Individualized Quality Control Plans

LabGuide 53

This LabGuide pertains to QSE Process Management and all Phases of the Path of Workflow.

Quality control (QC) is evolving! Without having to change the actual regulations, the CMS Interpretive Guidelines for Laboratories (Appendix C)[1] allow a way to accommodate new technologies by specifying provisions for an alternative to daily external quality control as long as "equivalent quality testing" is provided. Since 2004, this alternative QC was Equivalent Quality Control (EQC).

EQC

Many labs have implemented EQC, but over time concerns arose about its use. Often, labs did not have enough information to determine and mitigate all relevant sources of testing error. As a result, optimal QC may not have been performed for each test.

The IQCP interpretative guidelines will assist laboratories in implementing an individualized QC option that will replace EQC.

CMS participated in meetings with Accrediting Organizations (including COLA), industry, professional organizations, and government agencies to address "QC for the Future." From these meetings, CMS developed the concepts for the Individualized Quality Control Plan (IQCP). Via the Interpretive Guidelines, CMS will allow laboratories to implement IQCP, as a new alternative QC option that replaces EQC.

According to CMS:

> "The guidance and concepts for IQCP are a formal representation and compilation of many things laboratories already do to ensure quality test results. IQCP permits the laboratory to customize its QC plan according to test method and use, environment, and personnel competency while providing for equivalent quality testing. It is the 'Right QC.' "

IQCP is Quality Control based on Risk Management. Risk is a measure of the severity of impact of a potential error, multiplied by the probability with which an error is likely to occur and your ability to detect the error if it should occur. IQCP consists of the following key components:

- Perform and document a risk assessment that, at a minimum, evaluates potential for an error to occur related to each of these six components:
  - Testing personnel
  - Environment
  - Specimens
  - Reagents
  - Test System
  - Post –analytic process
- Establish the "right" QC plan for the test to detect and control potential sources of error (at a minimum, the manufacturer's QC protocol must be followed);
- Monitor the QC plan for effectiveness.

CMS has stated that there will be an educational, transition period that begins January 1, 2014 before IQCP goes fully into effect on January 1, 2016. Accrediting organizations, such as COLA, may also incorporate IQCP, but may have a slightly different implementation timeline. After the educational period, once IQCP is effective, EQC will no longer be a QC option.

When implementing IQCP, a lab may not perform less QC than specified in the manufacturer's QC instructions. The main differences between EQC and IQCP are:

- All specialties (except Pathology) will be eligible for IQCP. Only specific test methodologies were eligible for EQC.
- While EQC was based on standard qualifying studies, IQCP will be based on a risk assessment performed within your laboratory based on your unique circumstances.
- EQC focused on the analytic phase, where we traditionally think that QC resides. IQCP recognizes that all phases of testing impact quality, and the scope of risk assessments must encompass the entire testing process: pre-analytic, analytic, and post-analytic phases.
- IQCP focuses on the "right" QC for each test, which is not necessarily less frequent QC, which was the goal of EQC.

Even though there are differences, when EQC is no longer an option, COLA expects that labs that formerly used EQC will implement IQCP for those same tests, and possibly, for additional test methods.

IQCP is voluntary, and not necessary if the manufacturer's stated control procedures meet or exceed the CLIA requirement of two levels each day.

IQCP is voluntary. Your lab may use it for some tests, all tests (except Pathology) or no tests. Instead of implementing IQCP, laboratories can continue to run the CLIA "default" QC – two levels of controls each day of patient testing.[2] An IQCP is not necessary if the manufacturer's stated number, type, and frequency of control procedures meet or exceed the CLIA requirement of two levels each day. In this circumstance, you may not use IQCP to reduce the number of daily controls to less than 2 levels per day or to less than the manufacturer's recommendation if it is more than 2 levels per day.

In other words, since the manufacturer's QC recommendations will remain the minimum acceptable QC requirement, if the manufacturer recommends 2 or more levels per day, your lab may not develop an IQCP with less than the number specified by the manufacturer.

If the manufacturer's QC recommendations for the test are less than the default CLIA requirement of 2 levels per day (for instance if the manufacturer's instructions say to run controls with each lot number change), your lab may:

- Perform the default requirement of 2 levels per day AND run controls with each lot number change to satisfy the manufacturer's requirement
- Implement IQCP for the test (with the manufacturer's protocol as a minimum)

You may not simply follow the manufacturer's less stringent QC recommendations without performing a risk assessment first to determine if this amount of QC is the "right" QC.

Developing an IQCP

Begin by deciding whether to implement IQCP or the default QC (2 levels of QC each day or the manufacturer's QC recommendation, if more stringent) for each test. Phase out the use of EQC as an alternative QC, if you are using it in your laboratory.

Follow these steps to develop an IQCP:

- Gather and compile information for each test under consideration;
- Identify the risks (potential sources of error) for each test;
- Determine if you have a way to detect each type of error, and if so, describe how;
- Perform the risk assessment for each test;
- Determine the "right" QC for each test;
- Write your IQCP;
- Ensure all involved are trained to your IQCP;
- Monitor the effectiveness of your IQCP and make changes, if necessary.

While IQCP may seem quite confusing now, it will become less so as additional information and resources become available. It will be evident that IQCP is a valuable way of utilizing your current quality control and quality assessment data to focus on developing QC procedures that are appropriate and effective for your unique laboratory environment.

COLA will be incorporating IQCP protocols into the COLA accreditation criteria. Educational resources will be available through CRI (COLA Resources Inc.)

COLA will incorporate IQCP protocols into the COLA accreditation criteria, and provide more specific guidance and information as it is developed, including products available from its educational subsidiary, COLA Resources, Inc. (CRI). These educational products can assist in the identification of potential risks using tools such as process mapping and fishbone diagrams, and in the performance of risk assessments and the development of Individualized Quality Control Plans (IQCP).

1. CMS Interpretive Guidelines for Laboratories, Appendix C; http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Interpretive_Guidelines_for_Laboratories.html *last accessed September 2013*
2. Clinical Laboratory Improvement Amendments (CLIA), subpart K, 42CFR §493.1256(d)(3)(i) and §493.1256(d)(3)(ii): For quantitative procedures, the minimum requirement is two levels each day of testing. For qualitative procedures, the minimum requirement is to test a negative and a positive each day of testing. See Subpart K, Sec. 493.1256, Standard: Control procedures for more information. CLIA, subpart K, §493.1256; http://www.gpo.gov/fdsys/pkg/CFR-2003-title42-vol3/xml/CFR-2003-title42-vol3-part493.xml ; *last accessed September 2013*