Management Bulletin

Introduction to the Individualized Quality Control Plan (IQCP)

Introduction

The current buzz in the laboratory world surrounds the upcoming deadline for implementation of The Centers for Medicare & Medicaid Services (CMS) new quality control option, the Individualized Quality Control Plan (IQCP). The IQCP Education and Transition Period began on January 1, 2014, and will end on December 31, 2015.

As of January 1, 2016, IQCP will replace Equivalent Quality Control (EQC) which has been in place since 2004, and will be written into the CLIA Interpretative Guidelines for Laboratories 42 CFR 493.1256 Standard: Control Procedures. These new interpretative guidelines will apply to most non-waived tests and specialties except pathology and cytology. IQCP will not apply to waived tests.

What is IQCP?

IQCP is the alternative CLIA quality control (QC) option for non-waived tests. An IQCP will provide laboratories with flexibility in customizing QC based on their unique testing environment and patients. IQCP will include many practices that laboratories already engage in to ensure quality testing, not just the frequency and number of QC materials.

IQCP is a voluntary quality control program. Laboratories will continue to have the option to meet CLIA compliance by following QC regulations as written.

In simpler terms, IQCP is an all-inclusive approach to a quality control option based on Risk Management which is a three-step process that includes steps to identify and evaluate risks, implement practices to reduce risks, and monitor practices for effectiveness and adjust as needed.

IQCP Considerations

There are two basic considerations when determining if an IQCP is required:

1. If a test is **waived**, an IQCP is not required.
2. If a test is **non-waived** and the lab wishes to reduce QC below the CLIA requirements (typically two levels per day) and the manufacturer has no QC recommendation or a recommendation that is less than CLIA requirements, then an IQCP must be performed.

IQCP Components

There are three required components to an IQCP:

1. Risk Assessment (RA)
2. Quality Control Plan (QCP)
3. Quality Assessment (QA)

The Risk Assessment is the means for identifying and evaluating potential problems or errors that may occur in the testing process. CMS guidance documents do not require any specific process to be followed although they do require certain components to be present. The RA must cover **pre-analytic, analytic, and post-analytic** phases of the testing process. In addition, five mandatory risk components must be included in the evaluation: **specimen, environment, reagent, test system, and testing personnel.**

The Quality Control Plan is the summation of the control procedures put in place that reduces the likelihood of providing an inaccurate patient test result. **At a minimum, the QCP must include the**

number, type, and frequency of testing and criteria for acceptable result(s) of the quality control. The QCP may also describe the use of electronic controls, procedural controls, training, proficiency testing, and competency assessment. The QCP cannot be less stringent than the manufacturer's instructions for testing QC. Lastly, each QCP must be approved, signed, and dated by the laboratory director.

Quality Assessment is the third component required of the IQCP. QA is an ongoing review process that monitors the effectiveness of the Quality Control Plan. As with risk assessment and quality control plans, there is no definitive guidance to developing a Quality Assessment plan. Laboratories may choose to incorporate IQCP activities into their current QA plans; however, the IQCP QA plan should include written policies and procedures to monitor and assess, and when indicated, correct problems identified. Documents to consider for QA review may include but are not limited to:

- Proficiency testing records
- Patient results review
- Specimen rejection logs
- Preventive maintenance logs
- Corrective actions and follow-up
- Personnel competency records.

Keep in mind, QA is used to determine if the quality activities you have in place are working. If a failure of the process occurs, an investigation should be performed and documented, including any changes to the IQCP.

Inspections

If a laboratory chooses to implement IQCP, starting January 1, 2016, laboratory inspectors will specifically examine for IQCP compliance which must include:

- A Risk Assessment that includes the three phases of testing and five required components.
- The Risk Assessment must include data from the laboratory's own environment, instrument/equipment performance, and testing personnel.

- A written Quality Control Plan that defines types of control processes, criteria for acceptable performance, and QC frequency. QC may not be performed less frequently than defined in the manufacturer's instructions.
- The Quality Control Plan must be signed, dated, and approved by the Laboratory Director.
- An ongoing quality assessment of IQCP effectiveness

Conclusion

At first glance, IQCP may seem like a confusing concept and a daunting task to undertake. Remember, IQCP is only applicable to non-waived tests and is voluntary. You are not required to implement IQCP as long as you follow CLIA regulations. If you do choose to implement IQCP, do not to let the task overwhelm you. Take it one step at a time. Use the resources that are available through CMS and other agencies. In the end, the hard work will lead to quality control standards unique to your laboratory instead of one-size-fits-all concepts. Embrace the change-it's the future!

Additional Resources

More information can be found at the websites below:

CDC CLIA Website: http://wwwn.cdc.gov/clia/default.aspx

CDC IQCP Workbook and Resources:
http://wwwn.cdc.gov/CLIA/Resources/IQCP/

CMS CLIA Website:
http://www.cms.gov/CLIA/

CLIA Federal Regulations:
https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Regulations_and_Federal_Register_Documents.html

CLIA Brochures:
http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Brochures.html

CAP Website:
http://www.cap.org

COLA Website:
http://criedu.org/iqcp-2/

American Society for Microbiology (ASM)
http://clinmicro.asm.org/index.php/lab-management/laboratory-management/445-iqcp-iqcp

CLSI EP-23A "Laboratory Quality Control Based on Risk Management" (2011)

Additional questions may be directed to the electronic mailbox IQCP@cms.hhs.gov

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