**Accepted:** Revisions Related to IQCP Option for Clinical Laboratories

**Effective January 1, 2016,** The Joint Commission will implement a new voluntary quality control (QC) option for clinical laboratories. The Individualized Quality Control Plan (IQCP) will allow laboratories to customize QC policies and procedures based on a risk assessment of their health care setting, and it will be applicable to all specialties and subspecialties except pathology.

This new option is a result of the Centers for Medicare & Medicaid Services’ (CMS) January 2014 introduction of IQCP, which will replace the existing Equivalent Quality Control (EQC) after the education-and-transition period ends on December 31, 2015 (see March 2014 Perspectives, pages 5 and 6). In order for The Joint Commission to maintain its deeming authority, its standards and elements of performance (EPs) must meet or exceed CMS’s Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88) regulations.

Consequently, The Joint Commission has made the following revisions to the “Quality System Assessment for Nonwaived Testing” (QSA) chapter of the Comprehensive Accreditation Manual for Laboratory and Point-of-Care Testing (CAMLAB):

- Deletion of all EPs specific to EQC:
  - Standard QSA.02.04.01, EPs 1–8
  - Standard QSA.02.05.01, EPs 1–3
- Addition of a new standard and eight EPs (Standard QSA.02.04.01, EPs 1–8) that addresses the IQCP Interpretive Guidelines, including the following:
  - Components of an IQCP
  - Elements to include in a risk assessment and quality assessment
  - Development of a quality control plan
  - Review of the IQCP or changes prior to implementation by the laboratory director

As previously announced in Perspectives (see “Revised Laboratory Requirements: Immunohistochemistry and Microbiology” on pages 7 and 8 of the July issue), The Joint Commission also revised Standard QSA.04.01.01, EP 2 to reflect the January 9, 2015, revision to the CMS CLIA ’88 Interpretive Guidelines that removed all references to the Clinical and Laboratory Standards Institute (CLSI) and CLSI documents. With the deletion of the reference to the CLSI document on QC for Commercial Microbial Identification Systems; Approved Guideline (M50-A), laboratories are now required to either comply with all Joint Commission QC requirements or implement IQCP.

There are additional requirements that are eligible for IQCP located in the QSA chapter of the CAMLAB. A list of all IQCP-eligible requirements will be included in Appendix C: IQCP-Eligible Requirements, and laboratories will be able to filter and display only the IQCP-eligible requirements in the E-dition®.

IQCP is an optional quality control for clinical laboratories, and it may not be accepted in some states. As EQC will no longer be an acceptable option for QC compliance beginning January 1, 2016, Joint Commission–accredited laboratories will have the following QC options:

- Follow all Joint Commission quality control requirements as written.
- Implement IQCP as described in Standard QSA.02.04.01, EPs 1–8 and Appendix C: IQCP-Eligible Requirements. Laboratories that choose to implement IQCP are still required to follow all other non–IQCP-eligible Joint Commission accreditation requirements.
- With the removal of the streamlined QC option for microbiology, laboratories are required to either comply with all Joint Commission QC requirements or implement IQCP.

The following information about the IQCP model includes selected content from the March 2014 Perspectives.

The Individualized Quality Control Plan (IQCP) will allow laboratories to customize QC policies and procedures based on a risk assessment of their health care setting, and it will be applicable to all specialties and subspecialties except pathology.

**The IQCP Model**

The IQCP Interpretive Guidelines (available at http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-54.pdf) outline a risk assessment model for establishing the quality control frequency that will replace EQC. IQCP comprises the following three steps.

**Step 1: Risk Assessment.** The risk assessment is the identification and evaluation of potential failures and sources of errors in a testing process. To meet the requirements of IQCP, the risk assessment must cover all three phases of testing (pre-analytic, analytic, and post-analytic) and include the following five components:

1. Specimen
2. Environment
3. Reagent
4. Test System
5. Testing Personnel

The risk assessment needs to be completed per test system. Additionally, CMS states that “in laboratories with multiple, identical systems (same make and manufacturer), a single risk assessment may be performed. However, differences in testing personnel and environments where the test systems will be used must be taken into consideration. Due to these differences, you should determine if you need to perform a risk assessment for each individual location and/or device.”

