Only those standards with proposed revisions are included here.
Any General System Standards not addressed here remain in effect.

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Quality Management System

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Quality Management System Sustaining Standard of Practice 1 (QMS S1): ***Establishment of Specifications and Requirements*** The quality management system shall **establish written specifications and requirements** for the following quality system essential elements: 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;	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. References to applicable sustaining standards of practice for the establishment of specifications and requirements may include, but not limited to: 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

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l) mechanisms to verify test results prior to release; m) timely and accurate reporting of results, including alert results; n) enrollment in a CMS-approved proficiency testing program 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; o) evaluation of performance in proficiency testing and alternative assessments of examination procedures' performance; p) identification and resolution of nonconformities; q) complaint investigations; r) selection of referral laboratories; s) communications with patients, health professionals, referral laboratories, vendors, contractors, and any applicable accreditation and regulatory agencies; t) *document control: specimen processing & process verification*, and specimen retention; and, 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.	t) Retention S1, Retention S3 u) Quality Assurance S1, S2 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. t) *Document control: specimen processing & process verification* 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. *Document control: specimen processing & process verification* should allow complete documentation of the test process in a timely manner for test requisitions selected by representatives of the Clinical Laboratory Evaluation Program.

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Director Sustaining Standard of Practice 3 (DIR S3): Director Responsibilities 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: 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	The director remains responsible for all delegated activities and must provide evidence of ongoing monitors for the competent management of those delegations. 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. Directors who also function as supervisors must also follow Human Resources Sustaining Standard of Practice 3. 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. 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. 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.

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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; 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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Quality Assessment Sustaining Standard of Practice 3 (QA S3): Ongoing Verification of Examination Accuracy For all tests performed by the laboratory that are not included in Subpart I, (42 CFR 493 Subpart I) the laboratory: a) shall have a system for verifying the reliability and accuracy of test results; b) shall perform this verification process at least semiannually; c) shall evaluate all accuracy verification challenges: i. to ensure that results are consistent with the laboratory's specified performance criteria when an event is not graded by the external quality assurance program; ii. to identify shifts and trends regardless of the score received; and d) shall initiate and document a review of verification results within two weeks and subsequently perform and document corrective action when: i. the score received in an external proficiency testing program is less than 100 percent, the result(s) are unacceptable or indicate review is required; ii. results do not meet the laboratory's specified performance criteria; or iii. shifts and trends are identified.	Preferably the laboratory will participate in an external quality assurance (proficiency testing) program. If a laboratory chooses to use PT samples from a CMS-approved PT program for the purpose of meeting this standard, and the laboratory intentionally refers those samples to another laboratory or engages in inter-laboratory communication, it will be subject to the same enforcement sanctions as described under Proficiency Testing Sustaining Standards of Practice S4 and S5. When no external program exists the laboratory may evaluate the accuracy of testing through an internal proficiency testing program that may include performance of split-sample comparisons (patient and/or quality control samples) with another validated method; evaluation of clinical outcomes; blind testing of specimens with known results, or other equivalent system. For microscopic tests not included in a PT program, the laboratory supervisor may retest a random sample of specimens throughout the year while assessing all testing personnel. For tests such as KOH preparations and erythrocyte sedimentation rates, the laboratory may utilize duplicate testing performed by two different testing personnel. Laboratories unable to participate in a proficiency test event as a graded participant are required to establish alternate means to verify the accuracy and precision of the test system for all un-graded analytes. b) Semiannual is used to describe an event that takes place two times per year, with the first event taking place in the first six months of the a year and the second event in the last six months of a year, and where the interval between events is at least four months and not more than eight months. c) A laboratory's performance criteria should be based on established analytical specifications of the assay or clinical expectations. For example, the criteria used for evaluating quality control could be the criteria used for evaluating proficiency test results.

