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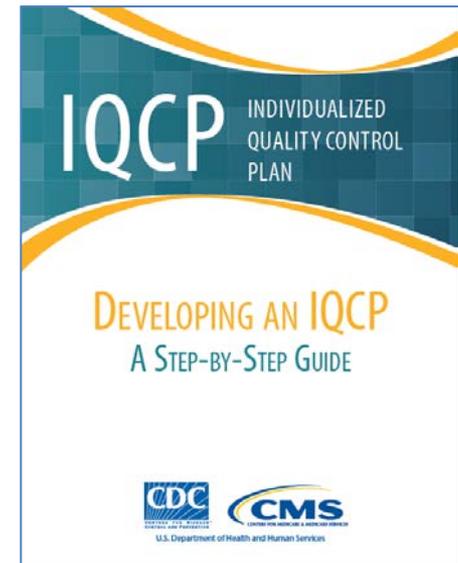
Developing an IQCP A Step-By-Step Guide

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Learning Objectives

- Become familiar with IQCP educational materials
- Recognize the parts of a complete IQCP
- Use example scenario and forms in the IQCP Workbook to create a customizable IQCP for your laboratory

S&C-13-54-CLIA

Published on August 16, 2013

S&C memo#13-54-CLIA Package

- Attachment 1: IQCP Interpretive Guidelines

Education and Transition Period

Jan 01, 2014 – Dec 31, 2015

- Time to learn about IQCP
- Identify any test systems that would qualify for IQCP
- Implement IQCP
- Recognized need for educational material
 - Brochures
 - Workbook

Educational Tools

- FAQs for IQCP
- Brochure #11 (July 2013)
 - CLIA Individualized Quality Control Plan: An Introduction
- Brochure #12 (November 2014)
 - CLIA Individualized Quality Control Plan: Considerations When Deciding To Develop an IQCP
- Brochure #13 (November 2014)
 - CLIA Individualized Quality Control Plan: What is An IQCP?
- IQCP Workbook (May 2015)
 - Developing an IQCP; A Step-by-Step Guide

Brochure 11 Individualized Quality Control Plan- Introduction

- What is IQCP?
- Do I have to use this IQCP approach?
- If I am currently performing EQC, do I have to use this approach?
- Will IQCP reduce the amount of controls that I have to perform with my laboratory testing?
- How will this affect my responsibilities as Laboratory Director?

Brochure 12 IQCP Considerations When Deciding to Develop an IQCP

- How do I decide if I even need an IQCP?
- Manufacturer's instructions for testing Quality Control
 - Meet or exceed CLIA requirements, or
 - Less frequent than CLIA requirements
- Examples of 3 scenarios
 - Describe what the manufacturer instructions say and how they relate to CLIA
- Flowchart: visual representation of the 3 scenarios

Brochure 13 - What is an IQCP?

- Risk Assessment (RA)
 - 5 components
 - Resources
 - Potential sources of error
- Quality Control Plan (QCP)
 - Strong, well documented plan provides quality test results
 - Number, Type and Frequency
 - Comprehensive to include electronic controls, procedural controls, training and competency assessment
- Quality Assessment (QA)
 - Monitoring QCP

