Changes to the Proposed (Dec 2006) *Clinical Laboratory Standards of Practice*

Part One: Changes to General Systems Standards

The prefix for the numbering the *General System* standards was changed, from FSP to F (for the Fundamental Standards) and from SSP or SS to S (for the Sustaining Standards).

Quality Management Systems		
Dec 2007 Tag Number	**Dec 2006 Tag Number**	**Summary of Changes**
Quality Management System Fundamental Standard		
QMS F1	QMS FSP1	Guidance was added to introduce the concept of the *Quality Systems Cycle.*
Quality Management System Sustaining Standards		
QMS S1	QMS SSP1	Reference to applicable standards for each of the specifications was added to Guidance. The text of the standard, which outlines the areas of the laboratory for which specifications and requirements must be established, was revised and reordered as follows: (a) and (b) no change; (c) added "and by responding to their concerns and problems"; (d) no change; (e) moved laboratory information systems here from (i) and revised language to make it clear that specifications must be established for *validation of systems*; (f) added a requirement for procedure manuals; moved the requirement for validation to (j) (h) no change; (i) formerly (e) (j) formerly (f), added "or verification as appropriate" (k) formerly (i); (l) changed language from "validation of test results" to "mechanisms to verify test results prior to release"; (m) changed language from "reliable and timely" to "timely and accurate"; (n), (o), (p), (r), (q); no change, appeared in 2006 version as (j), (k), (n), and (o), respectively; (s) formerly (q) was revised to add vendors and contractors to the list of entities; (t) expanded on the requirement for document control by adding "records management and specimen retention"; (u) added text to clarify expectations for quality assessment and continuous improvement of laboratory services.
QMS S2	QMS SSP5	No change to text of standard or guidance; the requirement for a Quality Manual was moved here to provide a more logical flow for this section.

Quality Management Systems Sustaining Standards (continued)		
Dec 2007 Tag Number	**Dec 2006 Tag Number**	**Summary of Changes**
QMS S3	QMS SSP2	This standard, formerly *Internal Audits,* is now called *Quality System Audits.* While laboratories are still expected to have formal auditing mechanisms in place, the requirement for an annual internal audit has been eliminated; instead laboratories are required to have a system to audit laboratory performance against their own QMS performance specifications on a continual basis and take corrective action as required. Guidance for (e) has been revised to clarify that the Department may review audit findings only when there is evidence of serious non-compliance.
QMS 4	QMS SSP3	No change to text of standard or to guidance.
QMS 5	QMS SSP4	The term "internal audit" was replaced with "quality systems audit" to be consistent with terminology used in QMS S3. No other changes to text of standard or to guidance.

Human Resources		
Dec 2007 Tag Number	**Dec 2006 Tag Number**	**Summary of Changes**
Director Fundamental Standard		
DIR F1	N/A	This fundamental standard for *Director Oversight* was added to emphasize that an effective laboratory director is a fundamental requirement.
Director Sustaining Standards		
DIR S1	HR SSP1	This standard for *Director Involvement* was renumbered to include it in the DIR series, the text of the standard was reworded for clarity, and guidance was added to clarify how a director's involvement will be evaluated.
DIR S2	HR FSP2	The first paragraph of HR FSP2 has been broken out into a unique DIR standard, *Director Affiliations,* to clarify that a director may be approved for no more than the five affiliations allowed under the CLIA regulations, and to clarify that the limitations on director affiliations apply to individuals serving as assistant directors if they are the sole certificate of qualification holder for a category.
DIR S3	HR FSP2	The second paragraph of HR FSP2 has been broken out as a separate standard, *Director Responsibilities;* information about the assessment of the director's role through survey outcomes and requirements for the delegation of duties has been moved from guidance to standard; guidance has been added to clarify the duties of a director that may not be delegated.

