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](http://www.jcrinc.com).

## New and Revised Standards and Elements of Performance (EPs)

### Applicable to Laboratories

**Effective July 1, 2015**

#### Document and Process Control (DC)

**Standard DC.01.02.01**
The laboratory performs testing based on written laboratory test orders.

**Elements of Performance for DC.01.02.01**

- **C 8.** Laboratory test orders for interpretation of Pap smears tests include the following: ⚫
  - The date of the woman’s last menstrual period
  - Information on previous abnormal reports, treatments, or biopsies

- **A 11.** Clinical standing orders, order sets, and protocols are dated, timed, authenticated, and included in the patient’s clinical record. ⚫

**Standard DC.02.04.01**
The laboratory retains records as required by law and regulation.

**Elements of Performance for DC.02.04.01**

- **A 2.** The laboratory retains immunohematology records, including blood and blood component records and transfusion records, for at least 10 years after the records of processing are completed or 6 months after the latest expiration date for the individual product, whichever is the later date, and histocompatibility records for at least 5 years or longer if required by law and regulation.

  **Note:** For immunohematology: When there is no expiration date for the blood or blood component, immunohematology records shall be retained indefinitely.

- **A 3.** The laboratory retains histocompatibility records for at least five years, or longer if required by law and regulation.

- **A 4.** The laboratory retains test orders for at least two years, or longer if required by law and regulation.

  **Note:** This includes the patient’s clinical record, if it is used as the test order.

- **A 5.** The testing laboratory retains instrument printouts for at least two years, or longer if required by law and regulation.

  **Note:** Retained records may be paper or electronic. Electronic systems must be able to retrieve all information printed on the original hard copy generated at the time of testing in order to be considered satisfactory for compliance.

- **C 6.** The testing laboratory retains an original test report or an exact copy, including preliminary, final, corrected, and reference laboratory reports, for the following periods: ⚫
  - At least 5 years for histocompatibility reports
  - At least 10 years after the records of processing are

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**Key:**
- **A** indicates scoring category A;
- **C** indicates scoring category C;
- ⚫ indicates that documentation is required;
- ⚫ indicates Measure of Success is needed;
- ⚫ indicates an Immediate Threat to Health or Safety;
- ⚫ indicates situational decision rules apply;
- ⚫ indicates direct impact requirements apply;
- ⚫ indicates an identified risk area.
completed or 6 months after the latest expiration date for the individual product, whichever is the later date for immunohematology reports

- At least 10 years for histopathology and cytology reports
- At least 2 years for all other reports

**Note 1:** The exact copy includes the name and address of the laboratory performing the test. The copy may be on paper or maintained in a computer system, microfilm, or microfiche record. A manual log containing duplicate information is also acceptable. For tests requiring an authorized signature or containing individual identifiers, the copy includes the signature or individual identifiers.

**Note 2:** The referring laboratory may permit each testing laboratory to send the test result directly to the authorized person who initially ordered the test. The referring laboratory must retain or be able to produce an exact copy of each testing laboratory’s test report.

**Note 3:** For immunohematology: When there is no expiration date, records shall be retained indefinitely.

**Standard HR.01.06.01**
Staff are competent to perform their responsibilities.

**Elements of Performance for HR.01.06.01**

**C 5.** Staff competence for nontechnical duties (for example, phlebotomy or histology specimen processing) is initially assessed and documented as part of orientation. [ ]

**C 6.** Staff competence for nontechnical duties (for example, phlebotomy or histology specimen processing) is assessed and documented once every two years, or more frequently as required by laboratory policy or in accordance with law and regulation. [ ]

**A 15.** The laboratory takes action when a staff member’s competence does not meet expectations. [ ]

**Standard HR.01.07.01**
The laboratory evaluates staff performance.

**Elements of Performance for HR.01.07.01**

**C 1.** The laboratory evaluates staff based on performance expectations that reflect their job responsibilities. [ ]

**C 2.** The laboratory evaluates staff performance once every two years, or more frequently as required by laboratory policy or in accordance with law and regulation. This evaluation is documented. [ ]

**C 5.** When an employee brings a nonemployee individual into the laboratory to provide care, treatment, and services (for example, when a pathologist brings a pathology assistant into the laboratory to assist with histology specimen processing), the laboratory reviews the individual’s competencies and performance at the same frequency as individuals employed by the hospital. [ ]

**Note:** This review can be accomplished either through the laboratory’s regular process or with the employee who brought staff into the hospital.

**Standard EC.02.04.01**
The laboratory manages laboratory equipment risks.

**Element of Performance for EC.02.04.01**

**A 4.** The laboratory identifies, in writing, frequencies for inspecting, testing, and maintaining laboratory equipment on the inventory based on criteria such as manufacturers’ recommendations, risk levels, or current laboratory experience. (See also EC.02.04.03, EP 12)

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

**Standard QSA.01.03.01**
The laboratory has a process for handling and testing proficiency testing samples.

**Element of Performance for QSA.01.03.01**

**A 7.** The laboratory staff who performed the proficiency testing and along with the laboratory director or technical supervisor sign attestations documenting that proficiency
testing samples were tested in the same manner as patient specimens.

