Two (2) Months to Go Before IQCP Implementation: NOW WHAT?

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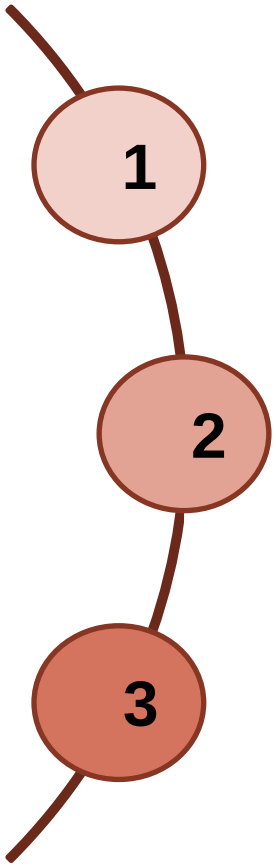
Objectives for today



1. Discuss why IQCP is a relevant QC option for selected testing
2. Describe the development process for CMS' IQCP
3. Identify unique requirements for lab's accredited by COLA, TJC, CAP

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So, It's Time to Consider IQCPs

QC Options	Now	Jan. 1, 2016
Default (2-3 levels external QC/day)		
EQC (Equivalent QC)		
IQCP (Individualized QC Plan)		

http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-54.pdf; www.cap.org; www.jointcommission.org; www.cola.org

Does IQCP development leave you feeling like this?

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Forget the Panic Button: IQCP is "*Kinder and Gentler*"

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Quick Review

Relevance of IQCP as a QC Option

- Ensures quality throughout the testing process
- Allows “customization” of QC
- Allows use of manufacturers’ built-in quality assessments to meet the required daily QC requirements
  - Avoids the default QC of 2 levels of external QC/test/day of testing
    - Can reduce daily QC to less than default, but never less than what the test manufacturer specifies

New CMS (CLIA) Approach to Quality

August 16, 2013

Individualized Quality Control Plan (IQCP): A New Quality Control (QC) Option

Effective Jan. 1, 2016

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

CMS CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 13-54-CLIA

DATE: **August 16, 2013**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Individualized Quality Control Plan (IQCP): A New Quality Control (QC) Option

Memorandum Summary

- **IQCP:** The Centers for Medicare & Medicaid Services (CMS) is implementing a new quality control option for laboratories based on risk management.
- **Interpretive Guidelines:** The IQCP Interpretive Guidelines, included with this Memorandum, contain procedures for laboratories and guidance for Regional Office (RO) and State agency (SA) surveyors.
- **Education and Transition Period:** The IQCP Education and Transition Period will begin on 01/01/2014, and conclude on 01/01/2016.
- **Training and Education:** CMS will provide IQCP training for RO and SA surveyors, and IQCP educational materials for laboratories.

Introduction

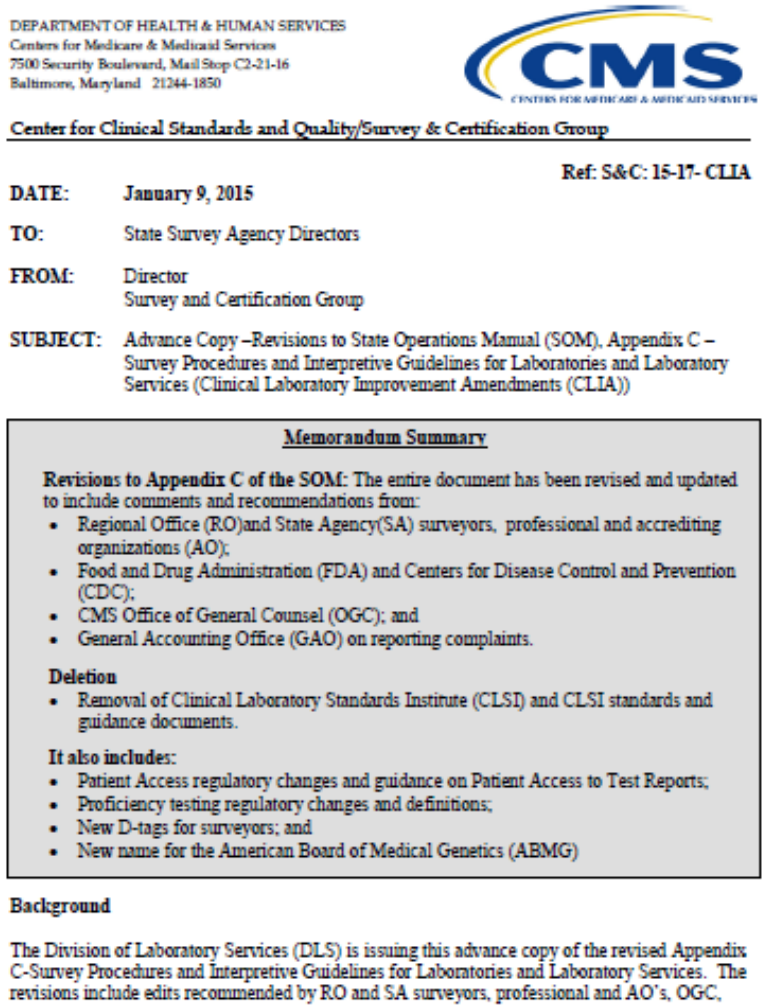
As previously communicated in S&C 12-03 CLIA and S&C 12-20 CLIA, CMS is implementing a new quality control option based on risk management, IQCP. IQCP will provide laboratories with flexibility in customizing Quality Control (QC) policies and procedures based on the test systems in use and the unique aspects of each laboratory.

IQCP is voluntary. Laboratories will continue to have the option of achieving compliance by following all Clinical Laboratory Improvement Amendments (CLIA) QC regulations as written. The laboratory director retains overall responsibility for ensuring that QC programs are established and maintained to assure the quality of laboratory services provided, and to identify failures in quality as they occur.

There will be an IQCP Education and Transition Period to allow laboratories an opportunity to learn about IQCP and implement the laboratories' chosen QC policies and procedures. Before the IQCP Education and Transition Period begins, training will be provided to CLIA surveyors.

http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-54.pdf

- *Revisions to SOM, Appendix C- Survey Procedures and Interpretative Guidelines for Laboratories and Laboratory Services (CLIA)*
- *Removal of references to CLSI standards and guidance documents (big impact on micro)*



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Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 15-17- CLIA

DATE: **January 9, 2015**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Advance Copy –Revisions to State Operations Manual (SOM), Appendix C – Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services (Clinical Laboratory Improvement Amendments (CLIA))

Memorandum Summary

Revisions to Appendix C of the SOM: The entire document has been revised and updated to include comments and recommendations from:

- Regional Office (RO)and State Agency(SA) surveyors, professional and accrediting organizations (AO);
- Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC);
- CMS Office of General Counsel (OGC); and
- General Accounting Office (GAO) on reporting complaints.