Human Resources Fundamental Standard		
Dec 2007 Tag Number	**Dec 2006 Tag Number**	**Summary of Changes**
HRF1	HR FSP1	No changes to the text of the standard or guidance; the HR standard series now appears after the DIR standards.
Human Resources Sustaining Standards		
HR S1	HR SSP2	No changes to text of standard or to guidance.
HR S2	HR SSP3	No changes to text of standard, guidance was revised to add the requirement for a CES evaluation and to clarify that personnel not required to be licensed by SED (including those employed in out-of state laboratories) will continue to be held to the requirements of 10 NYCRR.
HR S3	HR SSP4	Requirements to Part 58 regarding the expectations for the supervisor to be on-site and duties for supervisors consistent with those required under the CLIA regulations were added to the text of the standard; guidance was added to clarify the titles used by supervisors and expectations for delegation of their duties.
HR S4	HR SSP5	The text of the standard was revised to expand the requirement for sufficient staff to all technical personnel and duties for technical staff consistent with those required under CLIA regulations were added.
HR S5	HR SSP10	This standard for designation of a Quality Systems Manager was moved up so it immediately follows the standards for technical personnel and supervisors and guidance was added clarifying the expectations for a Quality Systems Manager.
HR S6	HR SSP8	The text of this standard was revised to reinforce that all levels of staff must be trained and to describe the required elements of a training program. Requirements for continuing education of staff were moved to a separate standard (HR S9) to distinguish them from the requirements for training.
HR S7	N/A	This new standard was added to extend the requirement for competency assessment to supervisory staff.
HR S8	HR SSP9	The text of the standard for competency assessment was reworded to indicate that there must be written documentation of competency assessment as required under CLIA regulations. The required intervals for performing competency assessments were moved from h) to the introductory paragraph, and guidance was added to mirror the requirements under HR S6.
HR S9	HR SSP8	The requirements for continuing education were moved to this separate standard (from HR SSP8) to distinguish them from the requirements for training.
HR S10	HR SSP6	No changes to text of standard. Guidance was revised to add the regulatory reference for workload standards.
HR S11	HR SSP7	Numbering change only-no changes to text of standard or to guidance.

Facility Design and Resource Management		
Dec 2007 Tag Number	**Dec 2006 Tag Number**	**Summary of Changes**
FDRM Fundamental Standard		
FDRM FS1	FDRM FSP1	The text of the standard was revised to add laboratory space as one of the specifications that must be considered and to clarify that compliance with this fundamental standard is the responsibility of both the laboratory director and owner.
General Facilities Sustaining Standards		
GF S1	GF SSP1	The word "sufficient" was added under (a) to clarify that laboratory space must be adequate for the work performed.
GF S2 to GF S4	GF SSP2 to GF SSP4	Numbering changes only-no changes to text of standard or to guidance.
Laboratory Equipment Sustaining Standards		
LE S1	LE SSP1	Numbering change only-no change to text of standard or to guidance.
LE S2	LE SSP2	The text of the standard was revised to indicate that preventive maintenance must be documented. Guidance was added to clarify that any recommendations from manufacturers authorizing changes to preventive maintenance procedures must be in writing.
LE S3	LE SSP3	Numbering change only-no change to text of standard or to guidance.
LE S4	LE SSP4	Guidance was added to clarify that alternate means of retaining equipment records for the required two years must be used of the instrument's internal system purges or overwrites data.
LE S5	LE SSP5	Numbering change only-no change to text of standard or to guidance.
LE S6	LE SSP6	The text of the standard was revised to allow additional options for monitoring CO_2 incubators.
LE S7	LE SSP7	The guidance for this standard was revised to clarify the requirements for monitoring UV decontamination systems.
LE S8	LE SSP8	The guidance for this standard was revised to clarify the requirements for monitoring temperature homogeneity of thermocyclers. Yearly checks are no longer required; however it is recommended that temperature be monitored on an ongoing basis.
LE S9	LE SSP9	Guidance was added to this standard to clarify the laboratory's responsibilities for the use of ancillary requirement.
Reagents and Supplies Sustaining Standards		
REAG S1 to REAG S2	REAG SSP1 to REAG SSP2	Numbering changes only-no changes to text of standard or to guidance.
REAG S3	REAG SSP3	The text of the standard was revised to conform to CLIA regulations requiring laboratories to follow manufacturer's specifications for using reagents, media and supplies and to assume responsibility for the results.

