HHS Public Access

Author manuscript

. Author manuscript; available in PMC 2016 November 15.

Published in final edited form as:

. 2015 November 15; 37(22): 177–185. doi:10.1016/j.clinmicnews.2015.11.001.

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

Nancy Anderson, MMSc, MT(ASCP)

Centers for Disease Control and Prevention, 1600 Clifton Road, NE, Mailstop F-11, Atlanta, GA 30329-4018, Telephone: 404-498-2741, Fax: 404-498-2219

Nancy Anderson: nla0@cdc.gov

Abstract

As of January 1, 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 their testing in their unique environments and by 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, (1) performing a risk assessment, (2) developing a QC plan, and (3) 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). Microbiology laboratories, as do other clinical 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 nonwaived (moderate complexity and high complexity) testing. The regulations included the QC required for certain microbiology reagents, stains, and tests and the 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 included 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 of monitoring the testing process (e.g. inclusion of electronic, internal, or procedural controls). This option, defined as “Equivalent Quality Control” or “EQC” allowed alternative QC procedures to be used if approved by the Centers for Medicare & Medicaid Services (CMS) and shown to provide equivalent quality testing to that achieved when meeting the CLIA QC requirements. 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 (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 assuring accurate and reliable laboratory test results for patient care. They came together at a “QC for the Future” meeting 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” or “IQCP” were born 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 towards assuring the quality of each testing process. Following the “QC for the Future” meeting, CLSI went on to gather these stakeholders together to develop a consensus document (CLSI EP23-A) that was published in 2011 and includes guidelines for laboratories to use in developing customized QC plans 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 as to how IQCP can be adopted.

CMS provided information about the IQCP process and its implementation in a Survey and Certification memorandum issued on August 16, 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 (made in-house), lot number (commercial) and shipment, and identification systems (that 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 each time of use; and checking media for sterility and 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 include 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) (9–11). These alternatives exempted certain commercially prepared culture media from initial QC testing, and decreased the QC required for ASTs once these systems had been shown to perform acceptably on an ongoing basis within the laboratory. Commercial microbial identification systems were also added to this list of tests for which approved QC alternatives existed following the 2008 publication of CLSI M50-A for streamlined QC of these systems (12). When an update to the *CLIA Interpretive Guidelines* was finalized in 2015, references to the CLSI microbiology documents were removed from them as an approved alternative to meeting the regulatory requirements for media, AST, and commercial identification systems (13). Without this alternative, laboratories using commercial media previously exempt from QC as listed in the CLSI media standard (9) or those 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 QC testing. Data collected from manufacturers describing quality standards met in preparing the commercial media or 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 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 preanalytic, analytic, and postanalytic phases of testing). This includes QC testing and other activities to detect errors that could lead to incorrect results and could have an impact on patient care. The IQCP approach is an all-inclusive voluntary approach to ensuring quality for nonwaived testing by providing each laboratory the option to tailor a QC plan for their unique testing environment and patient populations. It incorporates practices, data, and information that a laboratory already uses to ensure quality of the testing process and meet CLIA requirements, beyond testing a certain number of QC

materials at a designated frequency. IQCP provides a framework for laboratories to customize a QC program by assessing potential sources of error for five major components of the testing process, and establishing the appropriate QC and quality practices to reduce the likelihood of those potential errors. After a laboratory completes the process of assessing and documenting the risk of potential errors for a specific test, the Laboratory Director, who is responsible for signing off on each QC plan the laboratory develops, may determine the amount of QC and other quality practices the laboratory has been following are adequate to identify and reduce risks, and meet CLIA requirements. However, the risk assessment that is part of the IQCP process may uncover potential sources of error that have not been previously considered, and additional QC or quality procedures may need to be implemented. In either case, the IQCP approach will allow the Laboratory Director and other laboratory personnel to document activities already in place and develop a QC plan for the testing process in their unique setting.

