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Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C-15-15-CLIA

DATE: **December 19, 2014**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Release of Clinical Laboratory Improvement Amendment's (CLIA) Brochure #12, "Considerations When Deciding to Develop an IQCP" and Brochure #13, "What is an IQCP?"

Memorandum Summary

This memorandum announces the release of CLIA Brochure #12, *Considerations When Deciding to Develop an IQCP* and Brochure #13, *What is an IQCP?* These brochures will available on the CLIA website.

Background

These brochures are part of a series that provides basic information on CLIA's quality control option called Individualized Quality Control Plan (IQCP) that provides equivalent quality testing to meet the CLIA regulations for nonwaived tests.

These brochures are located 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 #12 Highlights:

- This brochure includes information that may be necessary before a clinical laboratory makes the decision to perform an IQCP.
- Scenarios are included to assist the reader with his/her decision making process in determining what quality control procedures to use for their current test systems.
- An easy to follow flow diagram accompanies the scenarios and illustrates the decision making process.

Brochure #13 Highlights:

- Section 1: Risk Assessment (RA) identifies RA components, resources and sources of error. This section also addresses what to do with the results of an RA.

- Section 2: Quality Control Plan (QCP) reviews details to consider when developing a QCP as well as responsibility for review and approval.

- Section 3: Quality Assessment (QA) addresses how to identify and select quality monitors that ensure problems can be identified as well as minimize the frequency of their occurrence.

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

Effective Date: 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

Attachments: (2)
CLIA Brochure #12, CLIA IQCP, Considerations When Deciding to Develop an IQCP
CLIA Brochure #13, CLIA ICQP, What is an IQCP?

cc: Survey and Certification Regional Office Management
Regional Office CLIA Surveyors

NOVEMBER 2014

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?

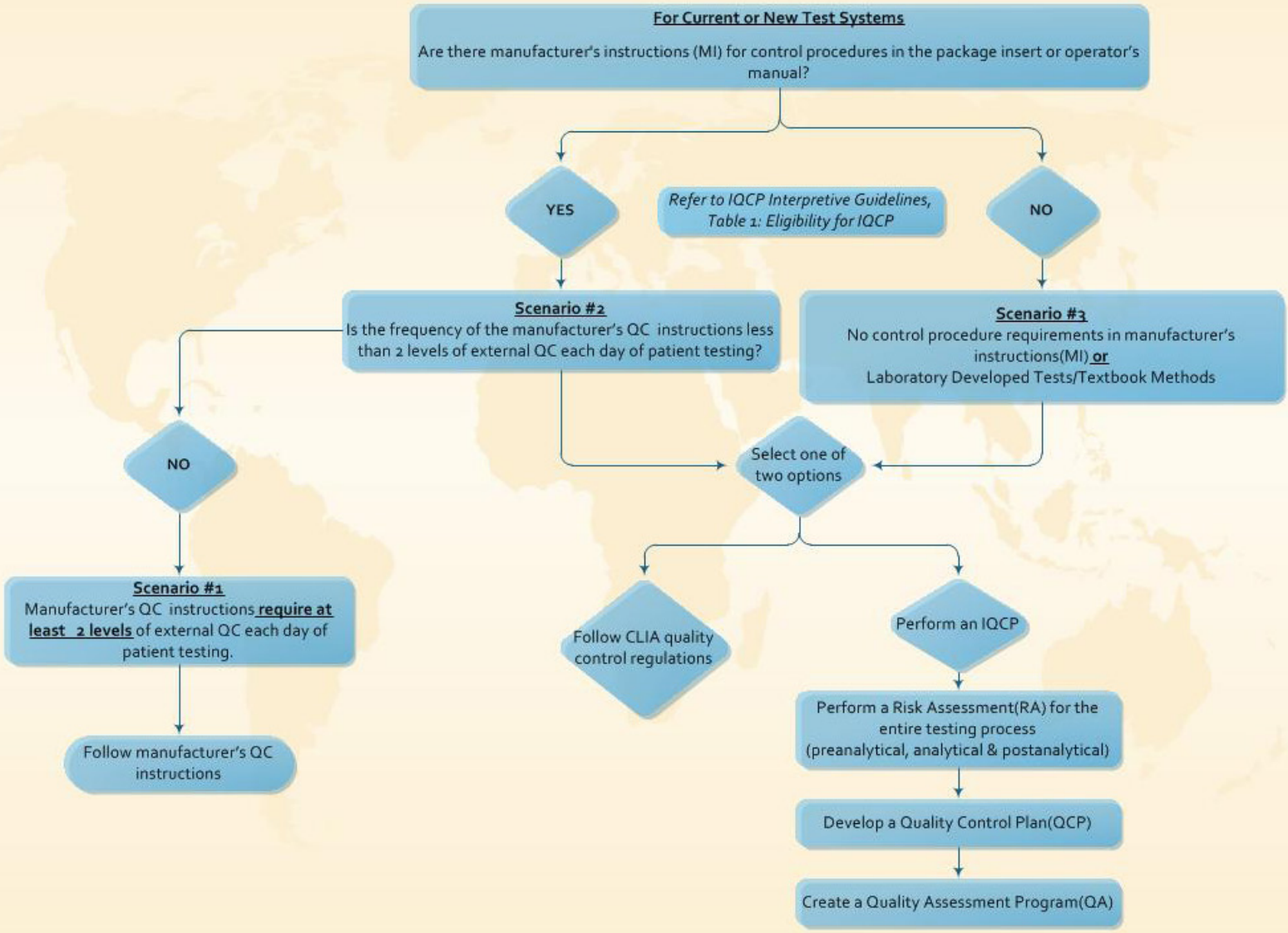
There are a number of resources available in the form of official interpretive guidelines and educational materials that can be found on the CMS CLIA website. Familiarity with these resources is essential for understanding the process of performing and creating an IQCP.

