November 2015

IQCP (Individualized Quality Control Plan) is an alternate Quality Control option approved by CMS as well as COLA. Many COLA labs have used EQC (Equivalent Quality Control) for at least one test system. EQC will no longer be an option as of January 1, 2016. COLA labs need to be in compliance with the transition from EQC to IQCP by January 1, 2016. In order to meet this timeline, COLA will end the IQCP transition period on December 7, 2015. This means that, if your lab is found during survey to be using an EQC protocol, your lab will be cited and will need to submit documentation following the survey that demonstrates that you have either implemented IQCP, or have reverted to the CLIA regulatory QC requirement for the test(s).

For any test for which you are using EQC and / or following manufacturer QC protocols that are less stringent than the CLIA regulatory requirement, you will need take one of the following actions prior to January 1, 2016:

1. **Revert to the regulatory Quality Control (QC) requirements.** The regulatory QC protocol varies, according to the type of test. If you are uncertain as to what the regulatory QC requirement is, please contact COLA for guidance.
   a. For **qualitative tests**, a positive and a negative control are required each day of patient testing. This includes, to name just a few, non-waived qualitative tests for infectious mono, rapid strep, H. pylori, serum hCG, HIV, Influenza, Gardnerella, Trichomonas, Candida, and Mycoplasma.
   b. For **quantitative tests**, two levels of controls, run like patient samples, are required each day of patient testing. This includes any quantitative test not covered under other specialty QC requirements (see c-e below).
   c. For Arterial Blood Gases, at least one control every eight hours of operation is required, using a combination of high and low controls each day of patient testing.
   d. For automated Coagulation tests, two levels of QC are required each eight hours of operation, and each time a reagent is changed.
   e. There are more specific QC regulatory requirements for Microbiology and associated subspecialties, molecular amplification methods, and others. Please call COLA for guidance if you are unsure of which regulatory requirement applies to a specific test you are performing.

OR

2. **Implement Individualized Quality Control Plans (IQCP).** IQCP consists of three components:
   a. **Risk Assessment** – you will need to identify potential errors that may lead to incorrect test results, and evaluate the risk associated with each. You need to include evaluation of potential errors in all three phases of testing, and related to all of the following:
      i. The specimen
      ii. The lab’s unique environment
      iii. Testing personnel
      iv. Reagents
      v. The test system
b. **The QC Plan** – from the risk assessment, and by reviewing your lab’s own data that demonstrates the performance of the test in your lab, you will need to develop a QC Plan that describes all the steps that you will take to minimize the chances of errors. The QC Plan must include the number, type, and frequency of Quality Controls run, as well as the criteria for acceptability. The QC Plan may also include other steps, identified via the risk assessment process, that you will take to minimize errors. The Lab Director must approve the QC Plan prior to implementation. Be sure to keep copies of your lab’s data that you reviewed, and be sure that your data support the QC Plan that you have developed.

c. **Quality Assessment** – plan to review your Risk Assessment and QC Plan at least annually, and after any quality failures occur, such as Proficiency Testing failures or incidents that indicate patient results may have been adversely affected.

**NOTE:** The manufacturer’s recommended QC protocol must always be met, regardless of whether you choose the regulatory requirement or IQCP.

It is important that, if you have chosen to implement IQCP, you get started early enough to allow the time necessary to complete the Risk Assessment, review your lab documents demonstrating the performance of the test in your environment, and to develop the QC Plan based upon your Risk Assessment and the review of your lab’s data for the test.

At this time, COLA continues to allow the use of approved CLSI protocols for Microbiology QC. If you are following one of these protocols, you may continue to do so without implementing IQCP. But we strongly encourage you to go ahead and start planning to implement IQCP for these tests. To do so, you will need to gather the data accumulated in your lab since implementing these protocols, such as QC and PT, and complete a risk assessment. This will help you not only demonstrate that the protocols have been effective, but also help you identify and document in your QC Plan all other activities, from all phases of testing, that help you assure accurate and reliable results.

Please note that, although COLA allows the use of approved CLSI protocols for Microbiology QC without implementation of IQCP, the state CLIA agencies do not. If your lab is subjected to a CLIA validation survey following a COLA survey, you will be required to implement IQCP for your Microbiology QC, in order to continue using the CLSI protocols.

COLA technical staff is available to answer questions and assist you with any questions about IQCP. We look forward to providing you with guidance and assisting you as you complete this important transition.