The three main steps needed to develop an IQCP for an individual testing process comprise (1) performing a risk assessment, (2) developing a QC plan (QCP), and (3) monitoring the plan through ongoing quality assessment (QA). This can be seen as a continuous cycle, with changes made as needed to continually assure the quality of the test and its results. [incorporate graphic image of the cycle – see page 22 of draft following references] An IQCP should address potential failures and errors in the entire testing process, including the preanalytic, analytic, and postanalytic phases of testing. Before starting the first step in this process, it is necessary to gather and review information already available to your laboratory and the testing process being evaluated. Once this information has been collected and reviewed, the risk assessment can be conducted and documented. Examples of information and records that may be used for this are:

- Manufacturer instructions, package inserts, or manuals
- Quality certificates, alerts, or bulletins from the manufacturer
- Data from test verification or establishment of performance specifications
- Historical QC data or records, including data from EQC studies
- Proficiency testing records
- Test process maps or flow charts
- Personnel training or competency assessments
- Records of complaint or corrective actions taken
- Scientific literature

Risk assessment

The risk assessment is the process of analyzing the testing process, and identifying and documenting potential failures and errors that could occur in each phase of testing. When considering an IQCP, a minimum of five components of the testing process must be included in the risk assessment. These are the (1) specimen, (2) test system, (3) reagent(s), (4) environment, and (5) testing personnel. Although not required by the CLIA IQCP

approach, if it is helpful, you may choose to further separate these components, such as including a sixth component covering test results rather than capturing this under one of the five components listed above.

In laboratories with multiple, identical test systems (same manufacturer and model), a single risk assessment may be performed. However, differences in testing personnel and environments where the test systems are used must be taken into consideration and if there are differences, these differences must be addressed in the risk assessment. Therefore, the risk assessment for a given test system will differ among laboratories and may differ if the same laboratory has identical devices that are used in different locations or by different groups of testing personnel. When evaluating your testing process, you may also find that some risks fit under more than one component. For example, an inadequate specimen volume could be caused by a problem with the specimen collection, the test system sampling mechanism, or a testing personnel error. Risks can be identified under more than one component or the component that is most appropriate for your laboratory setting and the particular test.

Documenting the risks of potential failures and errors and determining what mechanisms are needed to reduce the failures and errors can be done in different ways for each of the five components listed above. Some laboratories may choose to use fishbone diagrams, as outlined in CLSI EP23-A, to identify potential risks of errors of incorrect results and determine whether these risks are adequately controlled by current QC or other quality activities (6). Other laboratories may choose to develop tables that capture possible sources of error and identify whether and how the potential errors could be reduced, as illustrated in a step-by-step workbook developed by the Centers for Disease Control and Prevention (CDC) and CMS to assist laboratories in implementing IQCP (14). Professional and accreditation organizations also have tools available for documenting laboratories' risk assessments, QCPs, and QA activities. Regardless of which mechanism is used, an IQCP must include documentation that risks have been evaluated for each of the five IQCP components. Where applicable, risks identified in the preanalytic, analytic, and postanalytic phases of testing need to be included. Example questions to stimulate your thinking when conducting the risk assessment for the specimen, test system, reagent, environment, and testing personnel are given in the Risk Assessment Table [Include table provided on page 23 of draft]. Once the risk assessment has been completed, determining the frequency of occurrence and potential severity of harm of any identified risk can be documented in different ways, using some type of matrix or scoring system or by considering each risk and indicating when QC or other procedures are needed to reduce or mitigate the risks. The end result should be a determination of whether current practices are sufficient to detect possible sources of error or if additional procedures are needed to monitor or control the testing process.

Quality Control Plan (QCP)

Developing a plan to reduce risks or the likelihood of errors or incorrect results to assure the quality of testing is the next step in the IQCP process. The QCP is a written document describing practices, procedures, and resources needed by your laboratory to assure the

quality of a specific testing process and reduce the likelihood of providing inaccurate patient test results. The QCP must provide for immediate detection of errors that can occur due to test system failure, adverse environmental conditions, and variations in operator performance. It must also monitor over time the accuracy and precision of the test, which can be influenced by changes in the specimen, test system, reagent, environment, and testing personnel.

The QCP for each testing process needs to include, at a minimum, the number, type, and frequency of testing control materials, as well as the criteria for acceptability of those controls. It may also incorporate the use of electronic or internal procedural controls, equipment maintenance or calibration, personnel training and competency assessment, or other quality activities. Your risk assessment data must support the measures and activities included in your QCP. When reviewing the results of the risk assessment to assure that appropriate activities are in place to detect failures and errors, you may determine that some sources of errors are adequately controlled and no additional actions are needed. It is also possible that your customized QCP may include less QC than required by the CLIA QC regulations, but more than the manufacturer's instructions for testing control materials. This is acceptable, as long as your QCP is not less stringent than the manufacturer's instructions.