Reagents and Supplies Sustaining Standards (continued)		
Dec 2007 Tag Number	**Dec 2006 Tag Number**	**Summary of Changes**
REAG S4	REAG SSP4	The text of this standard was revised to indicate that the expiration date of reagents must be recorded. Guidance was added regarding inventory control procedures for backorders.
REAG S5 to REAG S6	REAG SSP5 to REAG SSP6	Numbering changes only-no changes to text of standard or to guidance.
REAG S7	REAG SSP7	The text of the standard was revised to add a reference to the manufacturers stated expiration date. Guidance was added to specify that laboratories may use reagents beyond their expiration date only if the manufacturer had provided written authorization to do so.
REAG S8	REAG SSP8	The text of this standard was revised to clarify that both primers and probes used for PCR may not be frozen and thawed repeatedly.
Safety Sustaining Standards		
SAFETY S1 through S3; SAFETY S5	SAFETY SSP1 through S3; SAFETY SSP5	Numbering changes only-no changes to text of standard or to guidance.
SAFETY S4	SAFETY SSP4	The text of the standard was revised to clarify that the laboratory must be in compliance with OSHA requirements for the disposal of needles and blood tube holders and that phlebotomy supplies must be used in accordance with the package insert.
SAFETY S6	SAFETY SSP6	The text of this standard was revised to clarify that the requirement for a NYS license to store radioactive materials applies only to laboratories located in the State. The wording of the guidance was reordered for clarity.
SAFETY S7	SAFETY SSP7	The text and guidance of this standard were revised to include the requirement that safety showers as well as eyewash stations, if used, must be tested routinely.
SAFETY S8 to SAFETY S11	SAFETY SSP8 to SAFETY SSP11	Numbering changes only-no changes to text of standard or to guidance.
SAFETY S12	SAFETY SSP12	Guidance was added to clarify that pipette bulbs are an acceptable mechanical device, for pipetting procedures.
SAFETY S13 to SAFETY S21	SAFETY S13 to SAFETY S21	Numbering changes only-no changes to text of standard or to guidance.
SAFETY S22	SAFETY SSP22	This standard was revised to clarify that the requirement for all laboratories to follow local, state and federal laws applies to the handling of regulated medical waste.

Laboratory Information Systems Sustaining Standards		
Dec 2007 Tag Number	**Dec 2006 Tag Number**	**Summary of Changes**
LIMS S1 to LIMS S3	LIMS SSP1 to LIMS SSP3	Numbering changes only-no changes to text of standard or to guidance.
LIMS S4	LIMS SSP4	The text of this standard was revised to clarify that the requirement for validation applies to any system changes. Guidance was added to specify that system installation or changes and any validation conducted by an independent IT Department must be approved by laboratory management.
LIMS S5 to LIMS S6	LIMS SSP5 to LIMS SSP6	Numbering changes only-no changes to text of standard or to guidance.
LIMS S7	LIMS SSP7	Standard Reporting S4 addresses the requirement that the laboratory retain the basis for any corrected results, which is not necessarily done using the LIMS. Therefore, the reference to "reason for change" is removed from LIMS S7.
LIMS S8	LIMS SSP8	Guidance was added to this standard to clarify that procedures should be in place to ensure that computer access is removed, for individuals who have left the laboratory.
LIMS S9	LIMS SSP9	Numbering changes only-no changes to text of standard or to guidance.
LIMS S10	LIMS SSP10	The text of this standard was revised to clarify that the requirement for ensuring accurate data entry applies to test results as well as tests requisitions. Guidance was added to provide examples of mechanisms for ensuring accurate data-entry, and to reinforce that the requirements for training and competency in the Human Resources section of these standards apply to personnel performing data-entry.

Standard Operating Procedures		
Dec 2007 Tag Number	**Dec 2006 Tag Number**	**Summary of Changes**
Standard Operating Procedures Fundamental Standard		
SOP F1	SOP FSP	Numbering change only-no changes to text of standard or to guidance.
Standard Operating Procedures Sustaining Standards		
SOP S1	SOP SS1	The text of this standard was revised to add the requirement that the laboratory maintain an accurate procedure manual. Guidance was added for procedures kept in an electronic format.

