practice for the establishment of specifications and requirements may include, but not limited to:</p> <ul style="list-style-type: none"> a) Human Resources S1, S3, S4, S5; Director S3(f) b) Human Resources S6, S7, S8 c) Director S3 d) General Facilities S1 e) Laboratory Information System S2, S4 f) Operating Procedures S2, S6 g) Requisition S3 h) Processing S4 i) Validation S1; Laboratory Equipment S1(a) j) Validation S5 k) Quality Control S1-S6 l) Process Review S2 m) Reporting S1-S6 n) Proficiency Testing S1-S8; Quality Assurance S3 o) Quality Assurance S3 (c)(d) p) Control of Non-Conformities S1 q) Complaint Resolution S1 r) Referral S1 t) Retention S1, Retention S3

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<p>l) mechanisms to verify test results prior to release;</p> <p>m) timely and accurate reporting of results, including alert results;</p> <p>n) enrollment in CMS-approved proficiency testing programs for tests performed that are included in Subpart I (42 CFR 493), or for those tests not included in Subpart I, participation in alternative assessments of examination procedures' performance;</p> <p>o) evaluation of performance in proficiency testing and alternative assessments of examination procedures' performance;</p> <p>p) identification and resolution of nonconformities;</p> <p>q) complaint investigations;</p> <p>r) selection of referral laboratories;</p> <p>s) communications with patients, health professionals, referral laboratories, vendors, contractors, and any applicable accreditation and regulatory agencies;</p> <p>t) <i>document control: specimen processing & process verification</i>, and specimen retention; and,</p> <p>u) quality assessment and continuous improvement of all laboratory practices, including but not limited to the establishment of objective monitors of process performance and management review of ongoing evaluations of laboratory performance.</p>	<p>u) Quality Assurance S1, S2</p> <p>c) Appropriate authority includes the delegation of responsibility to all laboratory personnel to bring concerns about laboratory practices or behavior that places the integrity of laboratory operations and services at risk to the attention of management, or if deemed necessary by laboratory personnel, to the attention of the Clinical Laboratory Evaluation Program.</p> <p>t) <i>Document control: specimen processing & process verification</i> means a system whereby the entire test process can be recreated through document review for purposes of substantiating the reported test findings. Associated records include the standard operating procedures in effect at the time of specimen analysis, test requisition, accession records, identification of resources (equipment, reagent and quality control lot numbers) used for the analysis, equipment maintenance and reagent and quality control material validation records, worksheets, test reports, and the identification of personnel who performed pertinent tasks in the test process. <i>Document control: specimen processing & process verification</i> should allow complete documentation of the test process in a timely manner for test requisitions selected by representatives of the Clinical Laboratory Evaluation Program.</p>
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Comment 1:

The proposed revision states the laboratory must enroll in a CMS-approved proficiency testing program, yet, not all surveys that are available from CMS-approved programs are listed in the eCLEP system.

Example: CAP J Survey

(Transfusion Medicine, Comprehensive)

1. We perform ABO, Rh, antibody detection, and antibody ID that meet the NYS equivalent list.
2. This survey also provides testing for both A and Rh subgroupings. However, NYS does not list these tests as equivalent for the J series so we must order two additional CAP surveys to meet the NYS equivalent criteria (ABOSG and RBCAT).

We recommend that all surveys of a CMS-approved program be available for selection in eCLEP.

What is the rationale for not making available all surveys of a CMS-approved program?

RESPONSE:

As of January 1, 2017, the New York State Proficiency Testing Program will be discontinued and there will no longer exist any NYS-defined equivalent proficiency testing program. As of January 1, 2017, laboratories will be required to enroll with a CMS-approved provider for all analytes that are described under 42 CFR Subpart H and I that the laboratory includes on its test menu. Subgrouping of blood antibodies is not a Subpart H or I analyte and is therefore not included on the eCLEP PT enrollment list. For analytes/tests such as these that are not included under Subpart H or I, laboratories are required to verify the reliability and accuracy of the test results at least twice annually in accordance with Quality Assurance Sustaining Standard of Practice 3 (QA S3): Ongoing Verification of Examination Accuracy. Compliance with QA S3 is verified during on-site surveys of the laboratory.

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Proposed Standard	Proposed Guidance
<p>Director Sustaining Standard of Practice 3 (DIR S3): Director Responsibilities</p> <p>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:</p> <ul style="list-style-type: none"> 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; 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; c) ensure that qualified personnel are employed including, where applicable that staff are not engaged in practices limited by license or beyond the scope of licensure; and by defining the qualifications and responsibilities of all laboratory technical staff and documenting training and/or competency; d) provide continuing educational to laboratory technical staff that is relevant to laboratory medicine; 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 skills; 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; g) promote a safe laboratory environment for personnel and the public; h) ensure that an approved procedure manual is available to all personnel; i) monitor all work performed in the laboratory to ensure that medically reliable data are generated; 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; 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; 	<p>The director remains responsible for all delegated activities and must provide evidence of ongoing monitors for the competent management of those delegations.</p> <p>The director may <u>not</u> 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; approval of process improvement initiatives, <u>and, review of proficiency testing results and investigations of suboptimal proficiency testing performance.</u></p> <p>Directors who also function as supervisors must also follow Human Resources Sustaining Standard of Practice 3.</p> <p>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.</p> <p>f) Permit application materials include the initial and annual permit application as well as entries submitted through the online eCLEP system. 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.</p> <p>f) the technical supervisor for cytopathology should perform workload assessment of cytotechnologists twice per year, according to Cytopathology Sustaining Standard of Practice 9 (CY S9): Establishing a Workload Limit.</p>