Gathering information and developing the QCP can be delegated in writing to qualified laboratory personnel. However, it is the overall responsibility of the Laboratory Director (named on the CLIA Certificate) to provide accurate and reliable test results that are appropriate for patient care, and this responsibility cannot be delegated. As part of this, the Laboratory Director must review each QCP and ensure that it meets the requirements set forth in the *CLIA Interpretive Guidelines*. The Laboratory Director must sign and date the initial QCP and must re-sign and date it if changes are made. The same resources mentioned for assistance with performing and documenting risk assessments are available for developing a QCP (6, 14).

Quality Assessment (QA)

The third step in implementing an IQCP is QA, defined as the continuous process of monitoring the effectiveness of a QCP and making changes necessary to correct identified problems or errors. It is the mechanism for assuring that a QCP and quality activities put in place are working. QA for IQCP is similar to the QA laboratories already conduct to identify and resolve issues with their testing, except that it focuses specifically on the five risk assessment components that were evaluated for developing the QCP. Laboratory personnel need to establish a review system and schedule for assessing a QCP to assure that it continues to provide accurate and reliable test results. If failures or errors are identified that can be attributed to the QCP, they need to be investigated to determine the cause and its impact on patient care. If needed, the risk assessment should be modified with new information that becomes available when testing processes change or errors are identified and the QCP should also be revised, as applicable. As with any QA process, any changes made to policies and procedures related to the risk assessment or QCP need to be documented and discussed with appropriate staff.

Microbiology IQCP Resources

Implementation of the IQCP approach is challenging for personnel in any laboratory, since they may not have experience in performing risk assessments or documenting the outcomes of those assessments to develop risk management (or QC) plans. However, microbiology laboratories have unique challenges since the microbiology testing processes are somewhat different from testing performed in other laboratory specialties. In addition, the removal of references to CLSI standards and guidelines in the *CLIA Interpretive Guidelines* has resulted in QC challenges for microbiology laboratories. The CMS CLIA IQCP website provides a number of links to educational brochures, the downloadable CDC/CMS workbook, and other documents explaining IQCP, and it includes an email box for questions (15). The CDC CLIA website includes an IQCP page with the CDC/CMS workbook and an email box where you can request hard copies of it (16). CLIA-approved accrediting organizations that have been approved to offer IQCP as an option have also developed tools and information and provide another source of assistance for their participant laboratories. Accredited laboratories should continue to meet their accrediting organization's current standards until they receive notice from that organization about any QC changes.

Valuable resources specifically for microbiology laboratories have been developed collaboratively by ASM, CLSI, and the College of American Pathologists (CAP) and can be accessed on the ASM Clinical Microbiology Portal (17) and on the CLSI website (18). The information on both sites is freely accessible to all, regardless of whether an individual or laboratory is a member of either organization. Among the tools and other resources on the sites are several microbiology IQCP templates in different formats that can be adapted by a laboratory for performing risk assessments, developing QCPs, and performing QA. The websites also include example IQCPs for various AST systems (commercial and disk diffusion). Additional examples for identification systems and culture media are expected on these sites in the near future. Example IQCPs for several commercial products, including the Cepheid Xpert® MRSA assay, the Vitek®2 commercial AST system, and Remel culture media are now posted at the ASM Portal website in a PowerPoint presentation made by Dr. Susan Sharp. When viewing or using any of these examples, it is important to remember that they cannot be used directly as your laboratory's IQCP. Rather they are intended as guidance in performing the risk assessment, creating the QCP, and monitoring the effectiveness of that QCP through QA. Each laboratory needs to customize and document their own IQCPs in their setting, with their test systems and personnel. [somewhere in this area of the newsletter please include the graphic list of website resources provided on page 24 of this draft]

In an effort to provide additional assistance to microbiology laboratories considering or implementing IQCPs for their testing processes, frequently asked questions and answers can be found at the ASM Portal (17) and on the CMS website (8). Select questions pertinent to microbiology collated from these websites are provided below. For the complete list of questions, please refer to the websites:

Q. Must an IQCP be performed if the laboratory chooses to comply with the QC requirements specified in the CLIA regulations?