For example, an i-STAT may be used in multiple locations and departments (for example, the emergency room, the intensive care unit, and respiratory therapy). In this situation, laboratories should determine if only one risk assessment is needed for all i-STATs or if varying factors (environment, different operators, and so on) exist pertaining to each i-STAT location that will require the laboratory to perform a risk assessment for each device location.

Resources for identifying potential errors include the manufacturer’s package inserts, training manuals, quality control data, proficiency testing data, quality assurance data, corrected reports, and internet searches. The laboratory’s specific testing data must be included in the risk assessment, thus ensuring the individualization of the risk assessment and IQCP. Laboratories may use any format they choose to document the risk assessment—as long as it includes all five components and all three phases of testing.

**Step 2: Quality Control Plan.** The quality control plan document describes the practices, resources, and procedures for controlling the quality of a particular test process and includes the number, type, frequency, and acceptability criteria of the quality control used to mitigate the risks. The document must provide for the immediate detection of errors that occur due to test system failure, adverse environmental conditions, and operator performance. In addition, the document must ensure that test results are accurate, reliable, and of adequate quality for patient care. One quality control plan is required for each location of a test system if the risk assessment identifies specific risks based on the location of the device. The laboratory may have one quality control plan that lists all of the locations of each device if the risk assessment confirms that each location has the same potential risks.

Using the i-STAT example in the previous paragraph, there may be one risk assessment for all i-STATs as one “test system”; in addition, there may either be three quality control plans specific to each location of the i-STAT or the laboratory may have one quality control plan that lists all of the locations of each device. As the quality control frequency may be different for each location based upon the specific risks identified, separate quality control plans per location may be necessary.

Laboratories may also develop one quality control plan for each potential error discovered during the risk assessment. The quality control plan must not be less stringent than the manufacturer’s instructions for testing quality controls. While the development and implementation of each quality control plan may be delegated (in writing) to a qualified member of personnel, all quality control plans must be reviewed, signed, and dated by the laboratory director listed on the CLIA certificate before implementation.

**Step 3: Quality Assurance.** Quality assurance is the feedback loop within which the quality control plan’s effectiveness can be continually monitored. Organizations may continue using their current quality assurance plans; however, the laboratory must investigate identified failures and adjust the quality control plan as necessary to prevent future failures. The laboratory must update the risk assessment with the new information, if necessary, and modify the quality control plan. As always, organizations should identify which patients could be affected by failure and then take corrective action.

**Eliminating EQC Procedures**

To prepare for the elimination of EQC, organizations should address the following questions.

**Where Is EQC Used in the Organization?** An organization should determine which instruments currently use EQC. Examples of instruments that commonly use EQC include, but are not limited to, moderate complexity kit testing, blood gas analyzers, Alere Triage Meter and Triage MeterPro, Abbott i-STAT, and Hologic Fetal Fibronectin.

**Which Quality Control Mechanism Should Be Used for Each Test?** For every test that is currently using EQC, an organization must decide whether it will follow CLIA quality control regulations or implement IQCP. If the organization decides to follow CLIA quality control regulations, its quality control procedures should be updated to reflect the regulations. If the organization decides to implement IQCP, it needs to complete the risk assessment per test system and the quality control plan per test system by location. In addition, the organization must ensure that there is adequate quality assurance in place for each quality control plan.

Additional background information about IQCP can be found at [http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads](http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads)
Official Publication of Joint Commission Requirements

IQCP-Related Revisions

Applicable to Laboratories

Effective January 1, 2016

Quality System Assessment for Nonwaived Testing (QSA)

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 7. The laboratory’s quality control procedure for each testing system or methodology includes the following:

- The range of quality control values used
- The frequency of quality control testing
- Adherence to the manufacturer’s recommendations
- The predicted reliability based on history
- The specialty and subspecialty requirements included in this chapter

Note: If the manufacturer’s quality control recommendations are absent or less stringent than the requirements outlined in Standard QSA.02.01.01, the laboratory develops an individualized quality control plan (IQCP) or meets the requirements in Standard QSA.02.10.01.

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

Rationale for QSA.02.04.01
Advancements in laboratory technology have led to test systems that often include alternative quality control monitoring systems, such as electronic simulators, internal controls, or procedural controls. These systems can monitor the entire analytical process or part of the analytic process. They may be used as the routine daily quality control when they have been properly validated and when external quality control is performed on a periodic basis. For test systems without internal monitoring systems, the frequency of external controls may not be reduced and traditional external quality control is required each day of patient testing.