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



NOVEMBER 2014

CLIA INDIVIDUALIZED QUALITY CONTROL PLAN

WHAT IS AN IQCP?

OVERVIEW

Discovering, Deciphering and Designing an Individualized Quality Control Plan (IQCP)

IQCP provides a framework for customizing a quality control (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.

What are the parts of an IQCP?

An IQCP requires:

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

SECTION 1:

IQCP RISK ASSESSMENT

WHAT IS RISK ASSESSMENT (RA?)

Risk Assessment is the means of identifying and evaluating potential problems or errors that may occur in your testing process. The testing process begins with the specimen collection (preanalytic) and continues through the analysis of the specimen (analytic) until the final test result is reported (postanalytic).

WHAT ARE THE COMPONENTS OF A RISK ASSESSMENT (RA)?

There are five components you must evaluate in your Risk Assessment (RA):

- ***S***pecimen
- ***T***est System
- ***R***eagents
- ***E***nvironment
- ***T***esting Personnel

Consider the potential errors that might be attributable to these five components in your testing process.

NOTE: You must evaluate these five components when performing your RA. However, you may identify additional risk factors to consider and are not limited to just these five components.

WHERE CAN I FIND RESOURCES FOR INFORMATION FOR CONDUCTING A RA?

The following list contains possible sources of information for conducting a risk assessment:

- Regulatory requirements
- Manufacturer's package insert (including intended use, limitations, environmental requirements, QC frequency, specimen requirements, reagent storage, maintenance, calibration, interfering substances, etc.)
- Manufacturer's operator manual
- Troubleshooting guide
- Manufacturer's alerts and bulletins
- Verification or establishment of performance specifications
- Testing personnel qualifications, training, and competency records
- QC data
- Proficiency testing data
- QA information, including corrective action
- Scientific publications
- Other information as appropriate

WHAT ARE SOME POTENTIAL SOURCES OF ERROR FOR THE FIVE RA COMPONENTS?

To discover those unique features of your program, and decipher what their impact is in your laboratory, below is a general list of potential sources of errors. As you review this chart, ask yourself:

- What are the chances of this error happening?
- Is there a step in the process that helps reduce the chance of an error?
- If not, how do I minimize or reduce the likelihood that this error could occur anywhere in the testing process?