A. No, IQCP is a voluntary option under CLIA, and it is not necessary if the laboratory chooses to meet the regulatory requirements. However, as of January 1, 2016, the previous EQC option in *CLIA Interpretive Guidelines* will no longer be acceptable. Any laboratory that chooses to do QC less frequently than the default regulatory requirements will need to implement IQCP and have data to support their QCP.

Q. Who is qualified to develop an IQCP?

A. The Laboratory Director (individual whose name is on the CLIA certificate) has the responsibility for ensuring an IQCP meets the requirements described in the *CLIA Interpretive Guidelines*. He or she must review, sign, and date the QCP when implemented. If changes are made, the Laboratory Director must re-sign the updated QCP. He or she may assign, in writing, specific duties for the IQCP to other qualified laboratory personnel, but is still responsible overall for the entire testing process.

Q. Will IQCP reduce the amount of QC testing needed for the test I am considering?

A. It is possible that your risk assessment will demonstrate that less QC than previously performed may be acceptable for your test system. However, appropriate documentation must be provided to justify the QC testing schedule included in a QCP. Many laboratories may have historical records that can support their current QC testing schedule; additional data would be required support a reduced QC testing schedule.

Q. Will laboratories need to perform new studies to gather data and other information for the risk assessment and QCP development for existing tests?

A. Much of the data or other information needed by a laboratory to perform the risk assessment for each test will be data that the laboratory should have maintained as part of routine operations, meeting CLIA requirements, and implementing quality systems. Data from verification of manufacturer’s performance specifications, QC and proficiency testing records, and documentation of corrective actions are several examples of documentation that could support an IQCP. The laboratory must use in-house data or other documentation that demonstrates the stability of the test system and supports the QC type, number, frequency described in the QCP.

Q. Does a laboratory need to perform CLIA-required QC for a certain period of time to collect supporting data for its IQCP?

A. CLIA is not prescriptive about the amount of data or evidence required for an IQCP, nor does it require that laboratories meet the default CLIA regulatory requirements for a specific time period as part of their risk assessment. The Laboratory Director is responsible for determining and documenting the most appropriate QCP for each test based on the data and other evidence available from various sources. Surveyors will continue to use the outcome-oriented survey process to determine whether the laboratory is providing accurate and reliable test results and other related services and is operating within the applicable CLIA regulations.

Q. Are laboratories required to use process maps, fishbone diagrams, or formal risk assessment charts and protocols, in conducting risk assessments and developing their QCPs?

A. No, CLIA does not mandate a specific method of documenting risk assessments or QCPs. Tools such as those listed are options that may be helpful to laboratories, but are not the only acceptable methods of documentation.

Q. Can laboratories use CLSI EP23-A "Laboratory Quality Control Based on Risk Management" in implementing an IQCP?

A. The CLIA IQCP approach was based on principles described in CLSI EP23-A, but it is not identical to that described in CLSI EP23-A. Laboratories are not required to follow that CLSI guideline when implementing IQCP. CLSI EP23-A can serve as a helpful resource in developing an IQCP but laboratories should be sure that their IQCPs meet the requirements specified in the *CLIA Interpretive Guidelines* and by their accrediting organization, as applicable.

Q. What is the minimum amount of QC testing allowed with an IQCP?

A. CLIA does not specify a minimum QC requirement under IQCP. QC cannot be less than that required or recommended by the manufacturer, and must be supported by the risk assessment and QC data.

Q. Why does a laboratory need to consider IQCP as long as they follow the manufacturer's QC instructions?

A. During the test system development, manufacturers challenge their tests in many ways to identify possible failures and build in features to reduce the risk of those failures. However, manufacturers' instructions for QC may not address all of the risks and variables that are specific for an individual laboratory's situation and these must be addressed under each of the required components of the risk assessment.

Q. Must a laboratory still follow the manufacturer's instructions if it chooses to implement IQCP?

A. Yes, at a minimum, the manufacturer's instructions must be followed. Regardless of whether a laboratory implements an IQCP or chooses to comply with the CLIA QC requirements, they are not permitted to perform QC that is less stringent than specified in the manufacturer's instructions.

