

CLIA

INDIVIDUALIZED QUALITY CONTROL PLAN

CONSIDERATIONS WHEN DECIDING TO DEVELOP AN IQCP

OVERVIEW

Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations require a laboratory to have quality control (QC) procedures to monitor the accuracy and precision of the complete testing process. QC consists of the activities used to detect errors that occur due to test system failure, adverse environmental conditions and variance in operator performance. External or liquid control materials may be included as part of the test/test system, provided separately or prepared in-house.

A new, flexible QC option is now available that provides you the opportunity to tailor an Individualized Quality Control Plan (IQCP) for your unique testing environment and patients. The scope of an IQCP is an all-inclusive approach to assuring the quality of the entire testing process. An IQCP includes practices, data and information that your laboratory already uses to ensure quality testing and meet CLIA, beyond testing a certain number of QC materials at a designated frequency. To ensure that these control procedures are equivalent to CLIA QC regulations and suitable for your laboratory, you will need to establish and document QC that is appropriate for your test system, testing environment and testing personnel. IQCP provides structure and guidance to perform this evaluation and determine the best QC protocol for your laboratory.

SECTION 1:

HOW DO I DECIDE IF I SHOULD DEVELOP AN IQCP? WHAT DO I NEED TO KNOW BEFORE I MAKE MY DECISION?

WHAT ARE THE ADVANTAGES OF AN IQCP?

IQCP provides a framework for customizing a QC program for your test systems and your laboratory's unique environment. By performing the steps in an IQCP, you will examine the potential sources of error in your pre-analytic, analytic and post analytic phases of testing, as well as establish the appropriate QC and quality practices which reduce the likelihood of errors occurring in your laboratory. After you complete this process, it is possible that you may determine that the amount of QC you have been doing all along is sufficient to achieve CLIA compliance. However, you could discover potential sources of error that you had not previously considered, and may need to implement additional QC activities. In either case you will have created a comprehensive QC program, which reflects your laboratory's unique operation, and the documentation which supports the rationale for your QC practices to ensure high quality testing.



I HAVE ALWAYS MET OR EXCEEDED THE CLIA CONTROL REQUIREMENTS AND STILL PLAN ON FOLLOWING MY EXISTING QC POLICY. AM I STILL REQUIRED TO PERFORM THE IQCP PROCEDURE?

No, if your QC policy is equal to or more stringent than the CLIA control requirements, you are in compliance. You still have the option to utilize the IQCP procedure which may be helpful in verifying your existing control procedures or identifying additional control measures for your test system.

I HAVE ALWAYS FOLLOWED MANUFACTURER'S INSTRUCTIONS FOR QC IN MY LABORATORY WHICH IS LESS THAN THE CLIA REQUIREMENT OF 2 LEVELS OF QC EACH DAY OF TESTING. WHY DO I NEED TO CONSIDER DOING AN IQCP?

Effective as of January 1, 2016, if you wish to continue your current QC practice you will need to perform an IQCP. During 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 the risks, potential errors and variables that are specific to your laboratory's situation. Developing an IQCP will address the risks that are specific to your laboratory and help you determine the appropriate QC for your patient testing.

MAY I CONSULT WITH THE MANUFACTURER WHEN DEVELOPING AN IQCP FOR MY TEST SYSTEMS?

You may consult with the manufacturer when identifying some of the risks associated with your test systems. This is appropriate if you have questions relating to the risks. The manufacturer may offer suggestions and provide input to your laboratory concerning the specifics of your IQCP, but your laboratory must develop and perform its own IQCP.

WHO IS RESPONSIBLE FOR THE LABORATORY'S IQCP?

The laboratory director is responsible for deciding whether the laboratory will utilize IQCP for some or all of its tests and for ensuring that the quality control plan (QCP) developed effectively meets the IQCP requirements. The laboratory director may assign, in writing, specific duties for the IQCP to qualified laboratory personnel but is still responsible overall for the entire testing process.



SECTION 2:

SCENARIOS TO HELP YOU WITH YOUR DECISION MAKING PROCESS IN DETERMINING WHAT QUALITY CONTROL PROCEDURES TO USE FOR YOUR TEST SYSTEM.

