The Centers for Medicare & Medicaid Services (CMS) introduced a new voluntary quality control option for clinical laboratories on January 1, 2014. The Individualized Quality Control Plan (IQCP) will replace existing Equivalent Quality Control (EQC) procedures after an education-and-transition period ending January 1, 2016.

Under the IQCP, which applies to all specialties and sub-specialties except pathology, organizations that meet manufacturers’ recommendations for quality control do not have to fully meet Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88) regulatory requirements. Because EQC will no longer be an acceptable option for CLIA ’88 quality control compliance in two years, organizations must decide whether they will follow the CLIA regulatory requirements as written or implement the IQCP by January 1, 2016.

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 the EQC. The 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 the IQCP, the Risk Assessment must cover all three phases of testing (Pre-Analytics, Analytics, and Post-Analytics) and include the following five components:

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

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); however, only one Risk Assessment needs to be completed per test system. 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 data testing must be included in the Risk Assessment, thus ensuring the individualization of the Risk Assessment and IQCP.

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. Using the i-STAT example in the previous paragraph, there would be one Risk Assessment and three Quality Control Plans specific to each location. Each Quality Control Plan must be signed by the laboratory director listed on the CLIA certificate.

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 Equivalent Quality Control, organizations should address the following questions.

Where is EQC used in the organization?

An organization should determine which instruments currently use EQC. Blood gas analyzers, Alere Triage Metter and Triage MeterPro, Abbott i-STAT, and Hologic Fetal Fibronectin are test instruments that commonly use EQC.

Which quality control mechanism should be used for each test?

For every test that is currently using EQC, an organization
The 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 there is adequate Quality Assurance in place for each Quality Control Plan.

**Will IQCP be implemented for other tests?**
The organization must decide if IQCP will be implemented for other tests. IQCP can be applied to all specialties and subspecialties—including laboratory developed tests—except pathology.

**IQCP and The Joint Commission**
The Joint Commission will follow CMS’s IQCP education-and-transition period guidelines, allowing accredited laboratories the opportunity to learn about IQCP and implement their chosen quality control policies and procedures. **Effective March 24, 2014,** The Joint Commission will follow an educational policy when surveying quality control requirements; however, laboratories may be cited for noncompliance if any of the following situations exists:
- If the laboratory does not perform quality control
- If the surveyor has serious concerns about test quality
- If an immediate threat to patient health or safety is identified

This change will be reflected in the addition of a new Note to the Rationale for Quality System Assessment for Nonwaived Testing Standard QSA.02.04.01. The box below underscores the new Note, which will appear in the spring 2014 E-dition® update and the 2014 Update 1 for the Comprehensive Accreditation Manual for Laboratories and Point-of-Care Testing. For more information, please contact qualitylabs@jointcommission.org.

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**Revision to Rationale for QSA.02.04.01**

**Applicable to Laboratories**

**Effective March 24, 2014**

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

**Standard QSA.02.04.01**

**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 1:** 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.

**Note 2:** Between January 1, 2014, and January 1, 2016, the following quality control options are acceptable per Centers for Medicare & Medicaid guidance:

- Follow all of the Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88) quality control regulations.
- Continue to follow the equivalent quality control (EQC) procedures as described in the current CLIA Interpretive Guidelines.

After January 1, 2016, EQC will no longer be an acceptable option for CLIA QC compliance.