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<ul style="list-style-type: none"> l) ensure that the laboratory is enrolled in CMS-approved proficiency testing programs for all testing performed by the laboratory that are included in Subpart I (42 CFR 493 Subpart I). For all tests performed by the laboratory that are not included in Subpart I, ensure that the laboratory adopts an alternate method to verify test accuracy and reliability; m) ensure that the laboratory adheres to the Department's administrative and technical requirements for proficiency testing; n) select all reference laboratories; o) maintain an effective working relationship with applicable accrediting and regulatory agencies, administrative officials, and the medical community; and p) effectively implement a plan of correction to deficiencies identified. 	
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Comment 1:

The proposed standard removes the option to have a delegated, responsible assistant director documenting the review of proficiency testing results and any investigations and corrective actions taken. The assistant director, having the appropriate Certificate of Qualification, is the primary expert in the specialty or subspecialty in a large reference laboratory.

We recommend amending the requirement to allow the laboratory director to delegate this responsibility to the assistant laboratory director who holds the appropriate Certificate of Qualification for the test(s) being assessed.

Comment 2:

The proposed revision states that the director may not delegate the review of proficiency testing results and investigations of suboptimal proficiency testing performance.

In a large multi-specialty clinical laboratory, assistant medical directors delegated by the permitted medical director are imperative to maintain a sustainable, safe and effective proficiency testing program. In our laboratory system, we have 35 approved permit categories with delegated assistant medical directors assigned. Each assistant director holds the proper certificate of qualification that renders them as the scientific expert in the permit category. Our laboratory performs over 400 proficiency test surveys a year. The medical director relies on the knowledge and expertise of the delegated assistant directors, who maintain the certificate of qualification in the specific permit category, to effectively oversee the proficiency test program in their permitted category.

Currently, all proficiency test failures and outcome investigations are shared with the NYS permitted medical director quarterly or more frequently depending on circumstance.

According to CMS Laboratory Standard 493.1407: Laboratory Director Responsibilities: "All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action." Our interpretation of "the appropriate staff" should be considered the delegated assistant medical directors who hold the certificate of qualification for the testing category and are specialists in that area.

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Based on this we believe that it is appropriate to have the delegated assistant director maintain the responsibility of proficiency testing in their permitted category with the facility medical director general oversight.

RESPONSE for Comments 1 and 2:

The proposed standards have been revised to allow for the assistant director responsible for the appropriate permit category to document the review of the proficiency testing results and investigation of suboptimal proficiency test performance.

Comment 3:

Does “proficiency testing results” mean the same thing as “proficiency testing performance evaluations”? Or are they different? It seems these two phrases are used to mean the same thing in different requirements. Are we interpreting correctly that they mean the same thing?

RESPONSE 3:

The phrase “proficiency testing performance evaluations” is intended to have the same meaning as “proficiency testing results”. Please be reminded that some proficiency testing modules are not formally assessed. While such modules do not satisfy proficiency testing requirements, they may be used for other purposes as long as the laboratory evaluates its own performance.

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<p>Proficiency Testing Sustaining Standard of Practice 1 (PT S1): Participation</p> <p>Each laboratory shall participate in a formally evaluated CMS-approved proficiency testing program for each category, subcategory and analyte that is included in Subpart I (42 CFR 493 subpart I) for which the laboratory seeks or currently holds a permit. Each laboratory shall notify the Department of the proficiency testing program that will be utilized to fulfill these proficiency testing requirements in the manner prescribed by the Department. Laboratories are required to subscribe for an entire calendar year with the proficiency testing program of choice and must authorize the proficiency testing vendor to release proficiency testing grades and/or results to the Department.</p>	<p>Participation in proficiency testing is recommended for all tests not included in Subpart I, if a formally evaluated program is available.</p> <p>Notification of proficiency testing enrollment is made annually in the fall via the eCLEP system on the Health Commerce System. For newly applying laboratories or laboratories applying for a new category, enrollment information is required at the time of application.</p> <p>Please reference federal regulations at 42 CFR §493.801.</p> <p>When laboratories use more than one method to determine results for a given analyte, only the primary method should be evaluated using proficiency testing. Secondary methods should be assessed as outlined in Validation Sustaining Standard of Practice 3 (Validation S3): Multi-systems Agreement.</p>

Comment 1:

My question is why would you limit NYS laboratories from using “QE” Quality Evaluation products marketed by Proficiency vendors such as College of American Pathologists and Wisconsin State Laboratory of Hygiene? QE products offer convenience of using proficiency testing (PT) samples to verify secondary instruments/methods, as well as providing simple and valuable competency challenges. To remain compliant with CLIA regulations, participants must test and report QE products AFTER the primary set due date. We had intended on using this for intact PTH(Dxl primary) and intra-operative PTH (Access2 secondary), as well as, Troponin I by Beckman Dxl (primary) and i-STAT (QE product secondary). Along the same lines would we be out of line to participate in different surveys for different matrices such as the CAP AL1 Whole Blood Alcohol/Ethylene Glycol/Volatiles and the CAP AL2 Serum Alcohol/ Ethylene Glycol/ Volatiles surveys? The Blood Gas Surveys test will proficiency test for electrolytes and glucose? Or having our Cath lab and Operating Room use different proficiency vendors for validation of Act? We like to limit our proficiency use but in some cases, as with the assays above, they provide valuable peer review and accuracy validation when results and matrices are different.

The above information would be used with that obtained with Validation S3 for QA purposes.

RESPONSE:

PT S1 defines *minimum* participation requirements for PT. The laboratory, can enroll in and participate in *additional* PT, quality evaluation, or similar products. As New York is a CLIA-exempt state, the Clinical Laboratory Evaluation Program is required to verify that all laboratories meet these minimum requirements set forth in 42 CFR Subpart H. Subpart H specifies that each laboratory must enroll in a proficiency testing program that meets the criteria set forth in Subpart I and is approved by HHS (CMS). As stated in the CMS Interpretive Guidelines under 42 CFR 493.801, PT is required only for the laboratory’s primary method. Any additional methods for the same analyte do not require formal participation in PT, but the laboratory would be expected to monitor assay performance as required

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by Validation Sustaining Standard of Practice 3 (Validation S3): Multi-systems Agreement and Quality Assessment Sustaining Standard of Practice 3 (QA S3): Ongoing Verification of Examination Accuracy.

Comment 2:

The proposed revision states the laboratory shall participate in a formally evaluated CMS-approved proficiency testing program for each category, subcategory and analyte that is included in Subpart I. We recommend that all surveys from CMS-approved programs be available in the eCLEP system when notifying the NYS Department of Health.

What is the rationale as to why not all surveys from CMS-approved programs are available in the eCLEP system when notifying NYS?

See example for QMS S1.

RESPONSE:

The PT products available from the CMS-approved providers were pre-screened for compliance with CLIA subpart I and suitability for the method/instrument/specimen matrix. CLIA subpart I requires a minimum number of events per year and samples per event. Surveys that do not meet these criteria were excluded. Similarly, a survey for multiple microbiology analytes, in which a given analyte is tested on only one or two of the five samples, generally is not listed as an option for the individual analytes. PT products incompatible with a method and/or matrix are not listed.

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<p>Proficiency Testing Sustaining Standard of Practice 8 (PT S8): Attestation</p> <p>The laboratory director and analyst(s) must sign the proficiency test provider attestation statement indicating the routine integration of the samples in the patient workload using the laboratory's routine method. The signed document must be kept on file in the laboratory for review by the clinical laboratory consultant during future on-site surveys.</p>	<p>The summary page(s) generated by online results submission, signed by the required personnel, fulfills this requirement.</p>

Comment 1:

The proposed revision removes the option to have a delegated, responsible assistant director sign the attestation form. The assistant director, having the appropriate Certificate of Qualification (CQ), is the primary expert in the specialty or subspecialty in a large reference laboratory.

We recommend amending the requirement to allow the laboratory director to delegate this responsibility to the assistant laboratory director who holds the appropriate CQ for the test(s) being assessed.

What is the rationale for not allowing the assistant director (CQ holder) to sign the attestation form?

RESPONSE:

The proposed standards have been revised to allow for the assistant director responsible for the appropriate permit category to sign the attestation form indicating the routine integration of the samples in the patient workload using the laboratory's routine method.

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<p>Proficiency Testing Sustaining Standard of Practice 9 (PT S9): Performance Review</p> <p>The laboratory must initiate and document a review of proficiency testing performance evaluations within two weeks of notification of release and investigate results when:</p> <ul style="list-style-type: none"> a) the score received in an external proficiency testing program is less than 100 percent or the results(s) are unacceptable or indicate review is required; b) results do not meet the laboratory's specified performance criteria; or c) shifts and trends are identified. <p>The laboratory director must document review of the investigation and approval of any corrective action taken.</p>	<p>This standard applies to all proficiency tests. This standard applies to educational analytes/events.</p> <ul style="list-style-type: none"> a) This applies to both the analyte score and the overall testing event score. <p>The laboratory director may not delegate the final review of the investigation and approval of corrective action.</p>

Comment 1:

The proposed standard removes the option to have a delegated, responsible assistant director documenting the review of proficiency testing results and any investigations and corrective actions taken. The assistant director, having the appropriate Certificate of Qualification, is the primary expert in the specialty or subspecialty in a large reference laboratory.

We recommend amending the requirement to allow the laboratory director to delegate this responsibility to the assistant laboratory director who holds the appropriate Certificate of Qualification for the test(s) being assessed.

RESPONSE:

The proposed standards have been revised to allow for the assistant director responsible for the appropriate permit category to document the review of the investigation and approval of any corrective action.