Q. The *CLIA Interpretive Guidelines* state that a laboratory's QCP cannot be less stringent than the manufacturer's instructions. Does this apply when the manufacturer recommends following the CLSI microbiology standards or guidelines for QC of its test system?

A. In stating the laboratory's QCP may not be less stringent than the manufacturer's instructions, CLIA requires the laboratory to follow all manufacturer's instructions, including the requirements and recommendations for performing QC and patient testing. If the manufacturer requires or recommends the use of external guidelines, then the laboratory must follow those instructions. If the external guidelines are less stringent than the CLIA

default regulations, the laboratory must also choose to either meet the CLIA requirements or develop an IQCP. CMS does not consider a reference made by the manufacturer to specific literature or documents for use as an educational tool to be the same as a manufacturer's instructions for QC or patient testing.

Q. How does the CMS S&C letter #15-07-CLIA regarding the removal of the CLSI microbiology references from the *CLIA Interpretative Guidelines* affect microbiology laboratory testing?

A. As mentioned in the S&C letter #15-07-CLIA, once IQCP becomes effective in 2016, the laboratory will have the following two options: (1) meet all applicable CLIA QC regulations, or (2) implement IQCP. Laboratories may use the historical QC data obtained while meeting the standards described in the CLSI microbiology documents as part of the risk assessment for developing an IQCP. For example, laboratory documentation of visual quality checks of media are considered acceptable in-house data that can be used for the risk assessment and resulting QCP. The laboratory may also include manufacturer's quality certificates as part of the information considered in its risk assessment.

Q. Is there a difference between exempt and non-exempt culture media under IQCP?

A. When the CLSI microbiology documents were referenced in the *CLIA Interpretive Guidelines*, commercial culture media listed in those references were exempt from the CLIA regulatory requirements for media quality. Other media not listed in the CLSI documents and *CLIA Guidelines* required checking each batch, lot number and shipment for sterility and ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response. With the removal of those references, laboratories using any culture media (commercial or noncommercial), will need to either meet the CLIA QC requirements for media (listed above) or are eligible to implement an IQCP, regardless of whether media was previously on the CLSI exempt list or not. As mentioned above, historical QC data collected while meeting CLSI standards and manufacturer quality certificates can be documentation considered as part of the laboratory's risk assessment and QCP.

Q. Is it acceptable to perform a single risk assessment and develop one QCP if multiple identical test systems (instruments or devices) are used by a single CLIA-certified laboratory or multiple laboratories within the same healthcare system?

A. If one CLIA-certified laboratory uses multiple identical test systems, the IQCP must take into consideration the unique environment, testing personnel, and other variables that could affect the testing for each. It is possible that one IQCP is adequate if these test systems are used by the same personnel at the same location with no environmental variables that could affect the testing. However, there must be documentation that each instrument had a separate verification process at the time it was put into use. If the instruments are used by the same CLIA-certified laboratory in different physical locations and by different personnel, the risk assessment and QCP must address the potential risks for each location. CMS recognizes that it is becoming more common for large multi-site systems to standardize processes where feasible to achieve efficient operations. It would be acceptable if laboratories in a multi-site

system collaborated on common elements such as the process and format for developing IQCPs. For test systems used by more than one CLIA-certified laboratory within the multi-site system, the laboratories may also collaborate on those portions that are common to all, for example, the manufacturer's QC instructions. However, the end product must include an evaluation of the risks associated with each individual location, and each QCP must be approved by the Laboratory Director for that laboratory. Each CLIA-certified laboratory must produce its own supporting data for its QCP and each device must be monitored at each location.

Q. When performing AST and microbial identification on a commercial automated instrument, does a laboratory need separate IQCPs for the AST component and the identification component? Similarly, are separate IQCPs needed for different panels tested on the same instrument?

A. CMS is not prescriptive on this topic. It is at the discretion of the Laboratory Director whether separate IQCPs are needed for the AST and identification components, or different panels, when tested on the same instrument. In making the decision, he or she should consider the variables that could affect each testing process and if they differ, the risk assessment and QCP need to address those differences.

Q. Is it acceptable to develop one IQCP to address two commercial test systems that perform similar testing but are manufactured by different companies (e.g. MicroScan versus Vitek®2 systems) or utilize different test methodologies or test principles (e.g. MIC versus disk diffusion for AST)?