**Note:** The laboratory director may delegate this responsibility in writing to a technical consultant meeting the qualifications of 42 CFR 493.1409 (for moderate-complexity testing) or technical supervisor meeting the qualifications of 42 CFR 493.1447 (for high-complexity testing).

**Standard QSA.01.05.01**
The laboratory verifies evaluates the accuracy and reliability of results obtained for both nonregulated analytes that are not included in a formal proficiency testing program and for those regulated analytes for which compatible proficiency testing samples are not available.

**Element of Performance for QSA.01.05.01**

**A 1. ** The laboratory has written policies and procedures that include acceptability criteria to verify evaluate the accuracy and reliability of results obtained for both nonregulated analytes that are not included in a formal proficiency testing program and for those regulated analytes for which compatible proficiency testing samples are not available.

**Note:** Acceptable methods of evaluating accuracy and reliability verification for nonregulated analytes include the following:

- The laboratory uses proficiency testing.
- Every six months, the laboratory sends five specimens to a Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88)–certified reference laboratory for comparison with its own results.
- Interlaboratory quality control results are used to verify evaluate the continuing accuracy and reliability of the tests not included in the proficiency testing program (for example, peer comparisons).
- Throughout the year, the technical supervisor of the laboratory retests a random sample of microscopic tests from each staff member who performs such testing.
- Duplicate testing is performed by two different individuals who perform such tests as reticulocyte counts, urine sediments, and crystal identification.

**Standard QSA.02.04.01**
The laboratory evaluates instrument-based testing with electronic or internal systems prior to using them for routine quality control.

**Element of Performance for QSA.02.04.01**

**C 5. ** The laboratory performs at least two levels of electronic or internal quality controls at the same frequency as required in the specialty and subspecialty sections of this manual, or more frequently if recommended by the manufacturer or defined by laboratory procedure. The electronic or internal quality control results are documented.

**Note:** The minimum frequency for performing two levels of electronic or internal quality controls can be found at the following specialties/subspecialties:
- Routine chemistry (refer to QSA.06.01.01)
- Blood gases (refer to QSA.06.02.01)
- Hematology (refer to QSA.11.01.01)
- Coagulation (refer to QSA.11.02.01)

**Standard QSA.02.05.01**
The laboratory evaluates noninstrument-based testing with internal quality control systems prior to using them for routine quality control.

**Element of Performance for QSA.02.05.01**

**A 3. ** If the laboratory uses noninstrument-based testing with internal positive and negative quality controls as the daily quality control, it performs external quality controls at its defined frequencies. The internal and external quality control results are documented.

**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).
Elements of Performance for QSA.02.10.01

A 14. The laboratory performs quality control testing before resuming patient testing when the following occurs:

- A complete change of reagents for a procedure is introduced, unless it is demonstrated that changing reagent lot numbers does not affect the range used to report patient test results, and quality control results are not adversely affected by reagent lot number changes.
- Major preventive maintenance or replacement of critical parts influences test performance.
- After calibration in order to verify that the calibration protocol was successful.

The quality control results are documented.

A 15. For quantitative tests, the laboratory tests quality control materials across the clinically significant values of the reportable test results during a 24-hour period.

A 16. A qualified* individual assesses the staining quality of stains to determine their ability to correctly stain typical cellular characteristics and facilitate an accurate patient diagnosis. The assessment is documented.


Standard QSA.05.10.01

The laboratory has written policies and procedures for identifying donor blood and recipient blood.

Element of Performance for QSA.05.10.01

A 2. Policies and procedures for identifying donor blood and recipient blood include the following:

- The blood recipient’s full name
- An additional patient identifier (for example, a clinical record number, health care account number)
- An identification system for tracking patients whose identities are unknown (because they are unresponsive, noncommunicative, or incoherent) until the patient’s identification has been confirmed
- A protocol for labeling of donor blood and recipient blood, including securely affixing the label to the units after crossmatching and retention of the label on the units until the transfusion is completed

Standard QSA.05.11.01

The laboratory has written policies and procedures for emergent release of blood.

Element of Performance for QSA.05.11.01

A 3. The laboratory completes tests on recipient blood, including ABO group, Rh type, screening for unexpected antibodies, antibody identification, and a major crossmatch between donor red cells and recipient serum as soon as possible. Abnormal results that may affect the patient’s safety are reported immediately by staff to the medical director and the clinician responsible for the patient’s care.

Note: When the screen and transfusion history for detection of unexpected antibodies is negative, the antiglobulin phase of testing is optional. Testing to detect ABO incompatibility (serologic or computer crossmatch) is required. (For more information, refer to Standard QSA.05.09.01.)

Standard QSA.05.14.01

The laboratory has written policies and procedures for modifying blood and blood components.