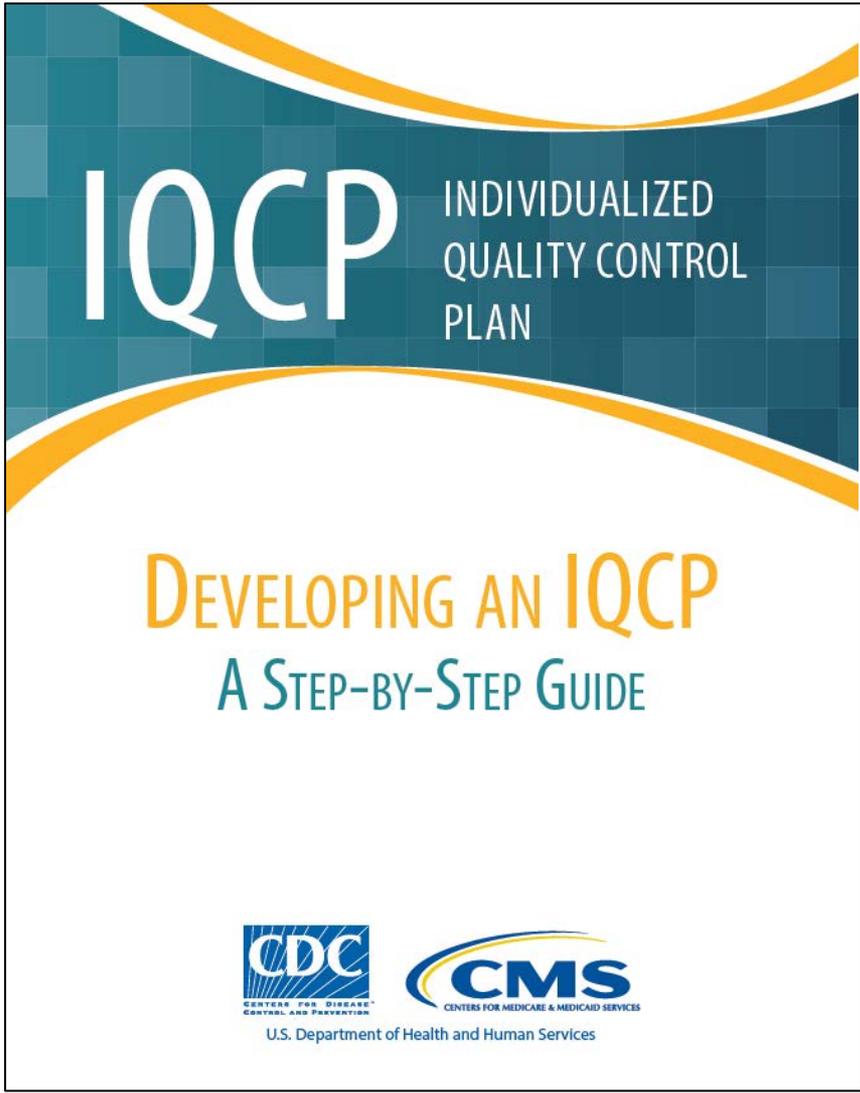
IQCP Workbook

Developing an IQCP; A Step-by-Step Guide

- Assists a laboratory with developing a *customized* IQCP for one or more test systems
- Incorporates an example scenario and forms
- Documentation of a complete IQCP: RA, QCP, QA



Navigating the Workbook



3+3+5

Three Steps of Developing an IQCP

- Risk Assessment
- Quality Control Plan
- Quality Assessment

Three Phases of the Testing Process

- Preanalytic
- Analytic
- Postanalytic

Five Risk Assessment Components

- Specimen
- Test System
- Reagent
- Environment
- Testing Personnel

Step 1: Risk Assessment

- Gather your resources
- Determine what you are already doing- what is happening in your laboratory

Gather the supporting data for your laboratory and record your findings below.



- Identify potential sources of error

Do you see a potential risk of an error in test results if:	Answer
<i>The manufacturer's instructions for specimen requirements including, but not limited to, specimen tube or container type, patient preparation, or specimen storage are not followed?</i>	Yes ___ No ___
<i>The current version of the manufacturer's instructions is not used?</i>	Yes ___ No ___
<i>The specimen is improperly labeled?</i>	Yes ___ No ___
<i>The specimen isn't accurately identified throughout the testing process?</i>	Yes ___ No ___
<i>Criteria for specimen rejection are not established and followed?</i>	Yes ___ No ___

WHAT IS HAPPENING IN MY LABORATORY?

The following is an example scenario for you to refer to throughout this workbook. The example is based on a fictitious laboratory and test system. It contains information about the laboratory, test system, and other pertinent information the laboratory has or can acquire in order to develop and implement an IQCP.

Scenario

Dr. Martin is the laboratory director for the Happy Day Physicians Group. She is considering implementing an IQCP for her laboratory. To determine if IQCP is a good option for Happy Day Physicians Group's laboratory to meet CLIA QC requirements, Dr. Martin has asked her laboratory supervisor, Kim, to take the lead in performing a risk assessment.

Kim decided to evaluate the test for magnesium performed on the Acme Chemotric System-Magnesium because the manufacturer's instructions recommended performing external QC less frequently than required by CLIA. She gathered supporting data to review what her laboratory is currently doing to reduce potential sources of error.

Supporting Data

- ✓ Test system is FDA cleared and moderate complexity under CLIA
- ✓ Laboratory follows the CLIA regulatory requirements for QC - two control materials of different concentration each day of patient testing
- ✓ Acme Chemotric System-Magnesium **package insert includes:**
 - Specimen collection time and collection tube requirements
 - Limitations of the test
 - Criteria for acceptable results
 - Use of an internal control process that performs internal QC on every reagent disc
 - Recommendations for performing external controls at least every 30 days; when there is a significant change in laboratory conditions; training or retraining of personnel is indicated; or when test results do not match patient symptoms or clinical findings
- ✓ Two years of successful PT performance reports
- ✓ Test performance specification verification studies demonstrating the test system's accuracy and stability
- ✓ **Specimen** - Review of specimen receipt logs for the past two years demonstrates gaps in documentation when requesting re-collection of specimens.