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Proficiency Testing	
Proficiency Testing Sustaining Standard of Practice 1 (PT S1): Participation 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.	Participation in proficiency testing is recommended for all tests not included in Subpart I, if a formally evaluated program is available. 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. Please reference federal regulations at 42 CFR §493.801. 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.
Proficiency Testing Sustaining Standard of Practice 2 (PT S2): Routine Analysis Unless instructed otherwise by the proficiency test provider, the laboratory shall handle, prepare, process, examine, test and report on the results obtained from the proficiency test samples it receives from the proficiency testing program provider in the same manner as patient specimens and using the primary method of analysis. Participation in proficiency testing must be rotated amongst all operators who perform the test.	The proficiency test specimens should be accessioned within the limitations of the laboratory system. The intent of the standard is that the proficiency test material will be handled as much like a patient sample as possible, with the exception of automatic reflex testing to another laboratory. Routine method is the analytical system, assay, test kit, examination or instrument used as the primary method for routine workload testing at the time of the proficiency test event. If the laboratory operates on multiple shifts, participation in proficiency testing shall be rotated through all shifts on a regular basis.
Proficiency Testing Sustaining Standard of Practice 8 (PT S8): Attestation The laboratory director, or the assistant director responsible for the permit category, and analyst(s) must sign the proficiency test provider's attestation statement indicating the routine integration of the samples in the patient workload using the laboratory's routine method. The signed document must be	The summary page(s) generated by online results submission, signed by the required personnel, fulfills this requirement.

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kept on file in the laboratory for review by the clinical laboratory consultant during future on-site surveys.	
Proficiency Testing Sustaining Standard of Practice 9 (PT S9): Performance Review The laboratory must initiate and 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 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. The laboratory director or assistant director responsible for the category must document review of the investigation and approval of any corrective action taken.	This standard applies to all proficiency tests. This standard applies to educational analytes/events. a) This applies to both the analyte score and the overall testing event score.
Proficiency Testing Sustaining Standard of Practice 10 (PT S10): Performance Review - Unsatisfactory Performance The laboratory must investigate the problem(s) that contributed to the unsatisfactory performance and implement corrective action, noting that discontinuation of a test is not, in and of itself, a root cause analysis nor corrective action. Documentation of investigation and corrective action must be retained by the laboratory for a minimum two years - except for Immunohematology where five year retention is required - and made available to the Department when requested.	Unsatisfactory performance is the failure to attain the minimum passing score for the category or analyte for a testing event, 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. Laboratories that are in application for a permit or new category of testing are required to provide documentation of the investigation and plan of correction in order to continue the application process.

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Proficiency Testing Sustaining Standard of Practice 12 (PT S12): Unsuccessful Performance – Remedial Action Laboratories that demonstrate unsuccessful performance are required to perform the following: a) identify the NYS-permitted laboratory to which it will refer clinical specimens when the laboratory is directed by the Department to cease or voluntarily ceases patient testing; b) evaluate patient test results obtained since the last acceptable run to determine if patient test results have been demonstrated to be inaccurate and unreliable, and notify clients and issue corrected reports as appropriate; c) identify root cause(s) of substandard performance, develop and implement a plan of corrective action; and report its findings to the Department; noting that discontinuation of a test, in and of itself, is not remediation, and, d) substantiate the effectiveness of corrective action by successful performance in two consecutive proficiency test events, one of which may be an out-of-sequence event provided by the proficiency testing program designated by the laboratory to fulfill proficiency testing requirements for the calendar year.	

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Proficiency Testing Sustaining Standard of Practice 14 (PT S14): Unsuccessful Performance – Continued Patient Testing If conditions a - e under Proficiency Testing Sustaining Standard of Practice 11 do not exist, and the Department determines the cause(s) of substandard performance can be remedied in a timely manner, the laboratory is notified of the unsuccessful performance in proficiency testing and is instructed to perform the following while patient testing services continue: a) investigate immediately the cause(s) of substandard performance in proficiency and report its findings to the Department within two weeks (ten business days) of notification of unsuccessful performance; i) a cease testing directive will be issued to the laboratory if the results of the investigation and plan of correction are not reported within ten business days or when the plan of correction is deemed unacceptable. b) evaluate patient test results obtained since the last acceptable run to determine if patient test results have been demonstrated to be inaccurate and unreliable, and notify clients and issue corrected reports as appropriate; and c) substantiate the effectiveness of corrective action by successful performance in two consecutive proficiency test events, one of which may be an out-of-sequence event provided by the proficiency testing program designated by the laboratory to fulfill proficiency testing requirements for the calendar year.	
Proficiency Testing Sustaining Standard of Practice 15 (PT S15): **STANDARD DELETED**	
Proficiency Testing Sustaining Standard of Practice 16 (PT S16): **STANDARD DELETED**	