Deletion

- Removal of Clinical Laboratory Standards Institute (CLSI) and CLSI standards and guidance documents.

It also includes:

- Patient Access regulatory changes and guidance on Patient Access to Test Reports;
- Proficiency testing regulatory changes and definitions;
- New D-tags for surveyors; and
- New name for the American Board of Medical Genetics (ABMG)

Background

The Division of Laboratory Services (DLS) is issuing this advance copy of the revised Appendix C-Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services. The revisions include edits recommended by RO and SA surveyors, professional and AO's, OGC,

http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-15-17.pdf

Everyone is Onboard!

CMS (CLIA) and
Accrediting Agencies'
IQCPs

Make sure to follow the requirements appropriate for your test site

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IQCP Reminder

Is it voluntary? **Yes, UNLESS**:	• QC is *less* stringent than CLIA's (2 external QC/day of testing) • You want to use manufacturers' quality assessments to meet daily QC
What testing is eligible?	• Non-waived • All specialties *except* pathology and cytology • Used in states that allow IQCPs
What is involved?	• Risk assessment • Quality control plan • Quality assessment for ongoing effectiveness

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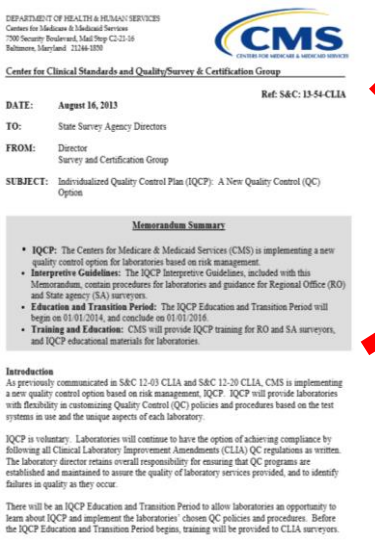
CDC/CMS IQCP Development Process



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Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 13-54-CLIA

DATE: August 16, 2013

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Individualized Quality Control Plan (IQCP): A New Quality Control (QC) Option

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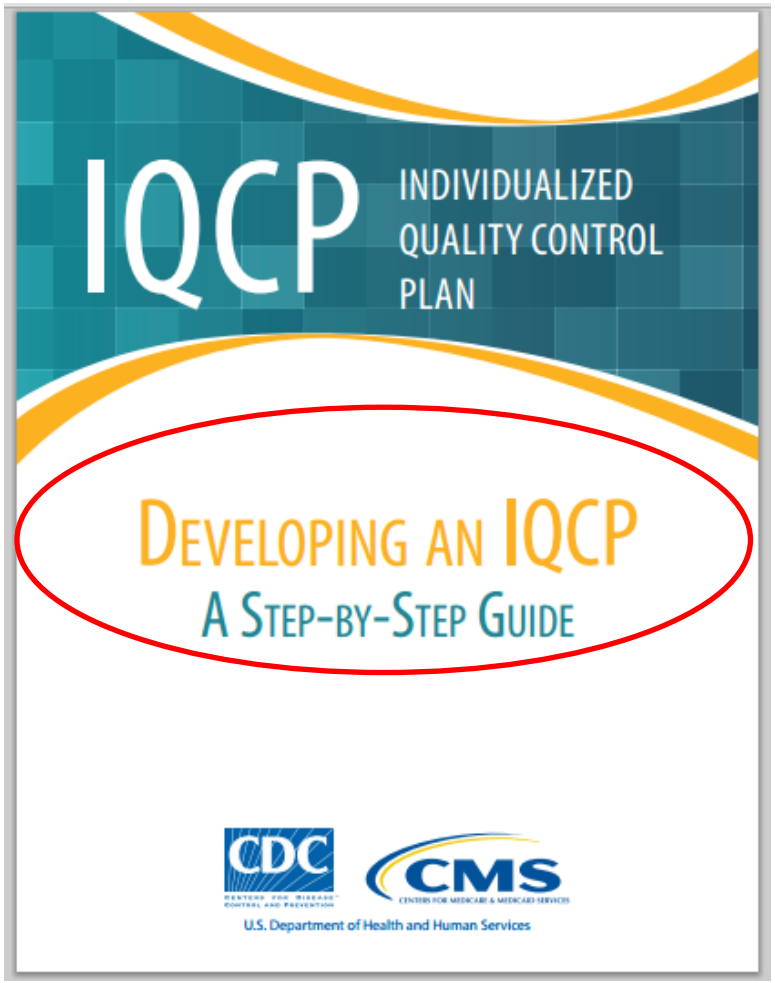
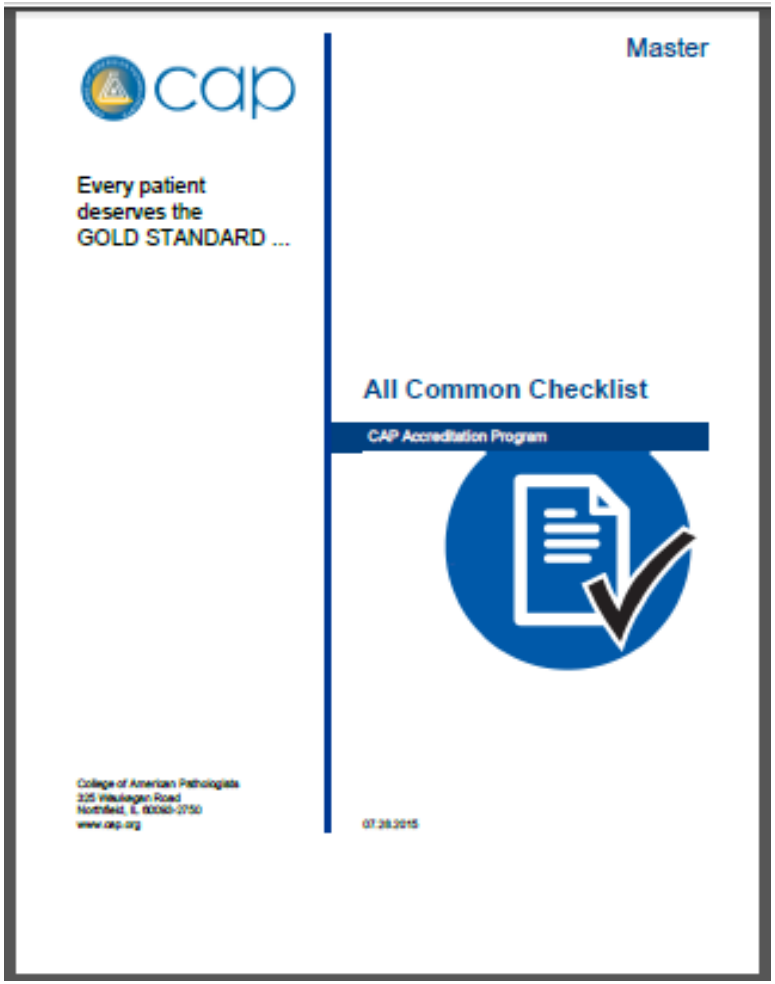


