Following a review of its application for deeming authority for clinical laboratories by the Centers for Medicare & Medicaid Services (CMS), The Joint Commission revised several elements of performance (EPs) for the laboratory accreditation program to meet the Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88). The Joint Commission’s Board of Commissioners accepted the new and revised EPs in December (effective February 1, 2012) and in February (effective March 30, 2012). The revisions effective in February are already included in the E-dition®, and the revisions effective in March will be available in the E-dition in mid-April. The new and revised requirements will appear in the 2012 Update 1 to the Comprehensive Accreditation Manual for Laboratory and Point-of-Care Testing, scheduled for publication in spring 2012. Any further changes to Joint Commission requirements will be provided in future issues of Joint Commission Online and Perspectives. The box below displays the new and revised requirements; new text is underlined and deleted text is shown in strikethrough. For more information, contact Donna Gillespie, associate project director, Department of Standards and Survey Methods, at dgillespie@jointcommission.org or 630-792-5935.

**APPLICABLE TO LABORATORIES**

**Effective February 1, 2012, and March 30, 2012, as specified**

**Leadership (LD)**

**Effective February 1, 2012**

**Standard LD.04.05.09**
The laboratory director is responsible for developing, implementing, and maintaining policies and procedures that guide and support the provision of services.

**Element of Performance for LD.04.05.09**

C 2. The laboratory director, or designee, signs and dates new laboratory procedures or changes in laboratory procedures before they are implemented. (See also DC.02.01.01, EP 1)

**Quality System Assessment for Nonwaived Testing (QSA)**

**Effective February 1, 2012**

**Standard QSA.02.01.01**
The laboratory verifies tests, methods, and instruments in order to establish quality control procedures.

**Note:** This standard also applies to instruments on loan when the original instrument is under repair.

**Element of Performance for QSA.02.01.01**

A 2. © When adding or replacing a modified test, method, or instrument, the laboratory establishes written performance specifications that include the following:

- Accuracy
- Precision
- Reportable range
- Analytical sensitivity
- Analytical specificity, including interfering substances

**Effective March 30, 2012**

**Standard QSA.02.02.01**
The laboratory performs calibration and recalibration.

**Element of Performance for QSA.02.02.01**

A 6. © The laboratory has a written procedure for corrective action when calibration or control results fail to meet the laboratory’s criteria for acceptability. The corrective action is documented.

*Continued on page 4*
Effective February 1, 2012

Standard QSA.05.09.01
The laboratory has policies and procedures for serologic and computer (if performed) compatibility testing of donor blood with recipient blood.

Element of Performance for QSA.05.09.01

A 2. Policies and procedures for compatibility testing include the following:
- A determination of recipient ABO Group and Rh type
- A serologic and computer (if performed) cross-match protocol
- An antibody screening protocol
- Actions to be taken in cases of positive antibody screens and direct antiglobulin tests
- Actions to be taken in cases of incompatible crossmatches
- A time frame during which a sample may be used for crossmatching before obtaining a new sample
- A time frame not to exceed three days for recipient serum or plasma samples if the recipient has been pregnant or transfused within the previous three months or if history is unknown or unavailable. The day the sample is drawn is day zero.

Note: The time frame does not exceed three days for recipient serum or plasma samples if the recipient has been pregnant or transfused within the previous three months or if history is unknown or unavailable. The day the sample is drawn is day zero.

Effective February 1, 2012

Standard QSA.08.03.01
The cytology technical supervisor uses quality improvement processes to measure, assess, and improve the cytology service.

Element of Performance for QSA.08.03.01

A 5. The laboratory reviews For all gynecological slides with current high-grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasm, the laboratory reviews with all normal or negative gynecological specimens received within the previous five years, if available to the laboratory (on site or in storage), and compares the results of the review for discrepancies, documents discrepancies, and issues a corrected report for any discrepancies that would affect patient care.

Effective February 1, 2012, and March 30, 2012*

*The revisions shown in gray shaded text are effective March 30, 2012.

Standard QSA.08.04.01
The laboratory establishes workload limits for staff who perform primary cytology screening.

Elements of Performance for QSA.08.04.01

A 5. For individuals who perform primary screening, the maximum total number of cytology slides staff may screen is as follows:
- For gynecological specimens:
  - 100 slides (manual screening)
  - 100 “full” slides (manual screening)
  - 200 “half” slides (manual screening: one half of the slide or less)
  - A combination of full and half slides (based on prorated time, not to exceed the preceding limits)
- For both gynecological and nongynecological specimens:
  - As specified by the manufacturer for automated or semiautomated screening devices

For gynecological specimens screened by automated or semiautomated screening devices, workload limits must comply with those specified by the manufacturer and as approved by the U.S. Food and Drug Administration (FDA).

Note 1: For manual screening, liquid-based gynecologic preparations cannot be counted as a half slide. All gynecological slide preparations (liquid-based or conventional) are counted as one full slide.

Note 2: The workload limit for staff reading slides requiring 100% manual review may not exceed 100 slides, as a result of automated or semiautomated analysis or in the routine workload. When performing evaluations using automated and semiautomated screening devices, the laboratory conforms to current manufacturer’s instructions.

Note 3: Nongynecological slide preparations made using liquid-based slide preparatory techniques that result in cell dispersion over one half or less of the total available slide may be counted as one half slide. All gynecological slide preparations (liquid-based or conventional) are counted as one full slide.
New and Revised Lab Requirements (continued)

Note 4: The 100-slide limit includes previously unevaluated gynecological slides, and nongynecological slides, previously unevaluated slides, 10% rescreen slides, and review slides. The 100-slide limit does not include previously examined negative, reactive, atypical, premalignant, or malignant gynecological cases; previously examined nongynecological cytology preparations; or tissue pathology slides examined by a technical supervisor. Technical supervisors who perform primary screening are not required to include tissue pathology slides and previously examined cytology slides (gynecologic and nongynecologic) in the 100-slide workload limit.

Effective February 1, 2012

A 7. The laboratory maintains records maintained for each staff member of the total number of cytology slides examined, regardless of the site or laboratory, and the number of hours spent examining slides for each 24-hour period.

Effective February 1, 2012

Standard QSA.08.05.01
Cytology slide staining provides acceptable quality.

Element of Performance for QSA.08.05.01
A 2. All gynecological smear specimens are stained using a Papanicolaou, or modified Papanicolaou, or another approved alternative staining method.

Effective February 1, 2012

Standard QSA.08.06.01
The cytology quality assurance system includes review of a random sample of negative gynecological slides.

Element of Performance for QSA.08.06.01
A 4. Records of the review of a random sample of negative gynecological slides are available and include initial examinations and rescreening results. The results are documented.