Potential Sources of Error for the five Risk Assessment Components

SPECIMEN

- Patient preparation
- Specimen collection
- Specimen labeling
- Specimen storage, preservation, and stability
- Specimen transportation
- Specimen processing
- Specimen acceptability and rejection
- Specimen referral

TEST SYSTEM

- Inadequate sampling
- Clot detection capabilities
- Capabilities for detection of interfering substances (e.g., hemolysis, lipemia, icterus, turbidity)
- Calibration associated issues
- Mechanical/electronic failure of test system
- Optics
- Pipettes or pipettors
- Barcode readers
- Failure of system controls and function checks
- Built-in procedural and electronic controls (internal controls)
- External or internal liquid quality control (assayed vs. unassayed)
- Temperature monitors and controllers
- Software/Hardware
- Transmission of data to LIS
- Result reporting

REAGENT

- Shipping/Receiving
- Storage condition requirements
- Expiration Date (may differ based on storage requirements)
- Preparation

ENVIRONMENT

- Temperature
- Airflow/ventilation
- Light intensity
- Noise and vibration
- Humidity
- Altitude
- Dust
- Water
- Utilities (Electrical failure/power supply variance or surge)
- Space

TESTING PERSONNEL

- Training
- Competency
- Education and experience
- Staffing

Footnote: The above list of risk factors is not all-inclusive. You may find more factors in your laboratory needing assessment.

IS THERE A SPECIFIC FORMAT SUCH AS A PROCESS MAP, DIAGRAMS, ETC. THAT MY LABORATORY SHOULD USE WHEN DEVELOPING AN IQCP?

CLIA does not require the use of any specific tools or format in the development of an IQCP.
CLIA is not prescriptive as to what tools or resources are to be used for a laboratory to meet the regulatory requirements of IQCP. It is the responsibility of the laboratory director to determine how to meet these requirements, i.e. acceptable tools, resources. The new IQCP option gives laboratories the flexibility to determine the appropriate tool(s) for their test system and environment.

WILL I NEED TO PERFORM ALL NEW STUDIES TO GATHER DATA/INFORMATION FOR THE RA AND THE DEVELOPMENT OF THE QCP FOR EXISTING TESTS IN MY LABORATORY?

Much of the data/information needed by your laboratory to perform the RA for each test will most likely be data that has been accumulated in the process of routine operations in the laboratory while meeting CLIA regulations and implementing quality systems. For example, verification of manufacturer's performance specifications, QC performance, maintenance records, and documents of corrective actions taken can all be used in your RA. You must have data that demonstrates the stability of the test system and supports the QC type and frequency in the QCP.

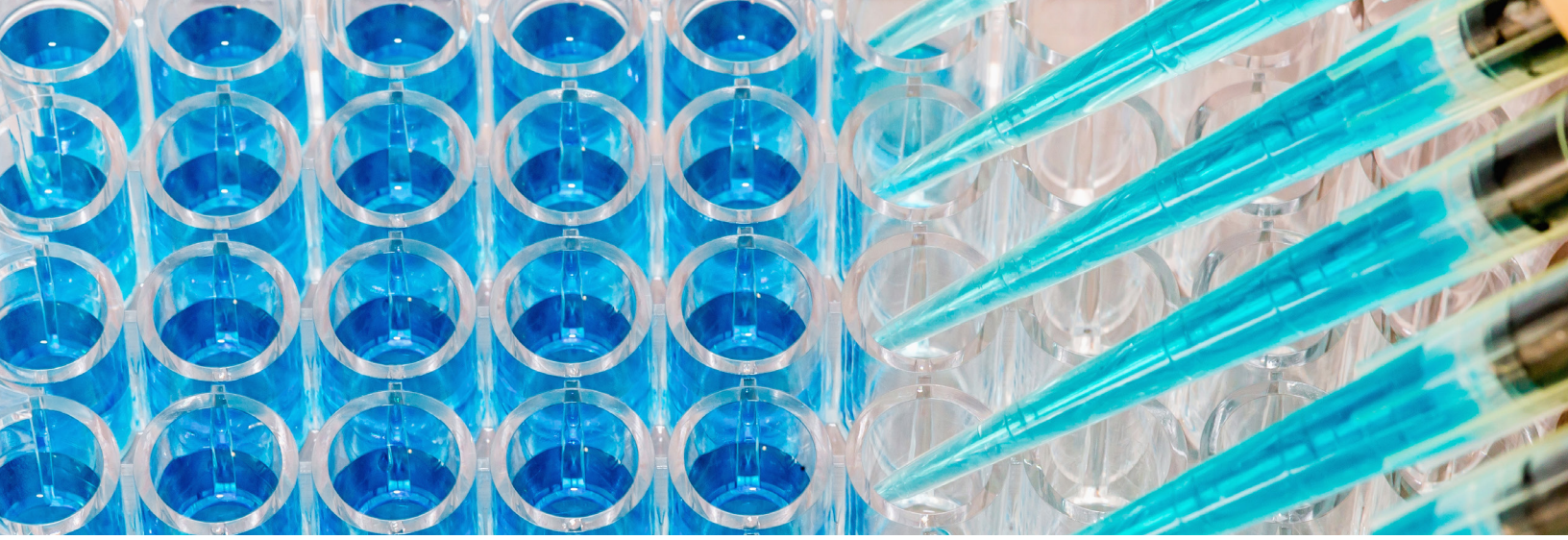
I HAVE SEVERAL DEVICES IN MY LABORATORY THAT ARE IDENTICAL. THEY ARE THE SAME MAKE AND MODEL NUMBER AND ARE LOCATED AT DIFFERENT SITES, BUT ARE UNDER THE SAME CLIA CERTIFICATE. HOW DOES THIS AFFECT MY IQCP FOR ALL OF THESE DEVICES?