Elements of Performance for QSA.05.14.01

A 1. The policies and procedures for modification of blood and blood components follow good manufacturing practice guidelines, and address the following:

- Maintaining sterility
- Using U.S. Food and Drug Administration (FDA) approved additives
- Pooling of multiple blood products
- Thawing procedures
- Storing and processing
- Assigning expiration date and time
- Labeling requirements
- Tracing blood or blood component from source to final disposition
- Documenting reports of unacceptable products and the corrective action and disposition taken
- Varying from established procedures is reviewed and affected products are approved prior to administration

* The AABB Technical Manual is a resource for component preparation procedures.

A 9. If an intact seal a closed system is not maintained during aliquot preparation of blood components, the expiration date of the product is changed to reflect that of an open system.

* For information on assigning expiration dates to blood components, refer to U.S. Food and Drug Administration (FDA) regulation 21 CFR 610.53.
Standard QSA.05.17.01
The laboratory has policies and procedures for transfusion-related activities.

Element of Performance for QSA.05.17.01
A 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
- Other transfusion steps
- 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)

Standard QSA.05.25.01
The laboratory, or designated department, monitors therapeutic phlebotomy, plasmapheresis, and apheresis procedures.

Element of Performance for QSA.05.25.01
A.7. The laboratory verifies each clinical chemistry test system through the use of quality control materials.

Standard QSA.06.01.01
The laboratory verifies each clinical chemistry test system.

Element of Performance for QSA.06.01.01
A.2. During a 24-hour period, the laboratory tests quality control materials used in clinical chemistry across a range of clinically significant values of reportable test results.

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 3. The cytology workload limit is based on the 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 staff’s primary screener’s initial cytologic interpretation with the technical supervisor’s confirmation of patient smears
- Other measures as established by the cytology technical supervisor

A 4. Workload requirements apply to all cytotechnologists, pathologists, and fifth-year pathology residents who perform primary cytology screening in the final year of training leading to board certification.

A 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 gynecological or nongynecological specimens or both.

For gynecological 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 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.

**Note 4:** The 100-slide limit includes previously unevaluated gynecological slides and nongynecological 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 gynecological cases; previously examined nongynecological cytology preparations; slides prepared for determination of specimen adequacy; or tissue pathology slides examined by a cytology technical supervisor.

### Standard QSA.08.05.01
Cytology slide staining provides acceptable quality.

#### Element of Performance for QSA.08.05.01

A.6. A CLIA-qualified cytotechnologist * assesses the staining quality of gynecologic and nongynecologic stains to determine the stain’s ability to facilitate a diagnosis.


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

#### Elements of Performance for QSA.08.06.01

A.1. A qualified * individual reviews a random sample of negative gynecological slides before reporting patient results. The review is documented.


A.2. The review of a minimum of 10% of negative gynecological slides includes the following:

- A random sample of 10% of all gynecological cases read by each primary screener and interpreted to be negative for epithelial cell abnormalities and malignant or premalignant conditions
- Low-risk and high-risk patients
- Patients identified as having a higher-than-average probability for developing cervical cancer
- Slides from each primary screener

(See also QSA.08.04.01, EP 3)

**Note 1:** During the initial screening process, primary screeners are not made aware of which slides will be reexamined.

**Note 2:** The 10% review of negative cases is not required for a one-person laboratory consisting of a cytology technical supervisor or for a laboratory that only employs pathologists qualified as cytology technical supervisors. However, all laboratories must establish and follow a program to detect errors.

### Standard QSA.08.06.03
The cytology laboratory has a process to correlate cytologic interpretations with the corresponding histologic finding.

#### Elements of Performance for QSA.08.06.03

A.1. The laboratory has written policies and procedures to detect and resolve disparities between nongynecologic cytological and histological findings.

A.2. The laboratory follows its policies and procedures to detect and resolve disparities between nongynecologic cytological and histological findings. The disparities and their resolutions are documented.

### Standard QSA.08.07.01
The cytology technical supervisor reviews cytology slides.

#### Element of Performance for QSA.08.07.01

A.3. All gynecologic and nongynecologic test reports reviewed by a cytology technical supervisor have a written or secured electronic signature.

### Standard QSA.11.01.01
On each day of patient testing, the laboratory verifies each hematology procedure and test parameter against known standards or controls within the range of clinically significant values.

#### Element of Performance for QSA.11.01.01

A.3. For each automated hematology test system, the controls used during a 24-hour period test a range of clinically significant values of reportable test results.

### Transplant Safety (TS)

#### Standard TS.03.01.01
The organization uses standardized procedures for managing tissues.
Element of Performance for TS.03.01.01

A 11. The organization complies with state and/or federal regulations when it acts as a tissue supplier. *

Note 1: The U.S. Food and Drug Administration (FDA) considers the routine policy or practice of shipping tissue to another facility as distribution which requires FDA registration. Returning unused tissue back to the tissue supplier is not considered distribution and does not require FDA registration.

Note 2: Embryos, oocytes, and semen are regulated by the FDA as human cells, tissues, and cellular and tissue-based products (HCT/Ps). Organizations that manufacture HCT/Ps (recovery, processing, storage, labeling, packaging, or distribution) require FDA registration. †

* Please refer to the following website:

† Please refer to 21 CFR 1271 for more information.