A good starting point for your decision making process is based on what the manufacturer's instructions state in the package insert or operator's manual about quality control. Review all documents provided for the test system. Are there manufacturer's instructions for control procedures in the package insert or operator's manual?

NOTE: A flowchart describing the scenarios below is attached at the end of this brochure. These scenarios are focused on tests that have no additional QC requirements other than 2 levels of external QC each day of patient testing. There are additional specialty/subspecialty and general requirements for some tests that are not addressed in these scenarios. For additional information, refer to the CLIA website at <http://www.cms.gov/CLIA/>.

SCENARIO 1

THE MANUFACTURER'S INSTRUCTIONS STATE TO PERFORM TESTING FOLLOWING THE CLIA QUALITY CONTROL PROCEDURE REQUIREMENT (2 LEVELS OF EXTERNAL QUALITY CONTROL EACH DAY OF PATIENT TESTING).

Because the manufacturer's instructions meet the minimum CLIA quality control requirement, you do not have to perform an IQCP for CLIA purposes. However, IQCP is an option which may be used to complement your current QC program, as long as at a minimum, you follow the manufacturer's QC instructions.

SCENARIO 2

THE MANUFACTURER'S INSTRUCTIONS DESCRIBE QC FREQUENCY THAT IS LESS THAN THE CLIA CONTROL PROCEDURE REQUIREMENT (2 LEVELS OF EXTERNAL QUALITY CONTROL EACH DAY OF PATIENT TESTING).

You have a choice. Perform quality control procedures using the CLIA quality control requirements, including daily testing of two levels of external quality control materials, and also follow all specialty/subspecialty requirements in the CLIA regulations for non-waived tests **or** perform an IQCP. Your quality control procedures must provide equivalent quality testing and may NOT be less than what the manufacturer requires.

An IQCP requires:

- Risk Assessment (RA)
- Quality Control Plan (QCP)
- Quality Assessment (QA)

An IQCP requires a Risk Assessment (RA) evaluation to identify errors or problems in the test process. You should use the results of your risk assessment to create a customized Quality Control Plan (QCP) and establish a Quality Assessment (QA) program to monitor whether the quality control plan ensures accurate test results. Please refer to Brochure 13 for a description of an IQCP before proceeding.



SCENARIO 3

THE MANUFACTURER'S INSTRUCTIONS DO NOT PROVIDE ANY INSTRUCTIONS FOR CONTROL PROCEDURES. WHAT DO I DO NOW TO COMPLY WITH THE CLIA REGULATIONS?

You again have a choice. Perform QC procedures using the CLIA requirement for daily testing of two levels of external control materials and also follow all specialty/subspecialty requirements in the CLIA regulations for non-waived tests **or** perform an IQCP. An IQCP permits you to design and establish control procedures which provide quality equivalent to the CLIA regulatory control procedures and best suits your testing environment, testing personnel, the test system, reagents and specimen required for testing.

NOTE: IQCP for text book procedures and Laboratory Developed Tests (LDTs) would fall under this scenario since there are no manufacturer's instructions.

MY LABORATORY IS LOCATED IN A STATE THAT HAS ITS OWN REQUIREMENTS FOR LABORATORY TESTING. WHICH REGULATIONS DO I FOLLOW?

If your state has requirements that do not allow for an IQCP option, you must follow your state requirements. For specific regulations, please contact your State Agency. A listing of State Agency CLIA contacts is found on the CLIA web site at <http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf>.

NOW THAT I HAVE MADE THE DECISION TO PERFORM AN IQCP, WHERE CAN I FIND GUIDANCE TO ASSIST ME WITH THE CREATION OF AN IQCP FOR THIS TEST SYSTEM?

There are a number of resources available in the form of official interpretive guidelines and educational materials that can be found on the CMS CLIA website. Familiarity with these resources is essential for understanding the process of performing and creating an IQCP.

WHERE CAN I FIND ADDITIONAL GUIDANCE ON IQCP?

For the most current information and additional brochures on IQCP, please visit the CLIA website at <http://www.cms.gov/CLIA/>

CONSIDERATIONS FOR DEVELOPING AN INDIVIDUALIZED QUALITY CONTROL PLAN (IQCP)

This flowchart depicts the scenarios described in Brochure #12

