The Joint Commission has approved the following revisions for prepublication. While revised requirements are published in the semiannual updates to the print manuals (as well as in the online E-dition®), accredited organizations and paid subscribers can also view them in the monthly periodical The Joint Commission Perspectives®. To begin your subscription, call 800-746-6578 or visit http://www.jcrinc.com.

Standards Revisions Related to Routine Maintenance

**STANDARDS REVISIONS RELATED TO ROUTINE MAINTENANCE**

**APPLICABLE TO LABORATORIES**

**Effective July 1, 2017**

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

**Standard QSA.02.03.01**
The laboratory performs calibration verification.

**Element of Performance for QSA.02.03.01**
3. Calibration verification is performed every six months.  
   **Note 1:** Semiannual calibration verification is not required when the laboratory performs calibration at least once every six months using three or more levels of calibration materials that include a low, mid, and high value.  
   **Note 2:** For automated cell counters, calibration verification requirements are met if the laboratory follows manufacturer’s instructions for instrument operation and the laboratory tests two levels of quality control materials each day of patient testing, provided the laboratory’s quality control criteria are met.  
   **Note 3:** Calibration verification is not required on instruments that are manufacturer-calibrated and/or tests that are considered non-quantitative. This exception only applies to those instruments that cannot be calibrated after implementation.

**Standard QSA.02.04.01**
The laboratory develops and implements an individualized quality control plan (IQCP) in an eligible specialty or subspecialty.

**Elements of Performance for QSA.02.04.01**
1. **Laboratories that develop and implement an individualized quality control plan (IQCP) include the following:** A complete IQCP that consists of the following three parts that the laboratory director signs and dates prior to implementation:  
   • Risk assessment  
   • Quality control plan  
   • Quality assessment

2. **Laboratories that develop and implement an individualized quality control plan (IQCP) include the following:** A risk assessment that is established by the laboratory in its own environment by its own testing personnel.  
   **Note:** The risk assessment may include test, method, or instrument verification data; performance specifications; or historical quality control data. Published or manufacturer data may also be included, but cannot be the only data source for the risk assessment.

3. **Laboratories that develop and implement an individualized quality control plan (IQCP) include the following:** A risk assessment that contains an evaluation of the following five components:  
   • Specimen  
   • Environment  
   • Reagent  
   • Test system  
   • Testing personnel

Key: ◆ indicates that documentation is required; ◆ indicates an identified risk area
4.  Laboratories that develop and implement an individualized quality control plan (IQCP) include the following: A risk assessment that encompasses the following three phases of the entire testing process:
   - Preanalytic
   - Analytic
   - Postanalytic

   Note: The risk assessment identifies the sources of potential failures and errors for a testing process, and evaluates the frequency and impact of those failures and sources of error.

5.  Laboratories that develop and implement an individualized quality control plan (IQCP) include the following: A risk assessment that includes the manufacturer’s instructions or other information needed to assess risk in all three phases of the testing process.

   Note: The risk assessment includes function and maintenance checks as required by, and not less than, manufacturers’ instructions.

6.  Laboratories that develop and implement an individualized quality control plan (IQCP) include the following: A quality control plan for devices at each location throughout a facility.

7.  Laboratories that develop and implement an individualized quality control plan (IQCP) include the following: A quality control plan (or changes in the plan) that the laboratory director signs and dates before implementation. (See also LD.04.05.09, EP 2)

8.  Laboratories that develop and implement an individualized quality control plan (IQCP) include the following: A quality assessment that includes documentation of corrective action and preventive action to monitor ongoing effectiveness.

Standard QSA.02.10.01
The laboratory performs quality control testing to monitor the accuracy and precision of the analytic process.

Note: This standard is considered in combination with the specialty and subspecialty requirements found in this chapter (for example, blood gas testing requires three levels of quality control materials each day of patient testing that the combination of controls and calibrators used each day of testing be rotated to check normal, alkalosis, and acidosis levels).

Element of Performance for QSA.02.10.01
11. If quality control materials are not available, the laboratory performs alternative quality control testing. The alternative quality control results are documented.

