activates or responders can, if needed, move occupants to an adjacent compartment.

This EP addresses the fire-rated barriers that create the compartments. These barriers are designed to protect the building occupants for a predetermined amount of time. For example, a fire-rated barrier is designed to keep fire on one side of the barrier for a certain time frame. The barrier needs to be continuous, with no gaps or unprotected openings. The barrier extends from the outside wall to the other outside wall, and from the floor to the underside of the floor (or roof) above.

However, this EP allows for real-world conditions in which the barrier may not be obvious. The key is that in all situations there must not be any gaps in protection. The EP uses the term *interstitial space*, which is a space above the ceiling not considered as another story, that typically has utility system distribution. If the fire barrier terminates at the bottom of the interstitial space, the separating member must maintain—and not reduce—the rating of the affected barrier.

**Fire Rating for Common Walls**

**EP 4** Common walls are fire rated for two hours that are within buildings (occupancy separation), between buildings, or the building has a common wall with a nonconforming building. (For full text, refer to NFPA 101-2012: 43.8; 18/19.1.1.4; 18/19.1.3.3; 18/19.1.3.4; 8.2.2.2)

If a health care occupancy shares a wall with a business occupancy, that wall is referred to as a common wall and needs to have a 2-hour fire-resistance-rated barrier (serving as a fire barrier). The requirement is the same for a common wall within a nonconforming building. This prevents the lessor occupancy from diminishing the ability of the health care occupancy to protect its occupants. Segregating the health care occupancy from other occupancies is important. This has a definite and direct impact on patient safety. If problems with the common wall are discovered, correcting these must be treated as a high priority (including applying Interim Life Safety Measures). Examples of problems that could be identified during survey include unprotected penetrations or a “head-of-wall” joint that is improperly sealed or installed.

**Looking Ahead**

Properly designed buildings, with appropriate fire safety and protection features, allow health care occupants to be protected in case of fire or other emergencies. The next column will continue to explore Standard LS.02.01.10 by discussing specific circumstances that may affect these protective design features.

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**Joint Commission Enhances Laboratory Requirements**

**Revisions Maintain Alignment with CMS, Keep Pace with Field**

The Joint Commission recently announced several revisions to requirements for accredited laboratories. These revisions, which are effective July 1, 2017, accomplish two objectives: to maintain alignment with Centers for Medicare & Medicaid Services (CMS) Clinical Laboratory Improvement Amendments (CLIA), and to address the most up-to-date evidence-based clinical practices.

To better align with CLIA Interpretive Guidelines, The Joint Commission updated requirements in the Comprehensive Accreditation Manual for Laboratory and Point-of-Care Testing (CAMLAB) addressing the following areas:

- Blood gas quality control testing
- Calibration verification on instruments that are manufacturer calibrated and/or tests that are considered nonquantitative

- Implementation requirement related to an individualized quality control plan (IQCP)
- Staffing and workload requirements for cytology

In addition to maintaining alignment with government regulations, The Joint Commission keeps the Laboratory Accreditation Program current by regularly evaluating whether standards and elements of performance (EPs) are meeting the needs of its customers. Revisions resulting from this ongoing maintenance of requirements include the addition of a new standard on mass spectrometry technology and revisions to standards addressing molecular and genetic testing.

*Continued on page 8*
Mass Spectrometry Technology

Laboratories have increasingly adopted the use of mass spectrometry in various settings such as drug testing and therapeutic drug monitoring. Mass spectrometry is a continuously advancing analytical technique that has been widely used in clinical laboratories since the early 1900s. To address specific issues and challenges on the application of mass spectrometry in clinical laboratories, The Joint Commission has expanded its clinical chemistry requirements by adding specific quality control and testing requirements for mass spectrometry.

The new mass spectrometry standard includes eight elements of performance (EPs) designed to ensure that laboratory procedures provide accurate results. These EPs address the following:

- Use of quality control materials and calibrators
- Mass calibration and optimum performance
- Detection and evaluation of carryover
- Establishment of reportable range and limit of detection

Molecular Pathology and Genetic Testing

The Joint Commission also performed a gap analysis on its molecular and genetic testing standards. As a result of the gap analysis, additional standards were added to address the following:

- Prevention of sample degradation
- Nucleic acid extraction
- Turnaround time requirement
- Indication for genetic testing

The expanded and updated standards are shown in the boxes that begin below (new text is underlined and deleted text is shown with strikethrough) and are posted on The Joint Commission website at http://www.jointcommission.org/standards_information/prepublication_standards.aspx. The revisions will be published in the spring 2017 Edition for the CAMLAB (scheduled to release in May).

