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The Individualized Quality Control Plan—Coming Soon to Clinical Microbiology Laboratories Everywhere!

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Abstract

As of 1 January 2016, microbiology laboratories can choose to adopt a new quality control option, the Individualized Quality Control Plan (IQCP), under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). This voluntary approach increases flexibility for meeting regulatory requirements and provides laboratories the opportunity to customize QC for testing in their unique environments and with their testing personnel. IQCP is an all-inclusive approach to quality based on risk management to address potential errors in the total testing process. It includes three main steps: (i) performing a risk assessment, (ii) developing a QC plan, and (iii) monitoring the plan through quality assessment. Resources are available from the Centers for Medicare & Medicaid Services, Centers for Disease Control and Prevention, American Society for Microbiology, Clinical and Laboratory Standards Institute, and accrediting organizations, such as the College of American Pathologists and Joint Commission, to assist microbiology laboratories implementing IQCP.

Introduction

Quality control (QC) of laboratory testing was mandated in the Clinical Laboratory Improvement Amendments of 1988 (CLIA) law (Public Law 100-578) (1) and is one of the key components of the standards required by the CLIA regulations (2). Along with other clinical laboratories, microbiology laboratories rely on QC as one indicator to assure their test results are accurate and reliable. The CLIA regulations implemented in 1992 included minimum QC requirements for all laboratories that perform non-waived (moderate-complexity and high-complexity) testing. The regulations included the QC required for certain microbiology reagents, stains, and tests, as well as the testing frequencies for each. Individuals and professional organizations that commented on those regulations noted the CLIA QC requirements should be revised over time as testing practices and technology changed and new information on the performance parameters of reagents or tests became available.

The American Society for Microbiology (ASM) subsequently presented data to the Clinical Laboratory Improvement Advisory Committee (CLIAC) on QC failures for commercial microbiology reagents and stains, suggesting that the regulatory frequencies for QC of a number of reagents and stains were excessive (3). As a result of these comments and the ASM data, the 2003 revision to the CLIA regulations contained reduced frequencies for testing many QC materials, including microbiology reagents and stains (4).

The 2003 revised regulations also attempted to increase flexibility under CLIA and give laboratories the opportunity to further reduce the QC performed when test systems incorporate internal systems for monitoring the testing process (e.g., inclusion of electronic, internal, or procedural controls). This option, defined as equivalent quality control (EQC), allowed alternative QC procedures to be used if approved by the Centers for Medicare & Medicaid Services (CMS) and if shown to provide testing quality equivalent to

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that achieved when the CLIA QC requirements were met. Details regarding EQC were included in the subsequently published CMS *State Operations Manual*, *Appendix C: Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services* (referred to below as the *CLIA Interpretive Guidelines*) (5).

In spite of the EQC option, laboratory professional and accrediting organizations, government and industry representatives, and the Clinical and Laboratory Standards Institute (CLSI) expressed a need for a QC strategy for the total testing process that would be adaptable to future technology and testing practices while ensuring accurate and reliable laboratory test results for patient care. These organizations came together at a meeting, QC for the Future, held in conjunction with the 2005 CLSI Leadership Conference, to discuss what would constitute the "right" QC and how to customize QC to assure the quality of test results in each unique laboratory setting. At this meeting, the seeds of the individualized quality control plan (IQCP) were planted as a voluntary approach to meeting CLIA requirements and reducing the risk of errors in all phases of the testing process.

IQCP is based on the premise, discussed at that meeting, that a risk management approach can be used to help laboratories identify where errors can occur in the testing process, determine ways to reduce or mitigate those errors, and design customized QC for their test systems in their unique testing environments. This approach acknowledges that laboratories, diagnostics manufacturers, and government agencies overseeing laboratories and test systems all have a role to play and information to contribute to assuring the quality of each testing process. Following the QC for the Future meeting, CLSI went on to gather these stakeholders to develop a consensus document (CLSI EP23-A), which was published in 2011; the document includes guidelines for laboratories to use in developing customized QC plans (QCPs) based on risk management (6). The IQCP option introduced in 2013 by CMS incorporates a process similar to that described in CLSI EP23-A, although it allows additional flexibility in how IQCP can be adopted.

CMS provided information about the IQCP process and its implementation in a survey and certification memorandum issued on 16 August 2013 (7). This memorandum includes the *CLIA Interpretive Guidelines* pertaining to IQCP, the timeline for implementation, and a list of frequently asked questions and answers. CMS subsequently issued an update to the frequently asked questions that included a specific section pertaining to microbiology laboratories (8).

CLIA QC Requirements for Microbiology

In addition to general CLIA QC requirements, the regulations include requirements for QC testing of reagents, disks, stains, and antisera with each batch (if made in house), lot number (commercial), and shipment and identification systems (which use two or more substrates and/or reagents) when prepared or opened for positive/negative/graded reactivity (as applicable). CLIA QC requirements also include checking fluorescent and immunohistochemical stains for positive/negative reactivity at each use and checking media for sterility and the ability to support growth, select or inhibit specific organisms, or produce appropriate biochemical responses before or concurrent with initial use. The five subspecialties of microbiology have specific QC requirements for certain tests, as well, including antimicrobial susceptibility tests (ASTs). The AST requirements for bacteriology include checking each batch of media and each lot number and shipment of antimicrobial agents using approved control organisms before or concurrent with initial use and each day tests are performed. All of these test systems and procedures, and others performed in microbiology, are eligible for using IQCP as an option to meet the CLIA QC requirements.

Historically, the *CLIA Interpretive Guidelines* incorporated several exceptions to meeting the microbiology QC regulatory requirements if the laboratory performed an alternative procedure approved by HHS as providing equivalent quality testing. HHS-approved alternative procedures for QC of media and ASTs were provided in the *CLIA Interpretive Guidelines* by referencing portions of standards and guidelines published and periodically updated by CLSI (previously NCCLS, the National Committee for Clinical Laboratory Standards) (9-11). These alternatives exempted certain commercially prepared culture media from initial QC testing and decreased the QC required for ASTs once the systems had been shown to achieve acceptable performance within the laboratory on an ongoing basis. Commercial microbial identification systems were also added to the list of tests for which approved QC alternatives existed following the 2008 publication of CLSI M50-A for streamlined QC of the systems (12).

When an update to the *CLIA Interpretive Guidelines* was finalized in 2015, references to the CLSI microbiology documents as an approved alternative to meeting the regulatory requirements for media, ASTs, and commercial identification systems were removed from them (13). Without this alternative, laboratories using commercial media previously exempt from QC because they were listed in the CLSI medium standard (9) and laboratories that had reduced their QC for ASTs and commercial identification systems based on CLSI standards or guidelines (10-12) will need to either meet the 2003 CLIA QC requirements or adopt an IQCP to support less frequent QC testing.

Data collected from manufacturers describing quality standards met in preparing commercial media, records that laboratories have maintained documenting the ongoing acceptable performance of ASTs, or commercial identification systems using the reduced QC can be used as part of the laboratory's documentation to support an IQCP. A caveat to any IQCP is that laboratories must always follow the manufacturer's instructions and cannot develop a plan that is less stringent or requires less QC than specified in those instructions.

IQCP as an Option for Your Laboratory

The CLIA regulations require a laboratory to have procedures to monitor the quality of the total testing process (including the