



Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C-13-59-CLIA

DATE: August 30, 2013

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Release of Clinical Laboratory Improvement Amendment's (CLIA) Brochure #11, CLIA Individualized Quality Control Plan Introduction

Memorandum Summary

Announcement: The CLIA Brochure #11, CLIA Individualized Quality Control Plan Introduction is now available on the CLIA website.

Introduction:

This brochure provides basic information on CLIA's new quality control option called Individualized Quality Control Plan (IQCP). This new option will be the alternative CLIA quality control (QC) that provides equivalent quality testing to meet the CLIA regulations for nonwaived tests.

The brochure can be found on the CLIA website: http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Brochures.html. State and Regional CLIA surveyors are requested to direct laboratories to the CLIA brochures website upon request.

Brochure Highlights:

- IQCP will offer laboratories flexibility in achieving QC compliance with current test systems. It also provides the ability to adapt to new and future technologies while still meeting CLIA requirements.
- IQCP applies to all non-waived testing performed in the laboratory, including existing and new test systems.
- All CLIA specialties and subspecialties are eligible for IQCP except Pathology.
- IQCP is voluntary.

- The laboratory director will be responsible for implementing and approving IQCP procedures in the laboratory.

If you have any questions regarding this memo, please direct them to the IQCP mailbox, IQCP@cms.hhs.gov.

Effective Date: The brochure attached to this memorandum is available immediately. Its availability should be shared with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/

Thomas E. Hamilton

Attachment: CLIA Brochure #11, CLIA Individualized Quality Control Plan - Introduction

A photograph showing two scientists in white lab coats and safety glasses looking through a compound light microscope. The scientist on the left is in sharp focus, while the one on the right is slightly blurred. They are both looking intently at the microscope's eyepiece.

CLIA

INDIVIDUALIZED QUALITY CONTROL PLAN

INTRODUCTION

THE FUTURE IS NOW

This brochure provides information on the Clinical Laboratory Improvement Amendment's (CLIA) new quality control option called Individualized Quality Control Plan, also known as IQCP. Your laboratory will now have the opportunity to tailor a quality control (QC) plan that is customized to your unique testing environment. IQCP offers your laboratory flexibility in achieving QC compliance with your current test systems. It also gives you the ability to adapt to new and future technologies while still meeting CLIA requirements.

So let's get started and find out a little more about IQCP...

WHAT IS IQCP?

IQCP stands for Individualized Quality Control Plan and is the alternative CLIA quality control (QC) option that will provide for equivalent quality testing to meet the CLIA regulations for nonwaived tests. IQCP will include many practices that your laboratory already engages in to ensure quality testing, not just the frequency and number of QC materials.

IQCP considers the entire testing process: pre-analytic, analytic and post analytic; thus, your laboratory will need to consider the corresponding risks in each of these phases and applicable regulatory requirements.

I'VE ALWAYS FOLLOWED MANUFACTURER'S INSTRUCTIONS FOR THE TESTS PERFORMED IN MY LABORATORY. WILL I NEED TO DO ANYTHING DIFFERENTLY?

Review the manufacturer's instructions for control procedures. If the manufacturer's instructions are absent or less stringent than the CLIA QC requirements (perform two levels of quality control each day of patient testing) then you must decide whether to implement the CLIA QC requirements or develop an IQCP. Performing an IQCP may allow laboratories to continue QC practices for nonwaived tests that meet manufacturer's instructions but are less stringent than CLIA QC requirements. You may have already acquired useful information, knowledge and experience in the performance of your test that would assist in the development of your IQCP. Contact the manufacturer for additional data that may help you develop an IQCP. If the manufacturer's instructions are equal to or more stringent than the CLIA QC requirements, then you will not need to do anything differently.



DOES THIS APPLY TO ALL TESTS I PERFORM OR JUST NEW TESTS THAT I SET UP IN MY LABORATORY?

IQCP applies to all nonwaived testing performed, including existing and new test systems. All CLIA specialties and subspecialties are eligible for IQCP except Pathology.

WILL I STILL NEED TO ESTABLISH PERFORMANCE SPECIFICATIONS AND VERIFY NEW TESTS?

Yes, this requirement is still the same. For additional information, see CLIA brochure #2 “Verification of Performance Specifications” on the CLIA website at www.cms.hhs.gov/clia.

DO I HAVE TO USE THIS IQCP APPROACH?

IQCP is voluntary. However, if you do not participate in IQCP, your laboratory must perform 2 levels of external controls on each test system for each day of testing and also follow all specialty/subspecialty requirements in the CLIA regulations for nonwaived tests.

IF I'M CURRENTLY PERFORMING EQUIVALENT QUALITY CONTROL (EQC) ON SOME OF MY TESTS, WILL I BE ABLE TO CONTINUE TO USE THIS APPROACH?

You can continue to perform EQC during the educational and transition period, but at the end of that period, you may no longer use the EQC approach. You may build on your existing quality practices and use the information, knowledge and experience gained from your EQC study as some of the resources for establishing the IQCP.

MY LABORATORY IS ACCREDITED AND HAS A CERTIFICATE OF ACCREDITATION (COA). AM I ABLE TO PARTICIPATE IN CLIA IQCP?

Your Accreditation Organization (AO) has had an opportunity to review and comment on IQCP during its development. It is their option to meet or exceed the requirements of IQCP. It is best to stay up to date with any information from your AO and continue to follow its laboratory accreditation requirements.



WILL IQCP REDUCE THE AMOUNT OF CONTROLS THAT I HAVE TO PERFORM WITH MY LABORATORY TESTING?

This new QC protocol will not necessarily reduce your QC requirements, but instead, will allow you to develop customized QC for your laboratory specific to your environment, patients, personnel, test systems, etc., in order to provide reliable and accurate patient testing.

HOW WILL THIS AFFECT MY RESPONSIBILITIES AS LABORATORY DIRECTOR?

As a laboratory director, your regulatory responsibilities do not change. You are responsible for implementing and approving IQCP procedures in your laboratory.

WHAT DOES THE TERM “EDUCATIONAL AND TRANSITION PERIOD” MEAN?

There will be an educational and transition period to allow laboratories time to learn about and implement IQCP. Until you are notified, you may continue to do what you are presently doing for QC.

WHERE CAN I FIND MORE INFORMATION ON CLIA IQCP?

Information and guidance to laboratories can be found on the CLIA website www.cms.hhs.gov/clia. Please check this website to stay current on all CLIA information.



NOTE: On January 24, 2003, the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare & Medicaid Services (CMS) published final laboratory regulations (CLIA) that became effective April 24, 2003. A summary of the updated requirements are included in this brochure. However, this brochure is not a legal document. The official CLIA program provisions are contained in the relevant law, regulations and rulings. For more complete information, you may access the regulations on the Internet at <http://www.phppo.cdc.gov/CLIA/regs/toc.asp>