http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIAbrochure13.pdf

COLLEGE of AMERICAN PATHOLOGISTS

New checklists 7-28-15



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http://www.cap.org

CAP: Updated July 2015 Checklists

- All Common Checklist
  - New IQCP section with 5 new requirements
    - COM.50200, .50300, .50400, .50500, .50600
- Other Checklists (e.g., POCT)
  - Revisions to existing QC requirements
  - Provisions for EQC *removed*
- CAP's IQCP is more restrictive in some areas
  - Must employ internal QC, e.g., electronic, procedural, or built-in
  - Must run external QC every 30 days and with new lots and shipments
- Labs can develop their own model for IQCP

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Good CAP IQCP summary

http://www.captodayonline.com/iqcp-worries-help-ends-begins/

IQCP worries? Help with what ends and begins

Anne Paxton

July 2015—Technically, it's true: The Centers for Medicare and Medicaid Services' new program, the Individualized Quality Control Plan, is a voluntary, alternative option that clinical laboratories can use to customize their QC plans according to test method, patient population, environment, and personnel competency.

For much of the laboratory community, however, "optional" is the last word association they would make with "IQCP." What many see is an entirely new quality control framework to grapple with every day; a looming cutoff date when the old, reliable system will become extinct; and potentially a major drain on their workday time and energy to cope with unfamiliar concepts of risk assessment.

Every lab accredited by the CAP has the expertise to do a risk assessment, Dr. Gerald Hoeltge says. "But now that risk assessment will have a structure and a table behind it."

It's no wonder that, as CMS' Jan. 1, 2016 implementation date nears, some laboratory directors are considering an Ativan prescription. But as a service to CAP-accredited labs—and with the aim of keeping panic at bay—the CAP has marshaled an array of resources to ease laboratories' transition to IQCP. Already available are workbooks, algorithms, templates, lists of frequently asked questions, and other guidance from the CMS, the CAP, the Clinical and Laboratory Standards Institute, and the American Society for Microbiology. Now, the CAP Laboratory Accreditation Program has integrated IQCP requirements into the 2015 edition of the All Common Checklist, which at CAP TODAY press time was scheduled for release at the end of July.

"For those who are writing individualized plans using IQCP, the Laboratory Accreditation Program wants to provide support, and so we're offering nuts-and-bolts help," says checklist commissioner Gerald A. Hoeltge, MD. "The All Common Checklist will have a brand-new section on IQCP that will itemize all the pieces that must be in place, and you can go to the College's 'Frequently Asked Questions' page for a really clear preview of what you'll need to do."

There's really nothing mandatory about IQCP, Dr. Hoeltge emphasizes. "Labs can continue to do the traditional two controls each day of testing. But we're getting toward the end of the transition period, and more labs are going to be thinking about IQCP and working toward it."

IQCP's downside is undeniable. Establishing an IQCP in a laboratory involves a significant amount of work compared with what was required to implement the Equivalent Quality Control (EQC) program as developed by CLSI, says Adrienne Malta, MT(ASCP), MBA, senior manager of inspection services for the College.

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Make sure the IQCP is inspection ready!

Inspector Instructions:

- Policies and procedures for the implementation of an IQCP
- Sampling of IQCP records with emphasis on tests with IQCPs implemented in the past two years for the following:
  - Risk assessment, including laboratory data and summary of findings
  - Manufacturer's product inserts and published data
  - Signed quality control plan defining all aspects monitored
  - Ongoing quality assessment monitoring records for QC, instrument/ equipment maintenance and function checks, complaints, errors, and corrective actions
  - Reassessment of quality control plan at least annually

If an IQCP is in use, the laboratory is required to complete the following forms provided by the CAP and provide a copy to the inspector:

- List of Individualized Quality Control Plans by Instrument/Device/Test - identifies all tests, instruments and devices using an IQCP
- Individualized Quality Control Plan Summary - provides key information on implementation and monitoring of the IQCP

Use the completed forms to identify an appropriate sampling of records to review.

Sampling of IQCP records to include: 1) a mix of manual and automated tests using an IQCP in the last two years; 2) a mix of tests using an IQCP where there are variations in the testing environment, personnel, multiple testing devices, etc.; and 3) a mix of tests using an IQCP that have had recurring problems with proficiency testing, quality control, instrument failure, errors, or physician complaints.

- What sources of information are used to perform a risk assessment prior to IQCP implementation?
- What steps were taken to ensure that tests already in place with internal quality control processes for daily QC (e.g. equivalent quality control) are in compliance with the IQCP requirements?
- How is the ongoing assessment of the IQCP quality control plan performed?
- How are physician complaints about the validity of test results for tests using an IQCP handled?
- What is the process to review errors for tests using an IQCP?
- Have there been any adverse patient events related to a test using an IQCP?