For more information, please contact Ron S. Quicho, MS, associate project director, Department of Standards and Survey Methods, at rquicho@jointcommission.org.

Reference


Note 3: Calibration verification is not required on instruments that are manufacturer calibrated and/or tests that are considered nonquantitative. This exception only applies to those instruments that cannot be calibrated after implementation.

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.

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:
Revisions to Maintain Alignment with CLIA ’88 (continued)

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. ② 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

**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.

4. ② 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 includes function and maintenance checks as required by, and not less than, manufacturers’ instructions.

5. ② 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. ② Laboratories that develop and implement an individualized quality control plan (IQCP) include the following:

A quality control plan for devices at each location

- Test system

7. ② Laboratories that develop and implement an individualized quality control plan (IQCP) include the following:

A quality control plan that includes documentation of corrective action and preventive action to monitor ongoing effectiveness.

**Standard QSA.02.06.01**

Each laboratory specialty and subspecialty has a quality control policy.

**Element of Performance for QSA.02.06.01**

6. Quality control limits and reportable ranges provide results with meaningful clinical applications.

**Note 1:** Package insert quality control limits may be too wide to meet the elements of performance (EPs) for this standard. Quality control limits are based at least in part on laboratory-specific data, except as indicated in the EPs for standard QSA.02.07.01.

**Note 2:** For manual tests that do not lend themselves to traditional commercial quality control methods, alternative procedural controls with established limits may be used to verify the results. For example, manual reticulocyte counts could be verified by a specified percentage agreement of the results from two slides.

**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. ② 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. ② 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

Continued on page 10
Revisions to Maintain Alignment with CLIA ’88 (continued)

- 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

1. 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.

2. 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.

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

### Standard QSA.05.06.01

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

#### Elements of Performance for QSA.05.06.01

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.

#### Elements of Performance for QSA.07.01.01

1. The laboratory establishes and follows a defined system for handling, testing, and reporting urine speci-
Revisions to Maintain Alignment with CLIA ’88 (continued)

mens 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 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 US 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 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 semiautomated gynecologic cytology screening devices approved by the US Food and Drug Administration (FDA), refer to http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TipsandArticle-sonDeviceSafety/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.

Continued on page 12
Revisions to Maintain Alignment with CLIA ’88 (continued)

5. - 8. 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. R

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


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


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


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]). R

40. - 8. 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/coo/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.


Standard DC.01.01.01
The laboratory establishes procedures for collecting specimens.

Element of Performance for DC.01.01.01
1. The laboratory has written procedures for collecting specimens that address the following:
   - Patient identification
   - Patient preparation
   - Specimen collection
   - Precautions for specimen collection, including preventing cross-contamination of primary samples and sample portions shared between testing centers
   - Specimen labeling, including the source, date, and when pertinent to the test being ordered, time of specimen collection and source of specimen, and other labeling information required by laboratory policy
   - Specimen receipt, processing (including maintaining cell and organism viability), storage, preservation, and transport
   - Specimen rejection criteria
   - Collection of reference laboratory specimens

Note: The laboratory may use a reference laboratory’s procedures—they need not be rewritten.

Standard DC.01.02.01
The laboratory performs testing based on written (paper or electronic) laboratory test orders.

Element of Performance for DC.01.02.01
4. Laboratory test orders. Orders for laboratory tests are legible.
Revisions Related to Clinical Chemistry and Toxicology (continued)

The laboratory report is complete and is in the patient’s clinical record.

**Element of Performance for DC.02.03.01**

9. The laboratory report includes the following information: The condition of unsatisfactory specimens, if applicable.

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

**Standard QSA.06.04.05**
The laboratory’s procedures for mass spectrometry provide for accurate results.

**Elements of Performance for QSA.06.04.05**

1. The laboratory has written quality control and testing procedures for mass spectrometry that address the following: The use of calibrators or quality control materials with each batch of patient samples prepared for analysis.

2. The laboratory has written quality control and testing procedures for mass spectrometry that address the following: Extraction and use of control materials that challenge each step of the testing process.

3. The laboratory has written quality control and testing procedures for mass spectrometry that address the following: Criteria and frequency for establishing mass calibration and optimum performance.

   **Note:** Some organizations refer to mass spectrometer optimum performance as being “in tune.” Additional information can be found in the current edition of Clinical and Laboratory Standards Institute (CLSI) document C62 (Liquid Chromatography–Mass Spectrometry Methods).

4. The laboratory has written quality control and testing procedures for mass spectrometry that address the following: The detection and evaluation of carryover.

