



IQCP — It's Here!!

CLIA's quality control (QC) education and transition phase concluded on Jan. 1, 2016. Laboratories must now perform CLIA default QC or implement an Individualized Quality Control Plan (IQCP). Equivalent Quality Control (EQC) will no longer be an acceptable option for QC. Laboratories performing QC at reduced frequencies will be cited deficiencies during CLIA surveys if they have not implemented an IQCP.

CLIA did not set minimum QC frequencies for IQCP. The laboratory and laboratory director must determine the appropriate QC frequency based on their risk assessment. The QC frequency cannot be less than the manufacturer's instructions. Performing no QC will not be acceptable.

IQCP:

- Allows laboratories the flexibility to establish a customized quality control (QC) plan
- Is adaptable to future technology
- Requires laboratories to think of QC in a broader sense that encompasses the whole testing process
- Includes all specialties/subspecialties except pathology, histopathology, oral pathology and cytology
- Is voluntary; laboratories may instead choose to perform CLIA default QC.

IQCP Components

An Individualized Quality Control Plan (IQCP) consists of three components: risk assessment, quality control plan and quality assessment.

The first step is to perform a risk assessment. The risk assessment should identify and evaluate the potential failures and sources of error that impact the testing process. The following components are required in a risk assessment: specimen, environment, reagent, test system and



testing personnel. The risk assessment must cover all phases of the testing process: pre-analytic, analytic and post-analytic. The risk assessment must be based on the laboratory's own new and/or historical data. Documentation of the risk assessment is required. The supporting data must be readily available and retained for the life of the IQCP plus two years.

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If you would like to receive CLIA Bits electronically, please send your e-mail address and company name to Bridget Weidner at bweidner@nd.gov.

Questions and Answers (Q&A)

The Centers for Medicare and Medicaid Services (CMS) provides specialized CLIA training courses for state surveyors. During these training courses, surveyors from across the country ask CMS staff questions regarding the survey process. Although the questions and answers do not represent official CMS policy, they contain valuable information regarding the survey process. The Q & A is a regular feature of the CLIA Bits newsletter. We hope you find this information interesting and useful. Readers are welcome to submit questions to bweidner@nd.gov or sheilman@nd.gov.

Q: A laboratory did not have time to establish an Individualized Quality Control Plan (IQCP) by Jan. 1, 2016. What should they do?

A: As of Jan. 1, 2016, the lab must perform CLIA default quality control. At any time in the future, the lab may develop and implement an IQCP.

Q: If a laboratory decides to perform CLIA default QC, do they need to develop an IQCP?

A: No, IQCP is only required if the laboratory does not wish to follow CLIA default QC requirements.

Q: Does each test on a platform need its own IQCP or can one IQCP be used?

A: IQCP may be developed for the whole testing platform. If there are risk factors unique to individual tests, they must be addressed in the IQCP.

Q: How long does the laboratory need to retain the supporting data for IQCP?

A: All supporting data used for the development of an IQCP must be retained for the life of the IQCP plus two years. Examples include: previous Equivalent Quality Control (EQC) data, temperature and humidity records, proficiency testing results, QC data, performance verifications, maintenance records, calibration and calibration verifications, accuracy verifications, competency evaluations, manufacturer's instructions, etc.

Q: Will test systems using Equivalent Quality Control (EQC) be grandfathered?

A: No test systems will be grandfathered. As of Jan. 1, 2016, laboratories must perform CLIA default QC or implement an IQCP.

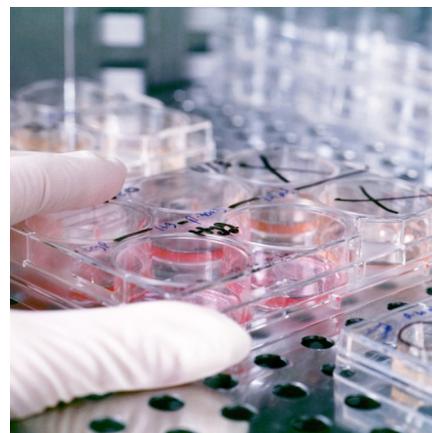
Q: If the laboratory follows the manufacturer's instructions for quality control performance, do they have to implement an IQCP?

A: If the manufacturer's QC instructions are less stringent than CLIA default QC, the laboratory must follow CLIA default QC or implement an IQCP to perform QC at a reduced frequency.

(Continued from page 1) IQCP Components

After the risk assessment is completed, the laboratory uses it to develop a quality control plan (QCP). The QCP must ensure the accuracy and reliability of test results. The number, type and frequency of quality control are to be included in the QCP. The laboratory director must approve, sign and date the QCP. This responsibility cannot be delegated.

The third component of an IQCP is quality assessment. The laboratory must establish on-going monitoring to ensure the effectiveness of their IQCP. The monitoring should include at least the following: specimen, environment, reagent, test system and testing personnel. If the laboratory identifies a testing process failure, they must investigate and perform corrective action. The risk assessment and QCP should be modified if necessary.



Manufacturer's Instructions

CLIA requires all testing, waived and non-waived, to be performed following the manufacturer's instructions. Review the manufacturer's instructions and compare to the laboratory's procedures to ensure proper performance. Check specimen type, storage requirements, specimen preparation (especially important with blood banking dilutions), etc. Periodically check with the manufacturer to ensure the laboratory has the most current version of the manufacturer's instructions. Although CLIA requires proficiency samples to be tested in the same manner as patients, manufacturers and proficiency companies may have different protocols for proficiency samples (e.g. blood banking and microbiology). Be sure the laboratory is following the correct protocol.

New CLIA Regulations

With the addition of Individualized Quality Control Plan (IQCP), the retirement of Equivalent Quality Control (EQC) and the removal of Clinical and Laboratory Standards Institute (CLSI) references, new CLIA regulations were released. The new regulations may be accessed on the CLIA website at <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html>. Click on "Interpretive Guidelines for Laboratories" and download "som107ap_c_lab."



Educational Opportunities

Disease 101 Conference

The North Dakota Division of Disease Control held a two day Disease 101 Conference Via WebEx on Dec. 3-4, 2015. The recorded presentations and their accompanying slides are now available at <http://www.ndhealth.gov/disease/Conference/Default.htm> on the left hand side under **Current Issues**. CEUs will be available for one year from the presentation date. Please share this information with anyone you feel can benefit from the information and CEUs. Twelve CEUs for nursing and a number of PACE credits for laboratory are available.

ASCLS-ND Annual Meeting

The American Society of Clinical Laboratory Scientists—North Dakota (ASCLS-ND) will be holding its annual state meeting in Bismarck on May 11-13, 2016. This is a good opportunity to network with fellow laboratorians, listen to interesting laboratory topics and earn continuing education units. For details, please check their website at www.asclsnd.org.



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Sources: Appendix C - Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services; State Operations Manual, Chapter 6 - Special Procedures for Laboratories; Centers for Medicare & Medicaid Services S&C: 13-54-CLIA; IQCP National Surveyor Training, November 2013; IQCP National Surveyor Training Part II, November 2015.

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