- Review an IQCP and confirm that all elements of the quality control plan are being monitored
- Review an IQCP that is shared by more than one testing location to verify that the risk assessment included an evaluation of each site or location and that each location is monitored as defined in the IQCP
- Review IQCP risk assessment summary, supporting data and approved quality control plan to confirm that the plan was approved by the laboratory director prior to implementation
- Review ongoing quality assessment data and error/incident logs to confirm that effective corrective actions have been taken

Accreditation Agencies

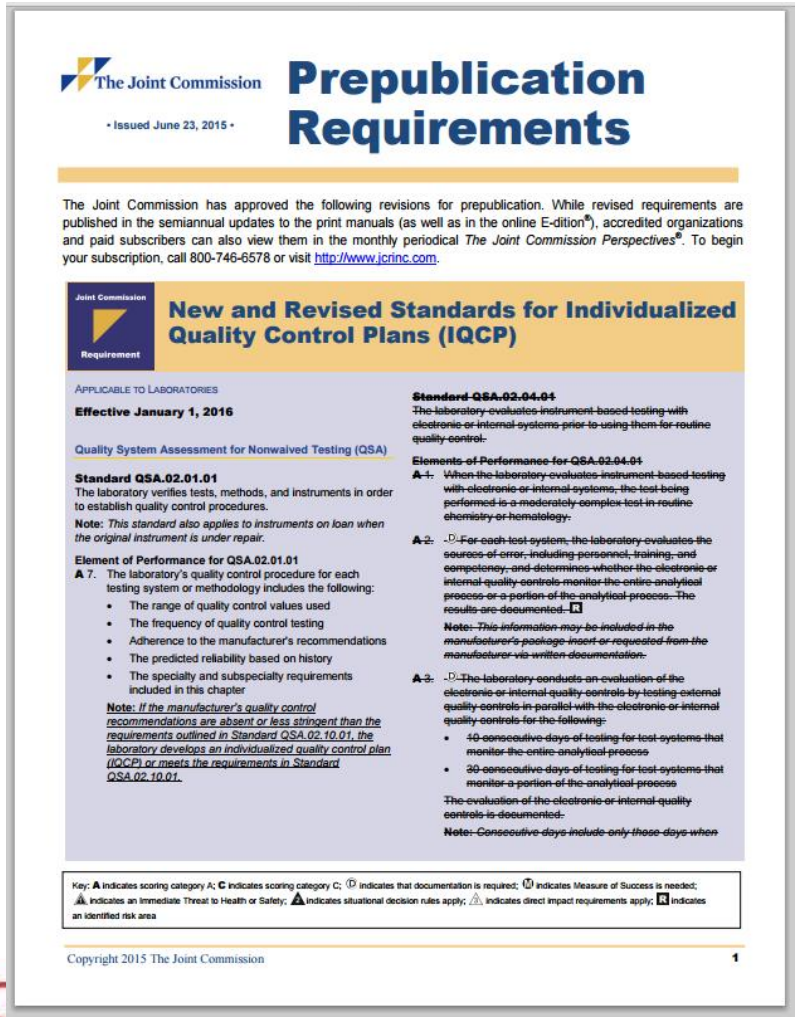
Quality Control

Like the CLIA requirements, COLA laboratories must establish a QC program for all tests performed in the lab.

COLA, like CLIA, now allows ***Individualized Quality Control Plans (IQCP)***

See **QC 31** and associated criteria.

The Joint Commission



The Joint Commission

• Issued June 23, 2015 •

Prepublication Requirements

The Joint Commission has approved the following revisions for prepublication. While revised requirements are published in the semiannual updates to the print manuals (as well as in the online E-dition®), accredited organizations and paid subscribers can also view them in the monthly periodical *The Joint Commission Perspectives®*. To begin your subscription, call 800-746-6578 or visit http://www.jcrinc.com.

Joint Commission Requirement

New and Revised Standards for Individualized Quality Control Plans (IQCP)

APPLICABLE TO LABORATORIES

Effective January 1, 2016

Quality System Assessment for Nonwaived Testing (QSA)

Standard QSA.02.01.01
The laboratory verifies tests, methods, and instruments in order to establish quality control procedures.

Note: *This standard also applies to instruments on loan when the original instrument is under repair.*

Element of Performance for QSA.02.01.01

A 7. The laboratory's quality control procedure for each testing system or methodology includes the following:

- The range of quality control values used
- The frequency of quality control testing
- Adherence to the manufacturer's recommendations
- The predicted reliability based on history
- The specialty and subspecialty requirements included in this chapter

Note: *If the manufacturer's quality control recommendations are absent or less stringent than the requirements outlined in Standard QSA.02.10.01, the laboratory develops an individualized quality control plan (IQCP) or meets the requirements in Standard QSA.02.10.01.*

~~**Standard QSA.02.04.01**~~
~~The laboratory evaluates instrument-based testing with electronic or internal systems prior to using them for routine quality control.~~

~~**Elements of Performance for QSA.02.04.01**~~

~~**A** 1. When the laboratory evaluates instrument-based testing with electronic or internal systems, the test being performed is a moderately complex test in routine chemistry or hematology.~~

~~**A** 2. Ⓓ For each test system, the laboratory evaluates the sources of error, including personnel, training, and competency, and determines whether the electronic or internal quality controls monitor the entire analytical process or a portion of the analytical process. The results are documented.~~

~~**Note:** *This information may be included in the manufacturer's package insert or requested from the manufacturer via written documentation.*~~

~~**A** 3. Ⓓ The laboratory conducts an evaluation of the electronic or internal quality controls by testing external quality controls in parallel with the electronic or internal quality controls for the following:~~

- ~~10 consecutive days of testing for test systems that monitor the entire analytical process~~
- ~~30 consecutive days of testing for test systems that monitor a portion of the analytical process~~

~~The evaluation of the electronic or internal quality controls is documented.~~

~~**Note:** *Consecutive days include only those days when*~~

Key: **A** indicates scoring category A; **C** indicates scoring category C; Ⓓ indicates that documentation is required; Ⓜ indicates Measure of Success is needed; ⚠ indicates an Immediate Threat to Health or Safety; ⚠ indicates situational decision rules apply; ⚠ indicates direct impact requirements apply; ◘ indicates an identified risk area