- ✓ **Instrument maintenance (Test System)-**
 - Review of instrument maintenance logs show no problems with test system's instrument mechanics for the past two years
 - Review of patient test results and two levels of external QC results for the past two years demonstrates no problems with the test system. QC outliers were resolved with corrective actions.
 - Review of troubleshooting logs demonstrate no indication of problems with the test system or patient results reporting for the past two years
- ✓ **Reagent**- Review of lot-to-lot reagent logs demonstrates no problems or indications of problems for past six months
- ✓ **Environment:**
 - **Room temperature logs**- Review of temperature logs demonstrates no problems with temperature for past year
 - **Refrigerator and freezer temperature log**- Review demonstrates minimal outlier temperature points with investigation and appropriate corrective action for the past year
- ✓ **Testing personnel training and competency** – Review of personnel training records for the past two years demonstrates no personnel turnover.

*NOTE REGARDING SUPPORTING DATA: Support your risk assessment with available data that include, but are not limited to, test performance specifications, manufacturer's package inserts, PT performance data, QC logs/data, specimen receipt and rejection logs, to determine a QC plan that will reduce potential sources of error.

Now let's review your supporting data

Gather the supporting data for your laboratory and record your findings below.



Your Risk Assessment

STEP 1: RISK ASSESSMENT

ASSESSING THE SPECIMEN RISKS



"Let's talk about the specimen..." Review the manufacturer's instructions, technical bulletins, your policies and procedures, patient instructions, and any other documents associated with the specimen. As you review these documents, stop and think about when and where in the testing process a potential error associated with the specimen may occur.

Specimen Scenario

Let's take a closer look at how Happy Day Physicians Group identified sources of error for the risk assessment component, specimen.



Kim reviewed the specimen receipt logs for the past two years and noted that, according to the laboratory's policy, not all personnel had properly documented requests for re-collection of specimens. Additionally, Kim noted some specimens remained unprocessed for more than 60 minutes without being properly stored.

A review of the refrigerator and freezer logs for the past year showed a few recorded temperatures outside of the acceptable range; however, they had been investigated and appropriate corrective actions were taken.

Kim identified the possible sources of error and recorded her findings in the Risk Assessment Worksheet.

Instructions needed to follow the Happy Day Physicians Group Risk Assessment Worksheets:

For each risk assessment component, Kim has gathered and reviewed the data sources and used the information to consider *"What could go wrong?"* during the entire testing process to complete the [Happy Day Physicians Group Risk Assessment Worksheets](#).

In **column 2**, Kim recorded the identified possible sources of error, and considered how these errors could be reduced.

In **column 3**, Kim indicated "yes" or "no" if there were actions the laboratory could take to reduce the sources of error.

In **column 4**, Kim recorded the actions the laboratory staff could implement to reduce the identified errors.

Note: To complete the risk assessment worksheet, consider your testing process in its entirety; from the time the order is placed, through collection, processing, analysis, and reporting (preanalytic, analytic and postanalytic processes). One of many possible examples to document your risk assessment follows. The information provided in this example should not be considered all-inclusive of potential risks, QC and QA procedures, and CLIA requirements that may apply for your laboratory.

12

Record Your Specimen Risk Assessment Questions/Findings



STEP 1: RISK ASSESSMENT

Happy Day Physicians Group Risk Assessment Worksheet

1	2	3	4
Risk Assessment Components	What are our possible sources of error? What can go wrong?	Can our identified sources of error be reduced?	How can we reduce the identified sources of error?
	Gather information, from the manufacturer's instructions and other resources, on how we should be performing the testing process.	Yes/No Not Applicable (N/A)	Indicate how to reduce possible error sources. <ul style="list-style-type: none"> Internal controls Actions taken by laboratory Safeguards in the test system or laboratory practices
SPECIMEN	Documentation of specimen re-collection. Manufacturer's instructions: <ul style="list-style-type: none"> Use lithium heparin tubes for whole blood or plasma specimens Use no additive or serum separator tubes for serum specimens 	Yes	Retrain testing personnel on re-collection policy. Train testing personnel to verify use of proper specimen collection tubes.
	Testing time frame/stability of specimen. Manufacturer's instructions: <ul style="list-style-type: none"> Whole blood - run within 60 minutes of collection Store serum or plasma in capped tubes at 2°C to 8°C for 48 hours or at -10°C for up to 5 weeks 	Yes	Train testing personnel to verify and document: <ul style="list-style-type: none"> Collection time and time of receipt in laboratory Proper storage and processing of specimen