Note: When using internal monitoring systems as the routine quality control, the laboratory still complies with other Joint Commission standards scored elsewhere in this manual, including, but not limited to, method validation, daily surveillance of results, ongoing competency assessment of the staff performing tests, ongoing instrument maintenance and testing, proficiency testing or other means of verifying accuracy of the method, performance improvement, and adequate oversight of the testing activity.

Elements of Performance for QSA.02.04.01
A 1. When the laboratory evaluates instrument-based testing with electronic or internal systems, the test being performed is a moderately complex test in routine chemistry or hematology.

A 2. For each test system, the laboratory evaluates the sources of error, including personnel, training, and competency, and determines whether the electronic or internal quality controls monitor the entire analytical process or a portion of the analytical process. The results are documented.

Note: This information may be included in the manufacturer’s package insert or requested from the manufacturer via written documentation.

A 3. The laboratory conducts an evaluation of the electronic or internal quality controls by testing external quality controls in parallel with the electronic or internal quality controls for the following:

- 10 consecutive days of testing for test systems that monitor the entire analytical process
- 30 consecutive days of testing for test systems that monitor a portion of the analytical process

The evaluation of the electronic or internal quality controls is documented.
IQCP-Related Revisions (continued)

**Note:** Consecutive days include only those days when the laboratory actually performs or would perform the test.

A.4. Through its evaluation and data analysis activities, the laboratory defines the variety and frequency of external quality control sufficient to prevent clinically significant errors in patient test results.

**Note 1:** Unless the manufacturer requires more frequent testing, the frequency of testing external quality controls may be reduced from daily to at least the following:

- Once monthly for test systems that monitor the entire analytical process
- Once weekly for test systems that monitor a portion of the analytical process

**Note 2:** For a test system without internal quality controls, frequency of external quality controls may not be reduced.

G.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)
- Coagulation (refer to QSA.11.02.01)

A.6. © The laboratory performs external quality controls at the following frequencies:

- As defined by the evaluation (either weekly or monthly)
- According to the manufacturer’s recommendations
- With each new lot number, shipment, or package of reagents

The external quality control results are documented.

A.7. © The laboratory performs external quality controls at the number of levels specified by the specialty and subspecialty requirements (for example, blood gases require three levels of quality control). The external quality control results are documented.

A.8. © The laboratory conducts an investigation, identifies the root causes, performs corrective action, and restarts the evaluation of the electronic or internal quality controls if any of the following occur:

- Proficiency testing is unsatisfactory
- Analytic system quality assessment is unacceptable
- Competency assessment is unacceptable

A.9. © The laboratory repeats the quality control and meets the criteria for acceptability before reporting patient results.

- There are two consecutive unacceptable quality control results (internal or external) for the same level or measurement either during the evaluation process or after the laboratory has reduced the frequency of testing external quality control materials.
- The laboratory repeats the quality control and meets the criteria for acceptability before reporting patient results.

The corrective action is documented. (See also QSA.02.12.01; EPs 4-8)

**Standard QSA.02.04.01**

The laboratory develops an individualized quality control plan (IQCP) in an eligible specialty or subspecialty.

**Elements of Performance for QSA.02.04.01**

A.1. Laboratories that develop an individualized quality control plan (IQCP) include the following: A complete IQCP that consists of the following three parts:

- Risk assessment
- Quality control plan
- Quality assessment

A.2. © Laboratories that develop 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.

A.3. © Laboratories that develop 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

A.4. © Laboratories that develop 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.

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A 5. © Laboratories that develop 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.

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

A 7. © Laboratories that develop 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)

A 8. © Laboratories that develop 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.02.05.01
The laboratory evaluates noninstrument-based testing with internal quality control systems prior to using them for routine quality control.

Elements of Performance for QSA.02.05.01
A 1. © If the laboratory uses noninstrument-based testing with internal positive and negative quality controls as the daily quality control, it performs an evaluation of the internal quality controls against the external quality controls.

A 2. © If the laboratory uses noninstrument-based testing with internal positive and negative quality controls as the daily quality control, it defines in writing the frequency of external quality controls based on the following:
- Its evaluation
- An interval that meets manufacturers’ recommendations
- The use of each new lot number, shipment, or package of reagents

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).

Element of Performance for QSA.02.10.01
C 2. © The laboratory uses quality control materials at levels and a frequency consistent with manufacturers’ recommendations. ©

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.