Issued June 23, 2015

http://www.jointcommission.org/assets/1/18/LAB_IQCP_2016_Prepub.pdf

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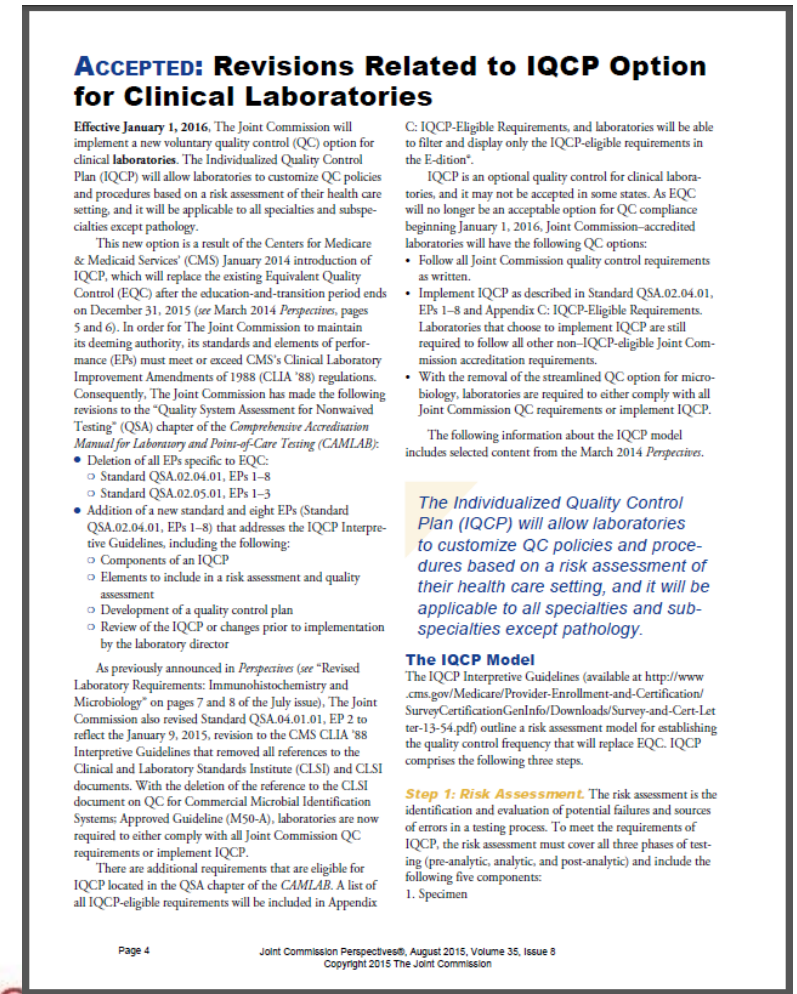

ACCEPTED: Revisions Related to IQCP Option for Clinical Laboratories

Effective January 1, 2016, The Joint Commission will implement a new voluntary quality control (QC) option for clinical **laboratories**. The Individualized Quality Control Plan (IQCP) will allow laboratories to customize QC policies and procedures based on a risk assessment of their health care setting, and it will be applicable to all specialties and subspecialties except pathology.

This new option is a result of the Centers for Medicare & Medicaid Services' (CMS) January 2014 introduction of IQCP, which will replace the existing Equivalent Quality Control (EQC) after the education-and-transition period ends on December 31, 2015 (*see* March 2014 *Perspectives*, pages 5 and 6). In order for The Joint Commission to maintain its deeming authority, its standards and elements of performance (EPs) must meet or exceed CMS's Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) regulations. Consequently, The Joint Commission has made the following revisions to the "Quality System Assessment for Nonwaived Testing" (QSA) chapter of the *Comprehensive Accreditation Manual for Laboratory and Point-of-Care Testing (CAMLAB)*:

- Deletion of all EPs specific to EQC:
  - Standard QSA.02.04.01, EPs 1–8
  - Standard QSA.02.05.01, EPs 1–3
- Addition of a new standard and eight EPs (Standard QSA.02.04.01, EPs 1–8) that addresses the IQCP Interpretive Guidelines, including the following:
  - Components of an IQCP
  - Elements to include in a risk assessment and quality assessment
  - Development of a quality control plan
  - Review of the IQCP or changes prior to implementation by the laboratory director

As previously announced in *Perspectives* (*see* "Revised Laboratory Requirements: Immunohistochemistry and Microbiology" on pages 7 and 8 of the July issue), The Joint Commission also revised Standard QSA.04.01.01, EP 2 to reflect the January 9, 2015, revision to the CMS CLIA '88 Interpretive Guidelines that removed all references to the Clinical and Laboratory Standards Institute (CLSI) and CLSI documents. With the deletion of the reference to the CLSI document on QC for Commercial Microbial Identification Systems: Approved Guideline (M50-A), laboratories are now required to either comply with all Joint Commission QC requirements or implement IQCP.

There are additional requirements that are eligible for IQCP located in the QSA chapter of the *CAMLAB*. A list of all IQCP-eligible requirements will be included in Appendix C: IQCP-Eligible Requirements, and laboratories will be able to filter and display only the IQCP-eligible requirements in the E-dition®.

IQCP is an optional quality control for clinical laboratories, and it may not be accepted in some states. As EQC will no longer be an acceptable option for QC compliance beginning January 1, 2016, Joint Commission–accredited laboratories will have the following QC options:

- Follow all Joint Commission quality control requirements as written.
- Implement IQCP as described in Standard QSA.02.04.01, EPs 1–8 and Appendix C: IQCP-Eligible Requirements. Laboratories that choose to implement IQCP are still required to follow all other non–IQCP-eligible Joint Commission accreditation requirements.
- With the removal of the streamlined QC option for microbiology, laboratories are required to either comply with all Joint Commission QC requirements or implement IQCP.

The following information about the IQCP model includes selected content from the March 2014 *Perspectives*.

The Individualized Quality Control Plan (IQCP) will allow laboratories to customize QC policies and procedures based on a risk assessment of their health care setting, and it will be applicable to all specialties and subspecialties except pathology.

The IQCP Model

The IQCP Interpretive Guidelines (available at http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-54.pdf) outline a risk assessment model for establishing the quality control frequency that will replace EQC. IQCP comprises the following three steps.

Step 1: Risk Assessment. The risk assessment is the identification and evaluation of potential failures and sources of errors in a testing process. To meet the requirements of IQCP, the risk assessment must cover all three phases of testing (pre-analytic, analytic, and post-analytic) and include the following five components:

1. Specimen

The Joint Commission

Topic Library Item

Revisions Related to IQCP Option for Clinical Laboratories

August 5, 2015

Download This File

Joint Commission Requirement.