Standard Operating Procedures Sustaining Standards-continued		
Dec 2007 Tag Number	**Dec 2006 Tag Number**	**Summary of Changes**
SOP S2	SOP SS2	Guidance was added to clarify that the required elements for procedures must be included in the manual only when relevant for a particular assay. Guidance was added for (g) to specify that summary lists of panic or alert values may be used but the panic or alert values for each assay must also be included in the procedure manual. Instructions for specimen storage, post-examination, are not pertinent to those responsible for primary sample collection; therefore requirements under paragraph (d) of REQ S3 have been moved to SOPM S2: Content.
SOP S3	SOP SS3	The text of this standard was revised to specify that any manufacturer's instructions used as part of the procedure manual must be current.
SOP S4	SOP SS4	Guidance was added to this standard to specify that the requirement for a process to ensure the accuracy of any SOP bench excerpts used in the laboratory applies also to any procedural notes used by technical personnel.
SOP S5	SOP SS5	Numbering change only-no changes to text of standard or to guidance.
SOP S6	SOP SS6	Guidance was added to this section to clarify the expectations for approval and sign-off of the procedure manual by directors and assistant directors and to specify requirements for changes to procedures.
SOP S7	SOP SS7	Numbering change only-no changes to text of standard or to guidance.

Pre Examination Procedures		
Dec 2007 Tag Number	**Dec 2006 Tag Number**	**Summary of Changes**
Pre Examination Fundamental Standard		
PEP F1	PEP FSP1	Numbering change only-no changes to text of standard or to guidance.
Requisitions Sustaining Standard		
REQ S1	REQ SS1	Guidance added to clarify that an exception to the requirement for prior approval for use of a non-permitted laboratory is allowed in cases of urgent need for testing and program staff is not available to process the referral request.
REQ S2	REQ SS2	Numbering change only-no changes to text of standard or to guidance.

Requisitions Sustaining Standard-continued		
Dec 2007 Tag Number	**Dec 2006 Tag Number**	**Summary of Changes**
REQ S3	REQ SS3	The text of the standard and guidance were revised to stress the importance of procedures for the proper identification of patients, and to require that two forms of identification be used. Guidance was added to specify that instructions must be provided for the proper collection of tissue specimens as well as blood and urine and other body fluids. Item (d) of the standard was revised to specify that the laboratory must have polices for specimen storage and retrieval as well as instructions. Instructions for specimen storage, post-examination, are not pertinent to those responsible for primary sample collection; therefore requirements under paragraph (d) have been moved to SOPM S2: Content.
REQ S4	REQ SS4	Guidance was added to conform with CLIA regulations specifying that the patient's chart or medical record may be used as a requisition or authorization for testing, provided it includes all the required information and is available for Department review. The text of the standard at (f) was revised to qualify that the time of collection must be recorded when required, and guidance was added that time of collection must be recorded when specimen stability is less than 24 hours. Guidance was added to (a) reiterating the requirement that two forms of identification be used.
Specimen Processing Sustaining Standard		
Processing S1 to Processing S9	Processing SS1 to Processing SS9	Numbering changes only-no changes to text of standards or to guidance.

Examination Procedures

Dec 2007 Tag Number	**Dec 2006 Tag Number**	**Summary of Changes**
Fundamental Standard		
EP F1	EP FSP1	Numbering change only-no changes to text of standard or to guidance.
Validation of Laboratory Procedures Sustaining Standards		
VAL S1 to S4	VAL SS1 to SS4	Numbering change only-no changes to text of standard or to guidance.
VAL S5	VAL SS5	The text of the standard under (b) (i) was revised to conform to CLIA regulations, which require that interfering substances be considered when validating methods for specificity. Text was added to the first paragraph of the guidance to clarify that the on-site verification by the manufacturer is just one aspect of validation and would not meet the intent of the standard, which specifies that the laboratory must be actively involved in validation of test methods.

