A revision announced in the March 2014 Perspectives to the “Quality System Assessment for Nonwaived Testing” (QSA) chapter of the Comprehensive Accreditation Manual for Laboratory and Point-of-Care Testing (CAMLAB) has been changed.

The Joint Commission had added Note 2 to the Rationale for Standard QSA.02.04.01 to communicate its expectations during the Centers for Medicare & Medicaid Services (CMS) Individualized Quality Control Plan (IQCP) education-and-transition period. However, the new note raised the following questions from the field.

**Must my laboratory continue to perform quality control for any test system(s) being considered for an IQCP?**

During CMS’s IQCP education-and-transition period, laboratories must continue to maintain compliance with existing Joint Commission requirements as well as Clinical Laboratory Improvement Amendments (CLIA) regulations related to quality control for all test systems.

**What will happen if my laboratory fails to perform quality control for any test system under consideration for an IQCP?**

Failure to maintain compliance with Joint Commission requirements or existing CLIA regulations related to quality control will result in citation for quality control noncompliance.

**Does the education-and-transition period apply to all quality control for all test systems?**

The education-and-transition period applies only to test system(s) being investigated by the laboratory for inclusion in an IQCP.

**Effective immediately,** Note 2 has been removed (see text with strikethrough in the box below) in order to minimize confusion. The Joint Commission is continuing to investigate the development and future implementation of IQCP into its accreditation standards. For more information in the meantime, visit the Joint Commission Connect™ extranet or contact your account executive at 630-792-3007.

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**CLARIFICATION:** Joint Commission Expectations During IQCP Transition

**What will happen if my laboratory fails to perform quality control for any test system under consideration for an IQCP?**

Failure to maintain compliance with Joint Commission requirements or existing CLIA regulations related to quality control will result in citation for quality control noncompliance.

**Does the education-and-transition period apply to all quality control for all test systems?**

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**Official Publication of Joint Commission Requirements**

**Removal of Note 2 from Rationale for QSA.02.04.01**

**Effective immediately**

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

**Standard 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 4:** 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.

- Implement the individualized quality control plan (IQCP) as described on the CLIA website at http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Individualized_Quality_Control_Plan_IQCP.html

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