August 5, 2015

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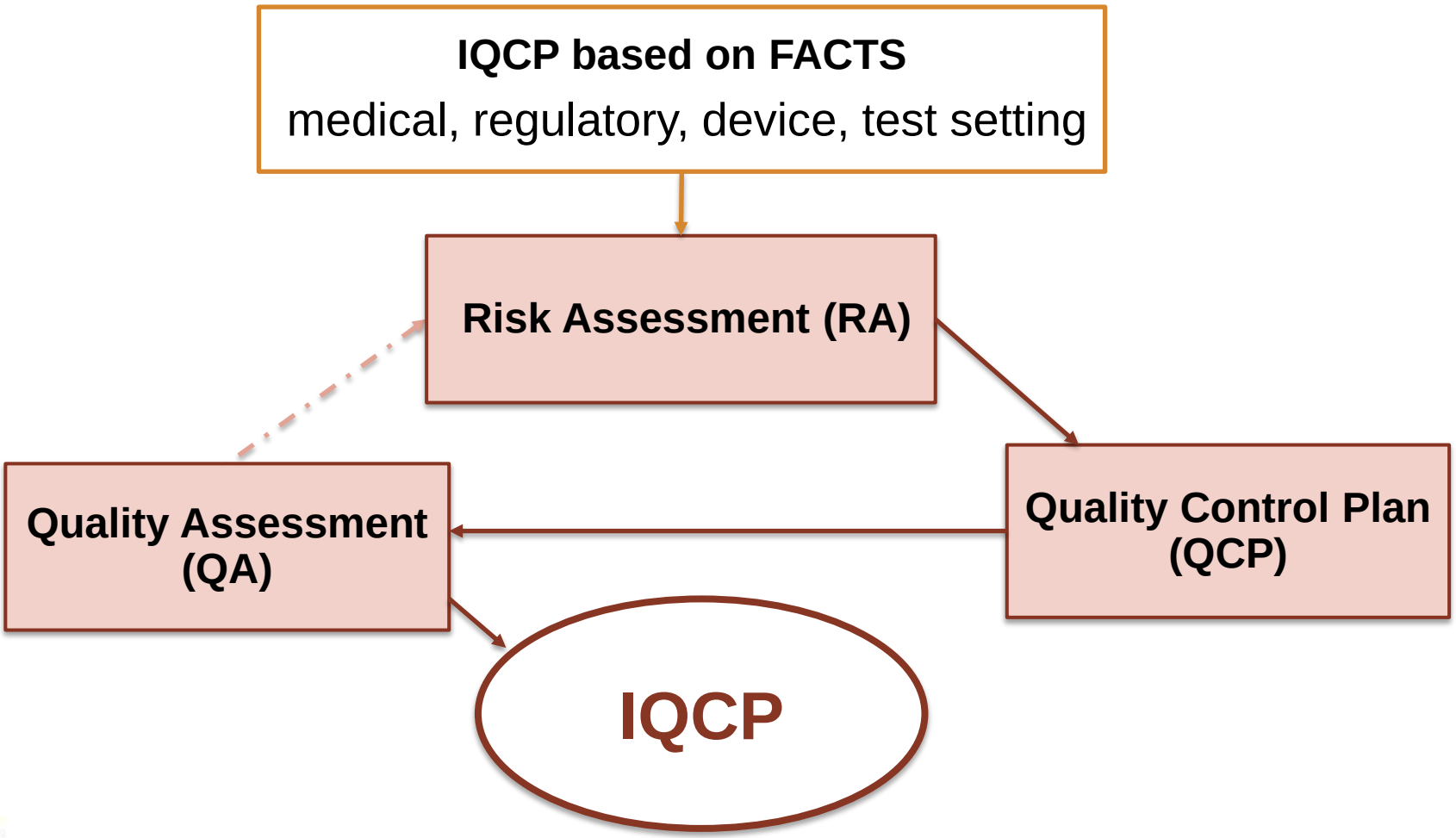
IQCP Goal: Quality Testing Processes for Quality Test Results. Sites need to…

- Identify possible sources of error (risk) in the entire testing process
- Determine whether or not *current* practices and protocols are eliminating these errors
- Decide how to reduce all significant errors identified *but not eliminated with current practices*
- Develop a QCP plan by identifying practices/protocols to address findings
- Assess these practices/protocols for on-going effectiveness

IQCP Development Process

(CLIA, CAP, TJC, COLA)



www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-54.pdf

Risk Assessment (RA)

An <u>in-house</u> activity conducted by <u>in-house</u> personnel:

- Review entire testing process to identify *<u>potential risks</u>* (failures/errors) that impact test result quality. Must at least review:
  - Specimen, testing personnel, environment, reagent, and test system

Pre-analytical → **Analytical** → **Post-analytical**

Think,
but don't *over* think!!

Clues for Review: Inspector Probes (§493.1256(d)): Specimen*

Has lab identified and evaluated the pre-analytical phase, as applicable, for:

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

*http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-54.pdf

Clues for Review: Inspector Probes (§493.1256(d)): Operator *

Has lab assessed risks associated with testing personnel by evaluating:

- Training
- Competency
- Appropriate education and experience qualifications
- Adequate staffing

*http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-54.pdf

Clues for Review: Inspector Probes (§493.1256(d)): Environment*

Has lab evaluated environmental conditions which may affect test system performance including, but not limited to:

- Temperature
- Airflow/ventilation
- Light intensity
- Noise and vibration
- Humidity
- Altitude
- Dust
- Water
- Utilities (electrical failure or supply variance/surge)
- Adequate space

*http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-54.pdf

Clues for Review: Inspector Probes (§493.1256(d)): Reagent*

Factors to consider for reagents, QC materials, calibrators, etc., may include, but are not limited to:

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

*http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-54.pdf

Clues for Review: Inspector Probes (§493.1256(d)): Test System*

Factors to consider for analyte and test system, may include, but are not limited to:

- Inadequate sampling
- Clot detection capabilities
- Interfering substances detection
- Mechanical/electronic failure
- Optics, pipettes or pipettors, barcode readers
- Failure of system controls and function checks
- Built-in procedural and electronic controls, external or internal liquid QC, temperature monitors and controllers
- Software/Hardware
- Transmission of data to LIA
- Result reporting

*http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-54.pdf

IQCPs will be inspected; they are regulatory.

Be ready…

Document (as you go) the collected facts, data [charts, graphs, tables], staff, processes, memos, instrument proof sheets, reported studies, etc.

