DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality /Survey & Certification Group

September 30, 2013

RE: Individual Quality Control Plan (IQCP) for Clinical Laboratory Improvement Amendments (CLIA) Laboratory Nonwaived Testing

The Centers for Medicare and Medicaid Services (CMS) is implementing IQCP as a new quality control option based on risk management for CLIA laboratories performing nonwaived testing. IQCP will provide laboratories with flexibility in customizing Quality Control (QC) policies and procedures based on the test systems in use and the unique aspects of each laboratory.

IQCP is voluntary. Laboratories will continue to have the option of achieving compliance by following all CLIA QC regulations as written. The laboratory director retains overall responsibility for ensuring that QC programs are established and maintained to assure the quality of laboratory services provided, and to identify failures in quality as they occur.

There will be an IQCP Education and Transition Period to allow laboratories an opportunity to learn about IQCP and implement their chosen QC policies and procedures. The IQCP Education and Transition Period will begin on **01/01/2014**, and conclude on **01/01/2016**.

Laboratories will have three acceptable QC options during the IQCP Education and Transition Period:

1. Follow the CLIA QC regulatory requirements as written.
2. Continue to follow the Equivalent Quality Control (EQC) procedures as described in the current Interpretive Guidelines, www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Interpretive_Guidelines_for_Laboratories.html.
3. Implement IQCP.

At the end of the Education and Transition Period (1/1/2016), EQC will no longer be an acceptable option to meet CLIA QC requirements and will be removed from Appendix C of the SOM. Therefore, it is important that laboratories understand that on this date, only two options will remain to meet CLIA QC compliance.

1. Follow the CLIA QC regulatory requirements as written, or,
2. Implement IQCP, as applicable

During the Education and Transition period, survey teams will be instructed not to cite QC deficiencies except in cases of immediate jeopardy, a laboratory has failed to implement any form of QC, or serious quality problems are identified. At the end of this period, laboratories will receive deficiency citations if they are not in compliance with one of the two options outlined in the previous paragraph.

The Attachment 1-IQCP document provides the procedures for laboratories that wish to use IQCP to meet CLIA QC requirements for equivalent quality testing. This attachment can be found at http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-54.pdf. IQCP builds on the key concept of Quality Systems, which was introduced in 2003 with the release of Subpart K, Quality System for Non-waived Testing, by including all phases of testing in the risk analysis for each test system.

Laboratories that receive CLIA certification by virtue of accreditation by a CMS-approved accrediting organization (AO), or are subject to regulation by an exempt state (ES), should continue to follow the requirements of their AO or ES.

Laboratories can find IQCP educational materials at the CLIA website: www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Individualized_Quality_Control_Plan_IQCP.html

If you have any questions, please contact your state agency or submit them to the **IQCP mailbox** at this web link: IQCP@cms.hhs.gov.

Sincerely,

/s/

Judith Yost
Director
CMS/Division of Laboratory Services