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Quality and safety

The Joint Commission to introduce new Individualized Quality Control Plan for clinical labs

Effective Jan. 1, 2016, The Joint Commission is to implement a new voluntary quality control (QC) option — the Individualized Quality Control Plan (IQCP), a result of the Centers for Medicare & Medicaid Services’ (CMS) January 2016 implementation of IQCP in the Clinical Laboratory Improvement Amendments of 1988 (CLIA ‘88) Interpretive Guidelines.

IQCP is to replace Equivalent Quality Control (EQC) and will allow clinical laboratories to customize QC policies and procedures based on a risk assessment. It will be applicable to all specialties and subspecialties, except pathology.

Due to the recent removal of the Clinical and Laboratory Standards Institute (CLSI) QC guidelines from CLIA ‘88, a number of QC changes are being made, including:

- Streamlined organism identification panel QC will no longer be accepted. Instead, a laboratory may opt to use a battery of organisms sufficient to render positive and negative reactions with all biochemicals prior to the use of each lot or shipment of reagent panels, or use the IQCP option to determine the type and frequency of QC.

- Weekly antimicrobial QC also will no longer be accepted, so a laboratory

FAQS REGARDING IQCP

Q. What methods must have IQCP?
A. IQCP is optional for laboratories. When the quality control type and frequency are not determined through the risk assessment process of IQCP, laboratories must use the type and frequency of QC prescribed by standards and regulations.

Q. What methods are eligible for IQCP?
A. IQCP may be used for nonwaived methods in all specialties and subspecialties except pathology, histopathology, oral pathology and cytology.

Q. If I do not do IQCP, how do I determine the QC requirements?
A. The required frequency for most QC is two levels per day of patient testing. Exceptions are in the standards of the specific specialty of testing and the CLIA regulations.

Q. What is the impact of the removal of Clinical and Laboratory Standards Institute (CLSI) references in CLIA regulations?
A. The impact is primarily in microbiology, in which certain quality control types and frequencies have been based upon CLSI documents.
may opt to perform antimicrobial susceptibility QC daily or use IQCP to determine the type and frequency of QC.

- The use of CLSI lists of commercial media for which the laboratory may accept manufacturer’s QC also will no longer be accepted. Laboratories may opt to perform QC on each lot and shipment of all microbiology media prior to use, or use IQCP to determine the type and frequency of QC, including acceptance of manufacturer’s QC.

The IQCP option may not be approved in some states. Laboratories that choose to implement IQCP are still required to follow all other non-IQCP eligible Joint Commission accreditation requirements.

CMS provides a step-by-step guide to developing an IQCP, a useful workbook and additional background information about IQCP. View the new Joint Commission IQCP requirements.

Lab Focus interviews an IQCP pilot program participant

Lab Focus asked Kelley Mitcham, laboratory director at Trinity Medical Center in Birmingham, Alabama, how things went when her lab piloted the IQCP option. Here were some of her answers, regarding the implementation:

LF: How did you decide where you should start?
KM: We read as many publications about IQCP that we could find and then decided on a format (table, fishbone diagram, flow chart).

LF: Were there any barriers you had to overcome?
KM: No; just the time to start working on it.

LF: Were there any surprises you discovered working through the process?
KM: Not really. For us, the template really showed us that we have good practices in place.

LF: You noted that select people at the lab led the development of each process. How did you determine who would lead and why?
KM: We used section heads (department supervisors), because they are the most knowledgeable of their departments and the tests they perform. Also, we used our lab quality coordinator, because she is the most knowledgeable about Joint Commission requirements. The lab director gave her approval on the format we chose to use. I asked a medical technician to coordinate the project. She did the research on IQCP to determine what we needed to do. Some of the work creating documents can be delegated to the staff, and then section heads can review and approve.
LF: How much time do you think is needed to get started on an IQCP implementation?
KM: Several months were needed to prepare the format and collect the information needed to create the documents for the entire lab.

LF: What is your best advice to laboratories that haven’t started the process yet?
KM: Look for templates already created that you can adopt. There is no need to reinvent the wheel if you don’t have to.

LF: For those looking for a template, where are some good places to research?
KM: Our primary tool was derived from information on the CMS website.

**Additional information regarding IQCP from SIG**
To better understand IQCP, here is some additional information about the optional QC method compiled from the most asked questions of The Joint Commission’s Standards Interpretation Group:

- IQCP is made up of three components: risk assessment, quality control plan and quality assessment. IQCP only applies to nonwaived testing. The risk assessment must include all three phases of testing – pre-analytic, analytic and post-analytic. The five components that must be included in risk assessment are: specimen, environment, reagents, test systems and testing personnel.
- In regard to if a test is classified as waived testing, the United States Food and Drug Administration is responsible for assigning the level of complexity. [More information](#).
- Once your risk assessment has been completed, the laboratory director will use this information to determine what QC activities need to be included in the QC plan. This may or may not include electronic or equivalent QC; it depends upon your individualized risks and how you choose to mitigate the risk.
- If you do not implement IQCP, you are required to follow all other Joint Commission standards and CLIA regulations for QC. The basic CLIA QC requirement is to perform two levels of QC materials each day of testing unless specialty requirements apply. If no commercial QC is available, the laboratory must devise an alternative mechanism for QC. The Joint Commission requires three levels of QC material for blood gases.

If you have a question for SIG, visit the [online submission form](#).

**Resources**

**New on the Web**
- **Webinar**: Quality control for Joint Commission-accredited labs is changing — are you ready? Presented by Stacy Olea, executive director, this webinar will explain IQCP and how it affects your accreditation. It will take place at 1 p.m. CT Aug. 12 and will be available on The Joint Commission website after the live session.

**See you there!**
Laboratory staff will be at the following meetings and conferences in 2015:
- **Oct. 15**: G2 Lab Institute, Hyatt Regency Washington DC. Dr. John Cochran and Stacy Olea, executive director, to speak during “Quality Counts: The Importance of Accreditation in an Age of Declining Reimbursements.”
- **Nov. 3-5**: Lab Quality Confab, New Orleans Sheraton Hotel. Stacey Olea, executive director, to participate in a panel discussion on regulatory readiness.