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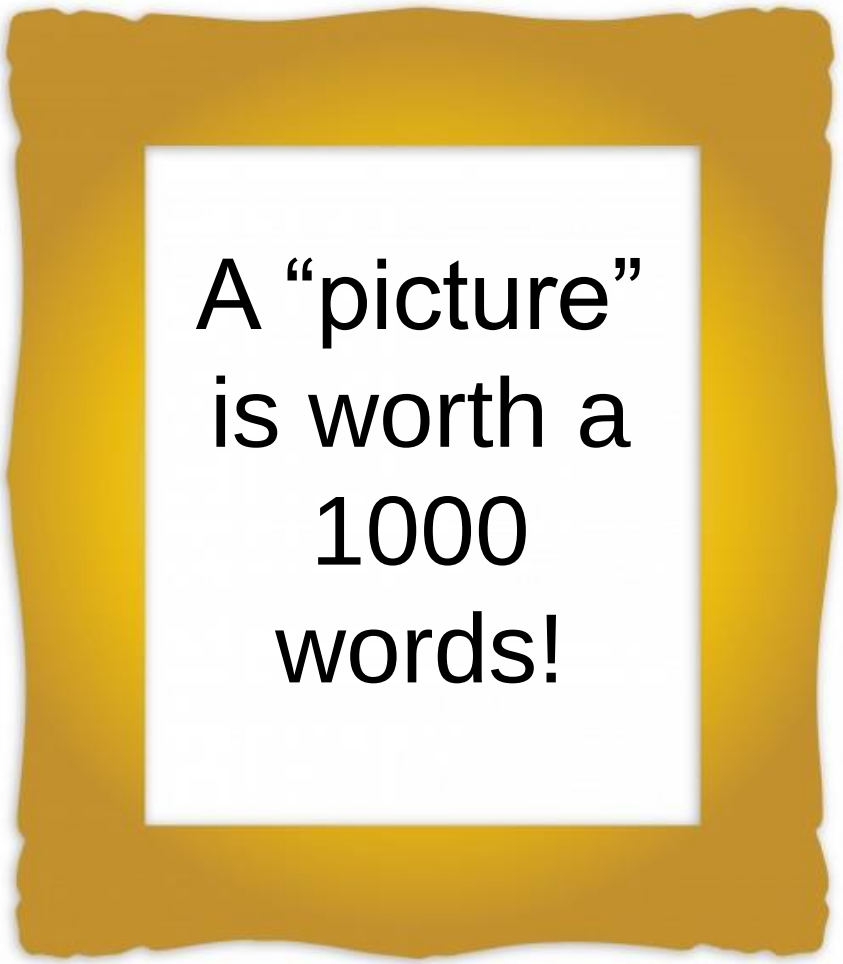
Remember, often…



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Throughout the Development Process

- Lists, Tables
- Process Flow/ Contingency diagrams
- Fishbone diagrams
- Potential Problem Analysis (PPA)
- Process decision program charts
- Word/Excel documents

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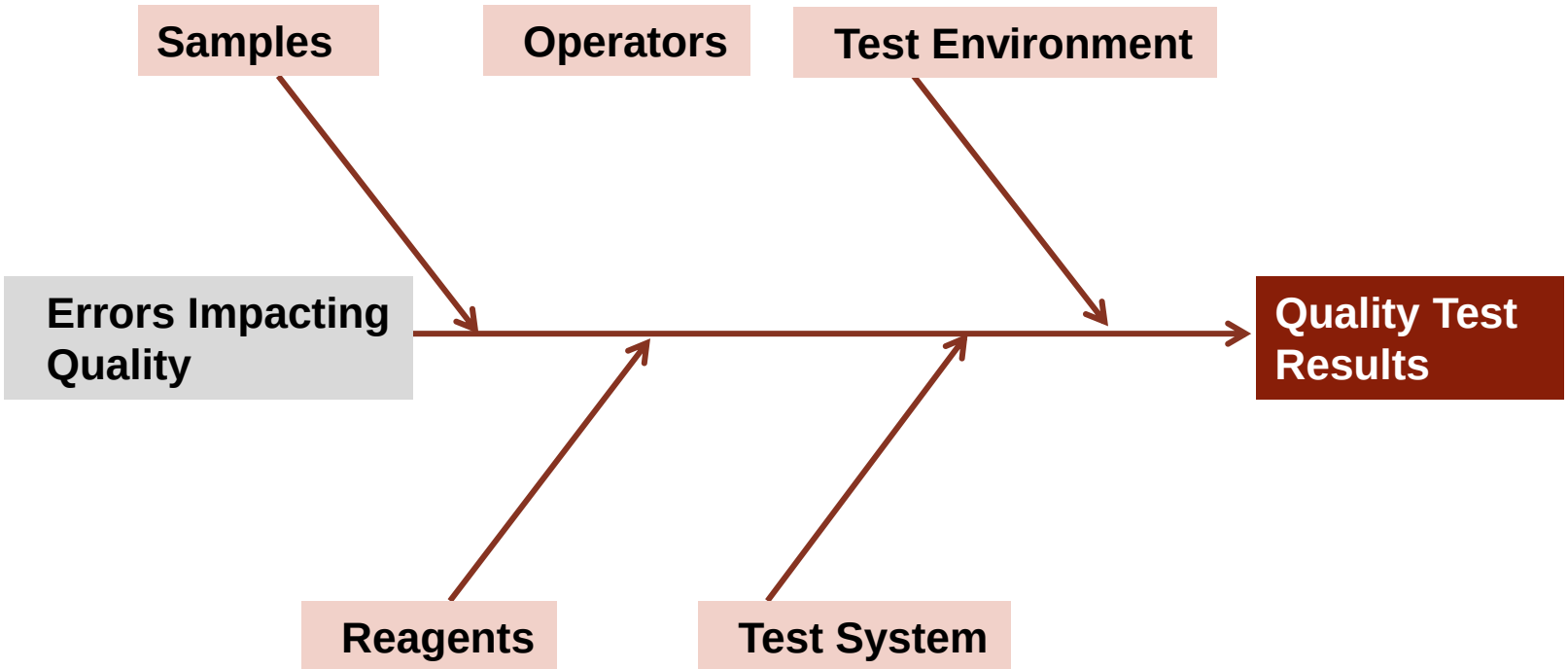
Fish Bone Diagram to Identify *Potential* Errors/Risks