Do you see a potential risk of an error in test results if:	Answer
The manufacturer's instructions for specimen requirements including, but not limited to, specimen tube or container type, patient preparation, or specimen storage are not followed?	Yes ___ No ___
The current version of the manufacturer's instructions is not used?	Yes ___ No ___
The specimen is improperly labeled?	Yes ___ No ___
The specimen isn't accurately identified throughout the testing process?	Yes ___ No ___
Criteria for specimen rejection are not established and followed?	Yes ___ No ___

Completing the Risk Assessment Worksheet

STEP 1: RISK ASSESSMENT

Steps to complete your laboratory's risk assessment worksheets:

After reviewing the example worksheet for each component, take **your** identified sources of error from the "Risk Assessment Questions/ Findings" for each component section, and follow the process taken by Kim to complete **your** laboratory's risk assessment worksheet.

Risk Assessment Worksheet

Laboratory Name _____ Test System Name _____

1	2	3	4
Risk Assessment Components	What are our possible sources of error? What can go wrong?	Can our identified sources of error be reduced?	How can we reduce the identified sources of error?
	Gather information, from the manufacturer's instructions and other resources, on how we should be performing the testing process.	Yes/No Not Applicable (N/A)	Indicate how to reduce possible error sources. <ul style="list-style-type: none"> • Internal controls • Actions taken by laboratory • Safeguards in the test system or laboratory practices
SPECIMEN			

Things to Remember

- You can perform a risk assessment, even if you do not intend to implement an IQCP.
- The risk assessment is a good way to identify gaps in your testing processes and will allow you to identify potential sources of error that can affect your test results.
- The risk assessment can be done at any time for any reason.
- You may perform Risk Assessments anytime your testing process or test systems change.
- The more you write down, the more likely you are to identify your gaps and sources of error.

STEP 2: QUALITY CONTROL PLAN

WHAT IS A QUALITY CONTROL PLAN?

A Quality Control Plan (QCP) describes practices, procedures and resources needed by your laboratory to ensure the quality of a testing process. The QCP includes measures to assure the accuracy and reliability of test results, and that the quality of testing is adequate for patient care.

The QCP must provide for immediate detection of errors that occur due to test system failure, adverse environmental conditions, and operator performance. It must also monitor, over time, the accuracy and precision of test performance that may be influenced by changes in the specimen, test system, reagent, environment, or variance in operator performance.

Create a plan that includes activities to reduce the likelihood of failures and errors identified from your risk assessment. Consider the amount of QC necessary based on the frequency and volume of patient testing.

NOTE: Laboratories cannot establish QC procedures that are less stringent than those specified by the manufacturer of the test system.



WHAT IS INCLUDED IN A QCP?

At a minimum, your QCP must include the number, type, and frequency of testing control materials, as well as criteria for acceptable quality control.

If indicated by the risk assessment, your QCP may also incorporate the use of:

- Electronic controls
- Equipment maintenance
- Internal controls
- Personnel training and competency assessment
- Equipment calibration
- Other specified quality control activities



Tips to Remember

- Detect Errors
 - Number, type and frequency
- Acceptability Criteria
 - Manufacturer's instructions
- Laboratory Director signature

STEP 2: QUALITY CONTROL PLAN

LET'S REVIEW

TIPS TO REMEMBER:

A complete QCP must:

- ✓ **Provide** for immediate detection of errors for each phase of the testing process (i.e. before, during, and after testing) for the test.
- ✓ **Specify** the number, type, and frequency of testing QC material(s).
- ✓ **Contain** criteria to determine acceptable QC results.
- ✓ **Require** the laboratory perform QC as specified by the manufacturer's instructions, but not less than the manufacturer's instructions.
- ✓ **Indicate** that your Laboratory Director reviewed, signed, and dated the QCP document.



If your QCP does not address all five items listed above, you do not have a QCP.

Go back and investigate what is missing.

Quality Assessment

QC ACTIVITY

VS.

QA ACTIVITY

STEP 3: QUALITY ASSESSMENT

WHAT IS QUALITY ASSESSMENT?

Quality Assessment (QA) can be described as a multi-part activity.