Validation of Laboratory Procedures Sustaining Standards-continued		
Dec 2007 Tag Number	**Dec 2006 Tag Number**	**Summary of Changes**
VAL S6	VAL SS6	Numbering change only-no changes to text of standard or to guidance.
Determination of Calibration and Calibration Verification Procedures Sustaining Standards		
CAL S1 and CAL S2	CAL SS1 and CAL SS2	Numbering change only-no changes to text of standard or to guidance.
Establishment of Quality Control Procedures Sustaining Standards		
QC Design S1	QC SS1	Text was added to the guidance for this standard to clarify that there are allowances in Design QC S2 to design less stringent quality control protocols for single use devices.
QC Design S2	QC SS2	Text was added to better clarify the factors that must be considered when designing a quality control protocol for single-use devices and to specify that the laboratory director must evaluate the capabilities of the system.
QC Design S3 to QC Design S5	QC SS3 to QC SS5	Standards renamed and renumbered only-no changes to text of standard or to guidance.
QC Design S6	QC SS6	The standard was revised to clarify that the when QC materials are not available, the laboratory must establish a process that detects immediate errors and monitors test performance over time. Guidance was added to specify that laboratories must use commercially prepared controls or otherwise characterized materials if they are available.
Process Quality Control Sustaining Standards		
Dec 2007 Tag Number	**Dec 2006 Tag Number**	**Summary of Changes**
Process QC S1	Process QC SS1	Numbering change only-no changes to text of standard or to guidance.
Process QC S2	Process QC SS2	The text of this standard was revised to qualify that these are minimum standards for running quality control; if there are more stringent requirements outlined in the *Specialty* sections of these standards or required by the manufacturer, the most stringent requirement must be followed. Genetic Testing was added as a link to the guidance section to indicate that this is one of the sections where more stringent quality control procedures apply.
Process QC S3	Process QC SS3	The terms “external” and “appropriate” were added to the text of both the standard and guidance to this section, to make a distinction between integrated function checks and true quality control materials.
Process QC S4	Process QC SS4	Guidance was added to accurately reflect requirements for serum protein electrophoresis, where separation is based on both size and charge, and running a normal serum sample and an abnormal serum sample might be adequate.

Process Quality Control Sustaining Standards-continued		
Dec 2007 Tag Number	**Dec 2006 Tag Number**	**Summary of Changes**
Process QC S5	Process QC SS5	Numbering change only-no changes to text of standard or to guidance.
Process QC S6	Process QC SS6	The text of the standard was reworded for clarity and guidance added to specify that quality control materials must be rotated across various shifts.
Process QC S7 to Process QC S8	Process QC SS7 to Process QC SS8	Numbering change only-no changes to text of standard or to guidance.

Post-Examination Procedures

Dec 2007 Tag Number	**Dec 2006 Tag Number**	**Summary of Changes**
Fundamental Standard		
Process Review F1	Process Review FSP1	Numbering change only-no changes to text of standard or to guidance.
Process Review Sustaining Standards		
Process Review S1 to S4	Process Review SS1 to SS4	Numbering change only-no changes to text of standard or to guidance.
Reporting Sustaining Standards		
Reporting S1 to S3	Reporting SS1 to SS3	Numbering change only-no changes to text of standard or to guidance.
Reporting S4	Reporting SS4	Guidance added to (c) clarifying the requirements for dates on amended reports.
Reporting S5 to S6	Reporting SS5 to SS6	Numbering change only-no changes to text of standard or to guidance.
Records and Specimen Retention Sustaining Standards		
Dec 2007 Tag Number	**Dec 2006 Tag Number**	**Summary of Changes**
Retention S1	Retention SS1	Revisions were made to clarify the intent of the document control standard.
Retention S2 to S6	Retention SS2 to SS6	Numbering change only-no changes to text of standard or to guidance.
Confidentiality Sustaining Standards		
Confidentiality S1 to S3	Confidentiality SS1 to SS3	Numbering change only-no changes to text of standard or to guidance.

Quality Assessment and Improvement		
Dec 2007 Tag Number	**Dec 2006 Tag Number**	**Summary of Changes**
Quality Assessment Fundamental Standard		
QA F1	QA FSP1	Numbering change only-no changes to text of standard or to guidance.
Quality Assessment Sustaining Standards		
QA S1 to QA S2	QA SS1 to QA SS2	Numbering change only-no changes to text of standard or to guidance.
QA S3	QA SS3	The text of the standard QA S3 (b) was revised to clarify that verification must be performed every six months as opposed to twice a year; guidance was added to clarify that laboratories that use external proficiency testing programs to satisfy this requirement are subject to the same sanctions outlined in these standards for interlaboratory communication or referral of NYSDOH proficiency testing specimens
Proficiency Testing Fundamental Standard		
PT F1	PT FSP1	Numbering change only-no changes to text of standard or to guidance.
Proficiency Testing Sustaining Standards		
PT S1 to PT S3	PT SS1 to PT SS3	Numbering change only-no changes to text of standard or to guidance.
PT S4 to PT S5	PT SS4 to PT SS5	Guidance added to specify sanctions for proficiency test referral and interlaboratory communication
PT S6 to PT S8	PT SS6 to PT SS8	Numbering change only-no changes to text of standard or to guidance.
PT S9 to PT S14	N/A	Six new standards and associated guidance were added to reflect the expectations for review of proficiency test results and the Program's procedures for handling unsatisfactory and unsuccessful performance.
Referral and Contract Laboratories Sustaining Standards		
Dec 2007 Tag Number	**Dec 2006 Tag Number**	**Summary of Changes**
Referral S1 to S3	Referral SS1 to SS3	Numbering change only-no changes to text of standard or to guidance.
Resolution of Complaints/Identification and Control of Non-Conformities Sustaining Standards		
Complaint S1 to Corrective Action S3	Complaint SS1 to Corrective Action SS3	Numbering change only-no changes to text of standard or to guidance.