   Note: Alternative quality control testing includes split sampling for testing by another method or in another laboratory or previously tested patient specimens tested in duplicate. This element of performance does not apply to Standard QSA.02.04.01 regarding the validation of electronic and internal monitoring systems.

Standard QSA.04.01.01
The laboratory tests chemical and biological solutions, reagents, and antisera used in bacteriology, mycobacteriology, and mycology for reactivity and deterioration.

Element of Performance for QSA.04.01.01
6. The laboratory performs quality controls each time a new batch, shipment, and lot number are prepared or opened and every six months thereafter or at a frequency consistent with laboratory policy or manufacturer’s instructions, if more stringent, for the following:
   - Bacitracin
   - Catalase
   - Coagulase plasma
   - The Cefinase brand method
   - Germ tube
   - ONPG
   - Optochin
   - Oxidase
   - Spot indole
   - X, V, and XV factor discs or strips
   - Yeast morphology media

   The quality control results are documented.

   Note: If the manufacturer’s quality control recommendations are absent or less stringent than the requirements outlined in Standard QSA.02.10.01, the laboratory develops an individualized quality control plan (IQCP) or meets the requirements in Standard QSA.02.10.01.
Standard QSA.04.04.01
The laboratory tests each type of microbiological culture media with selected organisms to confirm the required growth characteristics.*

*One source to determine specific organism recommendations is the current Quality Control for Commercially Prepared Microbiological Culture Media (Clinical and Laboratory Standards Institute (CLSI) M22).

Elements of Performance for QSA.04.04.01
3. Either the laboratory or the preparer performs quality control testing on new batches, lot numbers, and shipments of microbiological culture media, including sterility testing, using recommended organisms before or concurrently with the use of new batches of media. The quality control results are documented.

Note: If the manufacturer’s quality control recommendations are absent or less stringent than the requirements outlined in Standard QSA.02.10.01, the laboratory develops an individualized quality control plan (IQCP) or meets the requirements in Standard QSA.02.10.01.

5. The laboratory performs quality control testing on each batch, lot number, and shipment of specialized microbiological culture media with a relatively high failure rate for identifying fastidious organisms. The quality control results are documented.

Note: Additional practice guidance on transfusion-related activities can be found in current AABB standards.

Standard QSA.05.06.01
The laboratory conducts reactivity testing on the potency and reliability of reagents used for ABO grouping, Rh typing, antibody detection, and compatibility determinations.

Element of Performance for QSA.05.06.01
2. Each day the procedure is performed, and when a new lot of reagents is first used, the laboratory tests each opened vial at least one vial from each lot number of antisera, reactive cells, and reagents for reactivity. The reactivity results are documented.

Note: This testing includes positive and negative reactivity when recommended by the manufacturer.

Standard QSA.05.17.01
The laboratory has policies and procedures for transfusion-related activities.

Element of Performance for QSA.05.17.01
2. Policies and procedures for transfusion-related activities address the following:

- Positive identification of the blood recipient and the blood container, including matching the recipient information to the blood or blood component being transfused
- Use of filters, warming devices, and cell salvage processes, including the transfusion service director’s responsibilities for these activities
- Special or urgent situations (for example, life-threatening emergencies)

Note: Additional practice guidance on transfusion-related activities can be found in current AABB standards.

Standard QSA.06.02.01
The laboratory verifies the operation of each blood gas testing instrument through the use of quality control materials.

Element of Performance for QSA.06.02.01
1. The laboratory tests at least three different levels of quality control materials (acid, normal, alkalosis) for blood gas testing each day the procedure is performed. The combination of controls and calibrators used each day of testing are rotated to check normal, alkalosis, and acidosis levels. The quality control results are documented.

Standard QSA.07.01.01
The laboratory follows an approved clinical guideline * when performing urine tests on specimens that meet acceptability criteria.

* Additional information can be found in the current edition of Clinical and Laboratory Standards Institute (CLSI) document GP16-A (Urinalysis).

Elements of Performance for QSA.07.01.01
2. The laboratory establishes and follows a defined system for handling, testing, and reporting urine specimens that exceed stability requirements (for example, room temperature urine more than two hours old and refrigerated urine more than four hours old).