Monitor and Assess

The laboratory must establish and follow written policies and procedures to monitor and assess, and when indicated, correct problems identified. The monitoring should include, but is not limited to, the following risk assessment components: specimen, test system, reagents, environment, and testing personnel.

Corrective Action

The QA must also include a review of the effectiveness of corrective actions taken to resolve problems identified. The laboratory must update the risk assessment and modify the QCP, as necessary based on the information obtained from the QA.

QA vs. QC

Now that we have defined QA and before we begin to discuss QA activities, let's take a look at the differences between QC and QA activities.

Below is an example that explains the difference between a QC activity and a QA activity.

Example of a QC activity:

- ✓ Recording the room temperature on a log sheet
- ✓ Documenting controls on log sheets
- ✓ Documenting personnel training

Example of a QA activity:

- ✓ Reviewing the room temperature log sheet for problems and evidence of corrective actions
- ✓ Reviewing control documents for out of range values and corrective actions taken
- ✓ Reviewing personnel training records for completion of required trainings and competency assessments



Continuously Monitor

Risk Assessment

Quality Control Plan

Quality Assessment

STEP 3: QUALITY ASSESSMENT

LET'S REVIEW

Now that you have seen all parts of an IQCP and sample scenarios, you are ready to apply this process to your laboratory's test systems for which you choose to implement the IQCP process.

Important Points

Keep these points in mind when developing an IQCP:

- ✓ The IQCP is unique to your laboratory and is customized for your laboratory's specific testing considerations.
- ✓ The risk assessment must include the entire testing process and address all five components: specimen, test system, reagents, environment and testing personnel.
- ✓ The risk assessment should be updated to include all risk identified in your QA, as some risk originally identified may no longer apply.
- ✓ The QCP should include the number, type and frequency of testing control materials.
- ✓ The IQCP should include all activities performed to reduce your risk of failures and errors.
- ✓ The entire testing process continually evolves and the IQCP will need to be reviewed periodically to identify new sources of errors or failures.
- ✓ The QCP must be reviewed, approved, and signed by the Laboratory Director.



CLIA Survey

What does the IQCP Workbook change about the CMS process?

Nothing!



The routine outcome-oriented survey process remains the same.

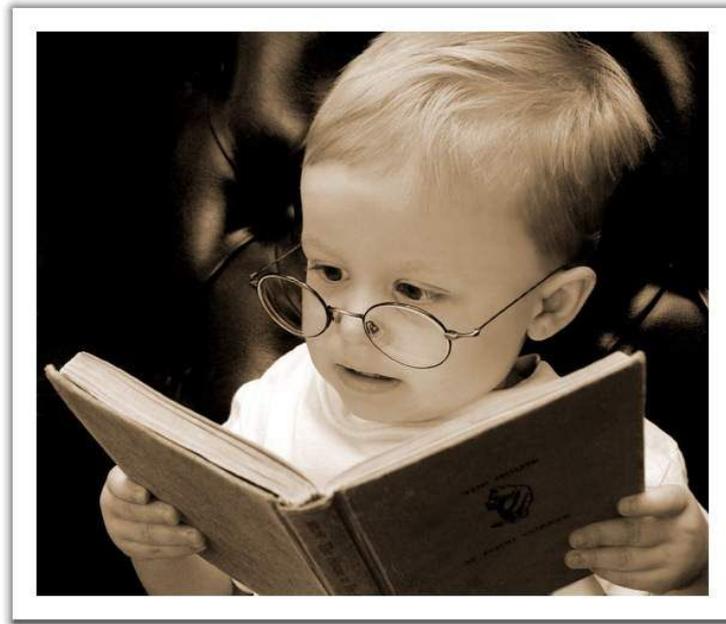
CLIA Survey

The IQCP Workbook is another tool in your laboratory's toolbox of information, that can be helpful with the IQCP process.



CLIA Survey

When a lab has used the workbook to document their IQCP...



Resources and Links

IQCP Brochures and FAQ on CLIA website:

<http://www.cms.gov/clia/>

IQCP Workbook can be downloaded at:

<http://wwwn.cdc.gov/CLIA/Resources/IQCP/>

[http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Individualized Quality Control Plan IQCP.html](http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Individualized%20Quality%20Control%20Plan%20IQCP.html)

Free hardcopies to be available by request from CDC by e-mailing iqcpworkbook@cdc.gov

Questions can be submitted to IQCP@cms.hhs.gov

Question & Answer Session

Send unanswered questions to: IQCP@cms.hhs.gov

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