5. The laboratory has written quality control and testing procedures for mass spectrometry that address the following: For quantitative tests, an established reportable range and limit of detection.

6. The laboratory has written quality control and testing procedures for mass spectrometry that address the following: Establishment and validation of identification criteria for the specific technique applied (for example, liquid chromatography–mass spectrometry versus gas chromatography–mass spectrometry).

   **Note:** Additional information can be found in the current edition of Clinical and Laboratory Standards Institute (CLSI) documents C62 (Liquid Chromatography–Mass Spectrometry Methods) and C43 (Gas Chromatography–Mass Spectrometry Confirmation of Drugs).

7. The laboratory has written quality control and testing procedures for mass spectrometry that address the following: Liquid chromatography–mass spectrometry includes evaluation, reduction, and monitoring of matrix effects and ion suppression.

   **Note:** Additional information can be found in the current edition of Clinical and Laboratory Standards Institute (CLSI) document C62 (Liquid Chromatography–Mass Spectrometry Methods).

8. The laboratory follows its procedures for mass spectrometry.

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**Official Publication of Joint Commission Requirements**

**Revisions to Address Molecular and Genetic Testing**

**Applicable to Laboratories**

**Effective July 1, 2017**

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

**Standard QSA.15.01.01**
The laboratory uses written policies and procedures for molecular testing.

**Elements of Performance for QSA.15.01.01**

2. The laboratory’s policies and procedures for molecular testing address the following: Appropriateness of testing.

   **Note:** For genetic testing, additional information might be required to select tests and to provide for accurate test interpretation and reporting of results (for example, a pedigree may be required to show genetic relationships).

4. The laboratory’s policies and procedures for molecular testing address the following: Prevention of sample degradation. (See also DC.01.01.01, EP 1)

4–5. The laboratory’s policies and procedures for molecular testing...
Revisions to Address Molecular and Genetic Testing (continued)

5-6. The laboratory’s policies and procedures for molecular testing address the following: The quality and quantity of nucleic acid required for a particular test.

6-7. The laboratory’s policies and procedures for molecular testing address the following: Investigation and corrective action for internal controls that fail to amplify.

7-8. The laboratory’s policies and procedures for molecular testing address the following: Competition between target and internal controls (for example, false negatives or the presence of a strong target signal with a negative internal control signal).

8-9. The laboratory’s policies and procedures for molecular testing address the following: Investigation of discrepant results between different methods.

9-10. The laboratory’s policies and procedures for molecular testing address the following: Reuse of patient specimens for quality control purposes.

10-11. The laboratory’s policies and procedures for molecular testing address the following: Confirmation of restriction endonuclease activity (for example, complete digestion, accurate fragment production).

11-12. The laboratory’s policies and procedures for molecular testing address the following: The criteria for analysis of autoradiographs, membranes, and electrophoretic gels (for example, the presence of a strong target signal, minimal background signal).

12-13. The laboratory’s policies and procedures for molecular testing address the following: Verification of patient nucleic acid integrity and labeling.

13. The laboratory’s policies and procedures for molecular testing address the following: Validation of the nucleic acid extraction and purification method, including elimination of inhibitory factors.

Note: Additional information can be found in the current edition of Clinical and Laboratory Standards Institute (CLSI) document MM19 (Establishing Molecular Testing in Clinical Laboratory Environments).

14-15. The laboratory follows its policies and procedures for molecular testing.

Standard QSA.16.01.01
The laboratory uses policies and procedures for molecular genetic testing.

Elements of Performance for QSA.16.01.01
3. The laboratory has written policies and procedures for molecular genetic testing that establish turnaround time requirements, as appropriate (for example, results of certain genetic screening tests require that the laboratory establishes an acceptable turnaround time for immediate diagnosis, so that the clinician can diagnose and provide a critical patient recommendation in a timely manner).

3-4. The laboratory follows its policies and procedures for molecular genetic testing.

Standard QSA.16.02.01
Molecular genetic testing reports include specific testing information.

Elements of Performance for QSA.16.02.01
1. The laboratory reports for molecular genetic testing include the following information: Indication for testing.

2. The laboratory reports for molecular genetic testing include the following information: List of mutant genes or alleles tested.

3. The laboratory reports for molecular genetic testing include the following information: Any recommendations for referral to a genetic counselor.

3-4. The laboratory reports for molecular genetic testing include the following information: Detection rate of the test.

4. The laboratory reports for molecular genetic testing include the following information: Standard nomenclature for genes and mutations.

5-6. The laboratory reports for molecular genetic testing include the following information: Clinical implications of any detected mutation(s).