A. In both situations described above, although the test systems may share some similarities, they are unique and the potential risks could differ. In each case, an individual IQCP would be required.

Q. What does CLIA consider to be the specimen for microbiology tests? Does the clinical specimen source need to be addressed?

A. The specimen is one of the components that must be included in a risk assessment. In microbiology, primary clinical specimens are used for some tests. In other cases, culture isolates are used and would be considered the specimen. It is the Laboratory Director's responsibility to determine what is considered the specimen for any particular test when conducting the risk assessment. If primary clinical specimens are used in testing, they would need to be addressed in the risk assessment and QCP. If a culture isolate is used, the Laboratory Director would need to decide whether variables related to the clinical specimen could affect that isolate, and if so, include that information in the risk assessment and QCP.

Q. Does IQCP apply to laboratory developed tests (LDTs) and molecular assays used in microbiology laboratories?

A. Yes, IQCP may be considered for LDTs and molecular microbiology tests.

Q. How will a laboratory know that QCPs developed for their testing processes are working?

A. An important part of IQCP approach is the QA or ongoing monitoring of the effectiveness of the QCP. The QA plan should be developed when the IQCP is implemented, and needs to include activities that will help to identify and resolve problems in the testing process and the QCP through continuous monitoring, investigation, and problem solving. An effective QA system will thereby allow adjustments to be made to the QCP as the data warrant.

Q. How will CLIA laboratory surveyors assess an IQCP that has been approved by the Laboratory Director?

A. Surveyors will use the outcome-oriented survey process for determining compliance with CLIA. This means that he or she will review a laboratory's IQCP to determine if the risk assessment includes all of the requirements, if the identified risks were evaluated, if the QCP includes any risk(s) that the Laboratory Director has determined needs to be mitigated, and that QA is occurring and ongoing. If these requirements are met and no problems are identified as part of the survey that can be attributed to the IQCP, the laboratory will be compliant with CLIA requirements. If the requirements are not met, the laboratory may be cited for deficiencies.

Timeline and Process for Adoption of IQCP

The education and transition period for laboratories to learn about IQCP, discontinue any EQC processes in place, and begin developing their QCPs began January 1, 2014 and extends through December 31, 2015. As of January 1, 2016, IQCP will become effective and laboratories inspected by CMS will have the choice of either meeting all applicable CLIA QC requirements or implementing the IQCP option. Laboratories inspected by CAP, the Joint Commission, or COLA, three accrediting organizations approved by CMS to allow the IQCP option, should check with these organizations to be sure that they meet the accreditation requirements for IQCP. Laboratories inspected by other accrediting organizations should check with those organizations and should continue to meet the accrediting organization's current QC standards until they receive notice of any changes. IQCP has been approved as an option in the CLIA-exempt states of New York (NY) and Washington (WA), so laboratories in those states need to be aware of and comply with the NY and WA IQCP requirements if they choose to adopt this QC option. Laboratories in states that are not exempt from CLIA also need to be aware of and meet additional state requirements, as applicable.

Acknowledgments

I thank and acknowledge the outstanding work of the CLSI IQCP Ad Hoc Working Group, consisting of Susan Munro, Linda Bruno, Mary Arndt, Barbara Robinson-Dunn, Janet Hindler, Susan Sharp, and Maria Traczewski, for their contributions in developing a number of excellent resources to assist microbiology laboratories implement IQCP. I also thank Diane Bosse and Anne Pollock for their assistance with preparing and reviewing this article.