Public Health Preparedness and Reporting		
Dec 2007 Tag Number	**Dec 2006 Tag Number**	**Summary of Changes**
Fundamental Standard		
Public Health F1	Public Health FSP1	Numbering change only-no changes to text of standard or to guidance.
Sustaining Standard		
Public Health S2	Public Health SS2	Numbering change only-no changes to text of standard or to guidance.

Part Two: Changes to Specialty Standards

Listed below are technical updates made to the Specialty Standards since the December 2006 proposed revision. The existing tag number system will be used until the Specialty Standards are revised to conform to the *Fundamental* and S*ustaining* framework used for the General System Standards.

Mycobacteriology		
Dec 2007 Tag Number	**Dec 2006 Tag Number**	**Summary of Changes**
TB26	N/A	This new standard was added to conform to CLIA regulations, which require laboratories to ensure that results for control organisms are within established limits before reporting patient results for antimycobacterial susceptibility testing.
Mycology		
MY12	MY12	This standard was revised to conform to CLIA regulations, which require laboratories to ensure that results for control organisms are within established limits before reporting patient results for antifungal susceptibility testing.
Hematology		
HM5	HM5	This standard was revised to conform to CLIA regulations, which require <u>each individual</u> performing manual coagulation tests to perform quality control testing.
Blood Services		
BS3	N/A	This standard was added to conform to CLIA regulations, which require documented inspections of blood product storage temperature alarm systems.
Cytogenetics		
CG10	CG10	Guidance added to CG10(c) to conform to CLIA regulations, which require laboratories to have records documenting the resolution is appropriate, based on the clinical information provided to the laboratory.

Part Two: Changes to Specialty Standards (continued)

The following changes were made to the Histocompatibility Standards to conform to CLIA regulations:

Histocompatibility		
Dec 2007 Tag Number	**Dec 2006 Tag Number**	**Summary of Changes**
HC8	HC8	HC8 (a) was modified to require that specificity of sera obtained locally be validated using a cell panel from a minimum of 40 subjects from various ethnic groups, including cells with antigens and common splits to which HLA antibodies are directed, cells possessing only one defined antigen at a locus, and additional cells as needed to identify an antibody with certainty.
HC16	HC16	This standard was modified to address requirements for storage alarm systems and emergency plans for alternative storage; HC16b was added to conform to CLIA requirement that laboratories establish a system to retrieve specimens for further testing in a timely manner.
HC 11	HC11	HC11(g) was added to require a protocol for ensuring that reagents used for typing are adequate to define all HLA-A, B and DR specificities that are officially recognized by the most recent WHO Committee on Nomenclature and for which reagents are readily available. HC11 (h) was added to require that laboratories have available and follow written criteria for the assignment of HLA antigens.
HC 24	HC24	HC24 (f) was added to address the sensitivity and specificity of the test system required to support clinical transplant protocols (for example, antigen or allele-level typing).
HC 26	HC26	Text was added to this standard to require, for nonrenal transplantation, that if HLA testing and final crossmatching were not performed prospectively because of an emergency situation, records must reflect any information concerning the transplant provided to the laboratory by the transplant candidate's physician.
HC35	N/A	This standard was added to require that laboratories performing HLA typing for the purpose of disease association studies must check each typing using materials to monitor the test components and each phase of the test system to ensure acceptable performance.
HC36	N/A	This standard was added to require laboratories to document all control procedures performed.