3. The laboratory establishes guidelines and policies to test pediatric urine specimens for reducing substances.
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
3. The cytology workload limit is based on the each staff member’s performance using evaluations of the following:
   - Review of 10% of the cases interpreted as negative (See also QSA.08.06.01, EP 2)
   - Comparison of the primary screener’s initial cytologic interpretation with the pathologist’s final interpretation (See also QSA.08.07.01, EP 2)
   - Other measures as established by the cytology technical supervisor

Note 1: Staff members include individuals who perform primary screening and individuals who perform quality control re-examinations.

Note 2: Individuals that qualify under CFR §493.1449(k) are not required to perform the 10% rescreen of negative cases on their own cases. This requirement applies exclusively to the cytology general supervisor and cytotechnologist.

5. For individuals who perform primary screening, the maximum total number of cytology slides staff may screen is 100 slides (or full slide equivalents) per 24-hour period for either gynecologic or nongynecologic specimens or both.

For gynecologic specimens screened by automated or semiautomated screening devices, workload limits must comply with those specified by the manufacturer 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 gynecologic 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: Nongynecologic 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.

Note 4: The 100-slide limit includes previously unevaluated gynecologic slides and nongynecologic slides, 10% rescreen slides, and review slides. Cytology 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.

Note 5: The 100-slide limit does not include previously examined negative, reactive, atypical, premalignant, or malignant gynecologic cases; previously examined nongynecologic cytology preparations; slides prepared solely for determination of specimen adequacy; or tissue pathology slides examined by a cytology technical supervisor.

6. The maximum number of cytology slides is examined in no less than an eight-hour workday.

Note 1: For the purposes of establishing workload limits for staff examining slides by nonautomated microscopic technique on other than an eight-hour workday basis (including full-time employees with duties other than slide examination and part-time employees), a period of eight hours must be used to prorate the number of slides that may be examined. Use the following formula: (number of hours examining slides x 100) ÷ 8 = maximum slide volume to be examined.

Note 2: For both nonautomated microscopic techniques and automated/semiautomated microscopic techniques, laboratories must consider the time spent reading each slide to achieve consistent quality results without exceeding the maximum workload requirements. For information on how laboratorians can safely calculate workload for semi-automated gynecologic cytology screening devices approved by the US Food and Drug Administration (FDA), refer to http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TipsandArticlesonDeviceSafety/ucm220292.htm.

Standard QSA.13.04.01
Surgical specimens sent to the laboratory are examined by or under the supervision of a qualified individual.

Elements of Performance for QSA.13.04.01
4. When a nonpathologist performs gross analysis under the supervision of a qualified pathologist: The individual’s work is reviewed by a qualified pathologist. The review is documented.
5. 4. When a nonpathologist performs gross analysis under the supervision of a qualified pathologist: The individual’s work is reviewed by a technical supervisor or qualified pathologist within 24 hours. The review is documented.

6. 5. An individual qualified * in anatomic pathology evaluates each microscopic section.


7. 6. For Mohs testing, an individual qualified * in anatomic pathology or a qualified dermatologist evaluates each microscopic section.


8. 7. The diagnosis for each surgical specimen is made by or under the supervision of a qualified * individual.


9. 8. The laboratory uses terminology for diagnoses from a nationally recognized, professionally accepted disease nomenclature (for example, the Systematized Nomenclature of Medicine-Clinical Terms [SNOMED-CT]).

10. 9. Cancer pathology reports use a synoptic format.

    * Additional information can be found in Cancer Program Standards 2012: Ensuring Patient-Centered Care by the Commission on Cancer of the American College of Surgeons at http://www.facs.org/cancer/cooc/programstandards2012.pdf.

Standard QSA.13.06.01
The equipment, methods, and stains used in producing microscopic slides provide tissue sections that facilitate a diagnosis.

Element of Performance for QSA.13.06.01
1. A pathologist qualified * in anatomic pathology assesses the staining quality (for example, equipment, methods, stains) of microscopic tissue sections to determine the stain’s ability to facilitate a diagnosis. The staining quality assessments are documented.