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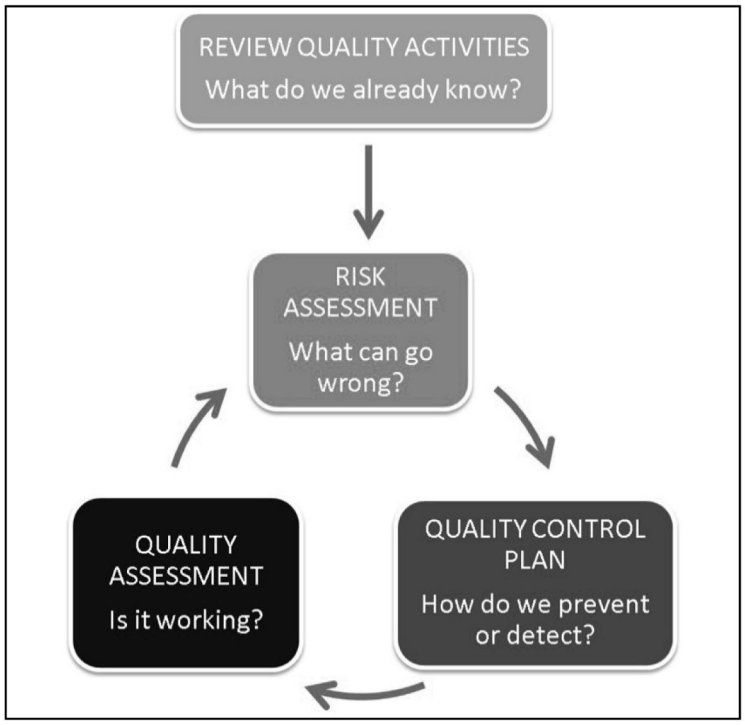
Individualized Quality Control Plan Cycle



RISK ASSESSMENT

Example Questions for Laboratories to Consider

	Do you see a potential risk of producing incorrect test results If:
Specimen	The instructions for patient identification and preparation are not followed?
	The instructions specimen collection, transport, and storage are not followed?
	The specimen is improperly labeled at the time of collection?
	The specimen isn't accurately identified throughout the testing process?
	Criteria for specimen rejection are not established and followed?
Test System	The current manufacturer's instructions (or laboratory's standard operating procedures) for testing are not available or used?
	Maintenance procedures are not consistent with the manufacturer's instructions or other established laboratory procedures?
	The limitations to the test system are ignored. For example, can medications interfere with the test system's performance or test results?
	Built-in monitors do not exist for the test system, e.g. the ability to detect inadequate specimen volume or improper dispensing of reagents?
	Safeguards are not built-in to prevent or detect cross contamination?
	Incubation times or temperatures are not consistent with the manufacturer's instructions or other established laboratory procedures?
	The laboratory information system (LIS) isn't transmitting results or other information accurately?
Reagents	Integrity of reagents (or media) are not checked when received? (e.g. some manufacturers ship reagents on dry ice or icepacks to maintain required temperatures)
	Storage requirements for reagents (or media) are not followed?
	Expiration dates on reagents (or media) are not adhered to?
	Manufacturer's instructions for reagent preparation are not followed? (e.g. reconstitution of reagents or bringing to room temperature)
	Reagents with different lot numbers are mixed? (Consider if the test system has a mechanism to identify reagent lot numbers or if the laboratory needs to track them manually)
	The specified type of water required by the test system is not used?
Environment	The manufacturer's instructions for space and the testing environment are not followed?
	The manufacturer's ventilation and airflow requirements are not adhered to?
	There is insufficient lighting and space for workflow and the test system?
	The manufacturer's instructions for maintaining the appropriate temperature and humidity for the test system are not followed?
	Workspace is not free of clutter, dust, or debris?
Testing Personnel	Laboratory personnel do not have a formal certification or license if required by the state?
	The laboratory does not have adequate personnel to perform patient testing in a safe and timely manner?
	There is no documentation of CLIA-required competency assessment for all laboratory personnel?
	Laboratory personnel are not trained on specimen requirements (collection and type) required for the test system?
	Laboratory personnel are not trained to follow the manufacturer's instructions in their entirety?
	Laboratory personnel make transcription errors when reporting results, either written or when using an LIS?

IQCP Website and Email Resources for Microbiology Laboratories

CMS CLIA IQCP Page: https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Individualized_Quality_Control_Plan_IQCP.html

CMS IQCP FAQs: https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/FAQs-IQCP.pdf

CMS IQCP email address for questions: IQCP@cms.hhs.gov

CDC CLIA IQCP Page: http://wwwn.cdc.gov/clia/Resources/IQCP/

CDC IQCP email address to request hard copies of the IQCP workbook: iqcpworkbook@cdc.gov

ASM Clinical Microbiology Portal for IQCP: https://clinmicro.asm.org/index.php/lab-management/laboratory-management/445-iqcp

CLSI IQCP Microbiology Website: http://clsi.org/wp-content/uploads/sites/14/2013/07/CLSI_IQCP_MicroInfo.pdf