The RA will be performed for the test system. Any variables of the five components should be taken into consideration when conducting the RA, e.g., education and experience of the testing personnel, environment, and use of the test system.

The QCP applies to the individual device. It is your laboratory's choice whether to have one QCP which includes all of the sites or individual QCPs for each site. Each device must be monitored in some way, as well as each location. Data must indicate that the QC established for each device is acceptable.

I HAVE COMPLETED THE RA. WHAT DO I DO WITH THE RESULTS OF MY RA?

Now that you have completed the RA, determine whether these identified risks need to be monitored or controlled regularly in the testing process or if they may already be addressed by the manufacturer in the design of the test system. This information will help you in developing your QCP.



SECTION 2:

IQCP QUALITY CONTROL PLAN

WHAT SHOULD I CONSIDER WHEN CREATING A QUALITY CONTROL PLAN (QCP)?

A strong, well-documented QCP will establish control procedures that reduce the likelihood of providing an inaccurate patient test result. Your QCP must at least include the number, type and frequency of testing and criteria for acceptable result(s) of the quality control(s). Your data must support the rationale for the number, type and frequency of testing. It's possible that you may find your customized QCP will be less than the CLIA control requirements, but more than the manufacturer's instructions for controls. However, at a minimum, your QCP must not be less stringent than the manufacturer's instructions for testing QC. The QCP may also describe the use of electronic controls, procedural controls, training and competency assessment and all other QC activities.

DOES MY LABORATORY DIRECTOR HAVE TO REVIEW, APPROVE AND SIGN THE QCP?

Yes, it is the responsibility of the laboratory director to review, sign and date the QCP before patient testing begins and results are reported. 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.

CAN ONE QCP ADDRESS MULTIPLE TEST PROCEDURES IF ALL TESTS ARE PERFORMED IN THE SAME MANNER?

For those cases in which similar methodologies are used, it is likely that some potential sources of error will be similar, while others will be unique to each test. Therefore, you must perform the RA and develop a QCP for each individual test system. The QCPs for these test systems may, or may not, be included in one QCP. The QCP must at least include the number, type, frequency of testing and criteria for acceptable result(s) of the quality controls(s).

CAN MY LABORATORY CHOOSE TO USE IQCP FOR SOME ANALYTES ON A PLATFORM AND NOT OTHERS?

Yes, you can choose to use IQCP for some or all of your test systems. However, you should indicate which test(s) use IQCP in your QCP.

SECTION 3:

IQCP QUALITY ASSESSMENT

HOW DO I IDENTIFY AND SELECT QUALITY MONITORS FOR A QUALITY ASSESSMENT (QA)?

Quality control records are a great place to start; but, you are not limited to just these records. Other documents may include:

- Proficiency testing records (test score, testing failures, trends),
- Patient results review,
- Specimen rejection logs,
- Turnaround time reports,
- Records of preventive measures,
- Corrective actions and follow-up and,
- Personnel competency records.

You may also create specific monitors, unique to the test system, that answer how often or how many times (within a time period for example) did a particular error occur? You are not limited to the number of monitors used to verify the continued performance of a testing process. Good monitors ensure that you continue to identify and minimize problems and that accurate test results are being reported. Keep in mind that your QA monitors may indicate a need to reevaluate the effectiveness of your 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/***