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IMPORTANT NOTICE REGARDING EQC AND IQCP IN CALIFORNIA

On June 24, 2015, Senate Bill (SB) 75 was signed by Governor Brown and chaptered by the Secretary of State. The provisions of this bill went into effect on July 1, 2015. This bill amended Section 1220 (d)(2)(B) of the California Business and Professions Code to read as follows:

> *(B) A quality control program that meets the requirements of CLIA in Subpart K (commencing with Section 493.1200) of Title 42 of the Code of Federal Regulations as in effect on January 1, 2015, and that may include the clinical laboratory's use of the following alternative quality control testing procedures recognized by the federal Centers for Medicare and Medicaid Services (CMS):*
> *(i) Until December 31, 2015, equivalent quality control procedures.*
> *(ii) Commencing January 1, 2016, an Individualized Quality Control Plan, as incorporated in Appendix C of the State Operations Manual adopted by CMS.*

As of June 24, 2015, the regulations found in CLIA 2003, subpart K, commencing with Section 493.1200 of Title 42 of the Code of Federal Regulations, are in effect in California. On June 24, 2015, and until December 31, 2015, California laboratories can choose equivalent quality control (EQC) as defined in CLIA 2003, and starting January 1, 2016, they can choose an individualized quality control plan (IQCP), which will replace EQC.

Equivalent Quality Control (EQC)
Quality control (QC) comprises the procedures used to detect errors that occur due to test system failure, adverse environmental conditions, and variance in operator performance, as well as the monitoring of the accuracy and precision of the test performance over time.

For each test system, a laboratory must test, at a minimum, two levels of external QC materials each day it performs a nonwaived test. On January 24, 2003, the federal Centers for Medicare and Medicaid Services (CMS) released the latest version of the Clinical Laboratory Improvement Amendments (CLIA), termed the "Final Rules." Title 42 of the Federal Code of Regulations (42 CFR), section 493.1256 of Subpart K introduced a new quality-control (QC) concept--equivalent quality control (EQC). Federal CLIA regulations now allow a laboratory to reduce the frequency of testing external QC materials (equivalent QC procedure) for certain test systems. For eligible test systems, an equivalent QC procedure may be used by a laboratory if it successfully completes a QC evaluation process approved by CMS that demonstrates the stability of the test system over time. For more information on EQC, see CLIA Brochure #4, Equivalent

Quality Control Procedures, available at https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/6066bk.pdf.

Individualized Quality Control Plan (IQCP)
The IQCP is the alternative CLIA QC option that will provide for equivalent quality testing to meet the CLIA regulations for nonwaived tests. IQCP will replace EQC on January 1, 2016 (42 CFR 493.1256(d)). On January 1, 2016, laboratories must be in compliance with their choice of QC procedure or deficiencies will be cited. This applies to CMS-certified, non-waived laboratories and covers all phases of the testing process.

IQCP will include many practices that a laboratory already engages in to ensure quality testing, not just the frequency and number of QC materials. IQCP considers the entire testing process: pre-analytic, analytic, and post analytic; thus, a laboratory will need to consider the corresponding risks in each of these phases and applicable regulatory requirements. IQCP applies to all nonwaived testing performed, including existing and new test systems. All CLIA specialties and subspecialties are eligible for IQCP except Pathology.

IQCP is optional. If a laboratory chooses not participate in IQCP, the laboratory must perform 2 levels of external controls on each test system for each day of testing and also follow all specialty/subspecialty requirements in the CLIA regulations for nonwaived tests.

Laboratories can continue to perform EQC during the educational and transition period, but at the end of that period at midnight on December 31, 2015, they may no longer use the EQC approach. Laboratories may build on their existing quality practices and use the information, knowledge, and experience gained from their EQC study as some of the resources for establishing the IQCP.

More information about IQCP can be found in the brochures found on the CLIA website (https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html?redirect=/clia):
Brochure 11: CLIA Individualized Quality Control Plan Introduction
Brochure 12: Considerations When Deciding to Develop an IQCP
Brochure 13: What is IQCP?

CMS, in collaboration with the CDC, also released the IQCP Workbook, which is geared primarily towards physician office laboratories (POL) and other smaller laboratories.

Other information and guidance to laboratories can be found on the CLIA website www.cms.hhs.gov/clia. Please check this website to stay current on all CLIA information.

Laboratories accredited by accrediting organizations should consult the appropriate accrediting organization to ascertain their policy on IQCP prior to making changes.