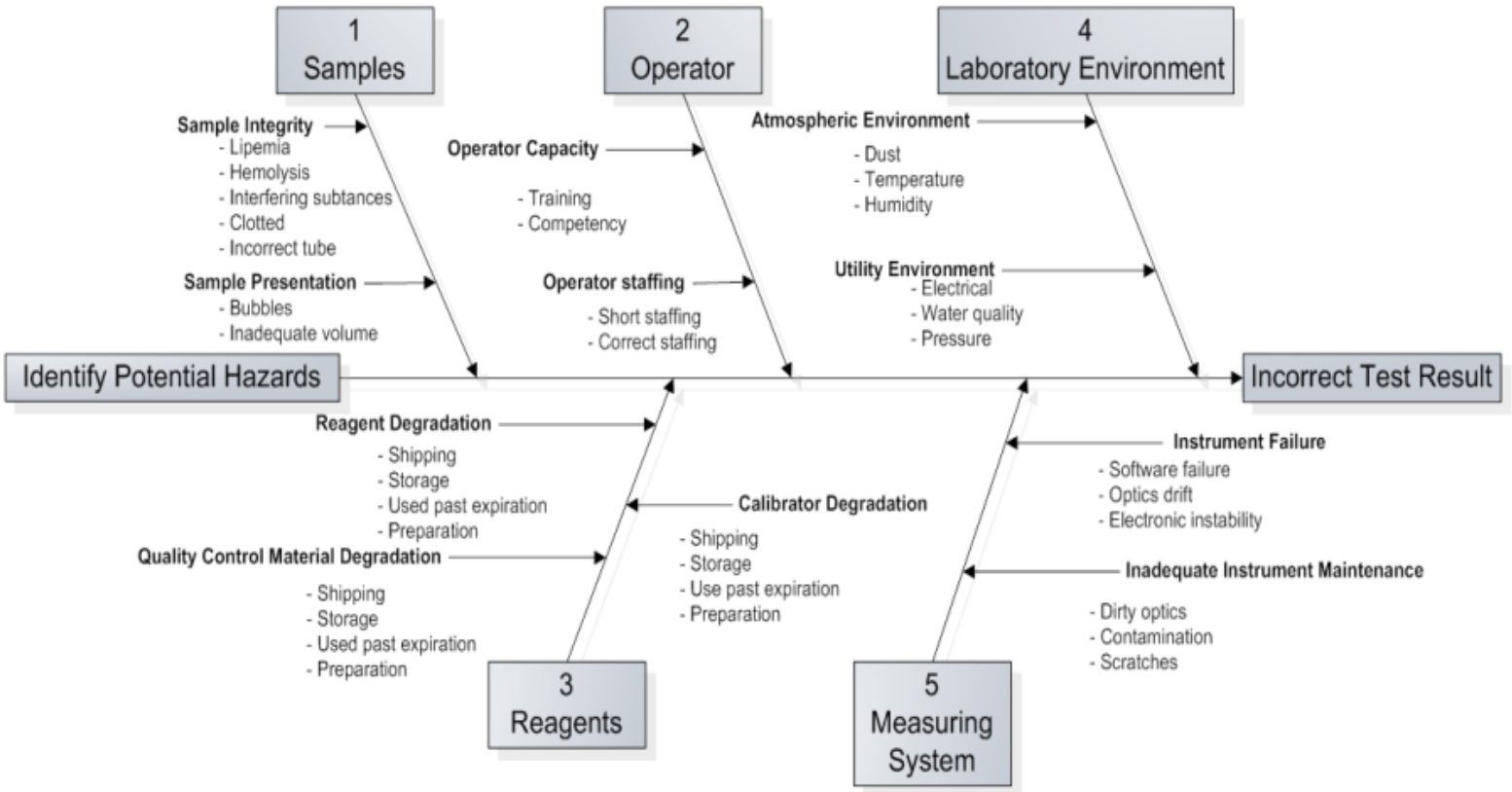


Risk Assessment (RA)

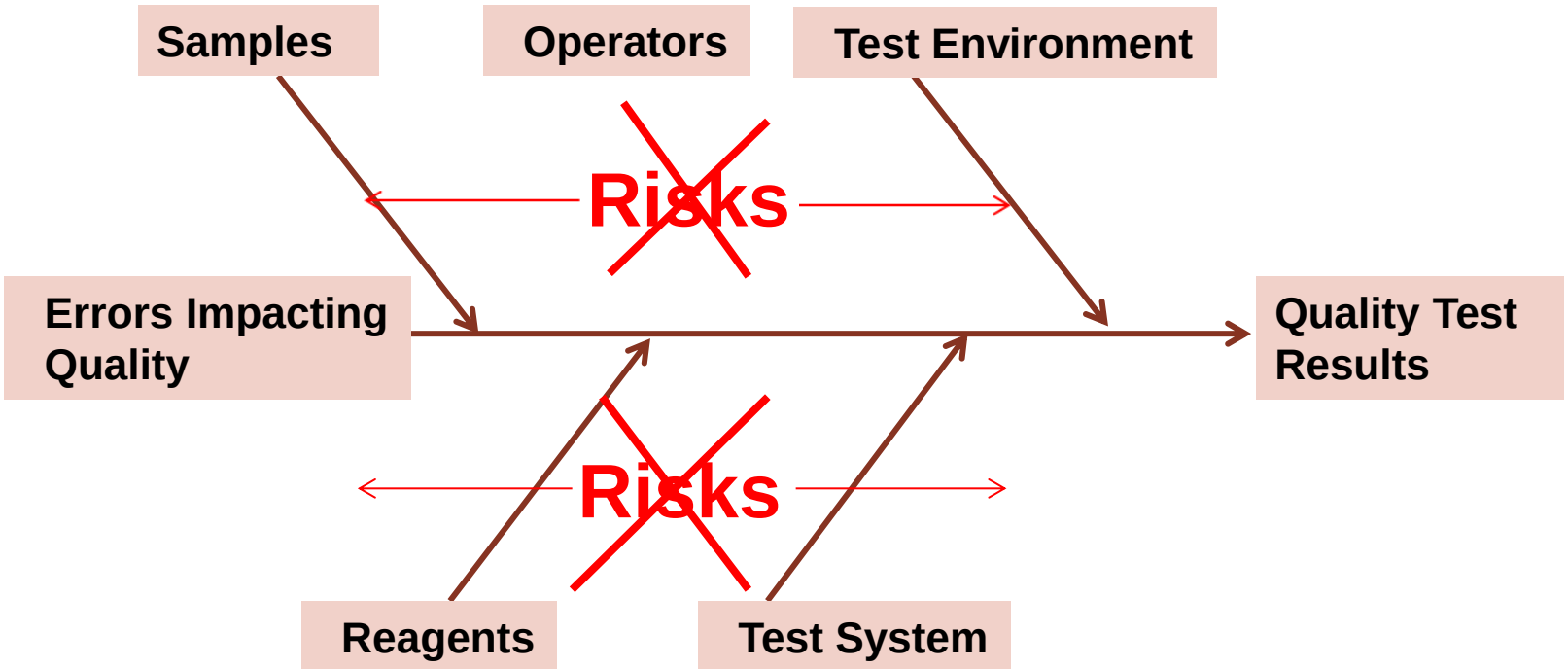
1.Identify risks

Pre-analytical | Analytical | Post-analytical

Example of common risks in the testing process



IQCP Goal: Quality Test Results Eliminate All *Significant* Risks



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CDC/CMS Example: Worksheet **to** Document RA Process/Findings

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. • Internal controls • Actions taken by laboratory • Safeguards in the test system or laboratory practices
SPECIMEN			

http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/IQCP-Workbook.pdf

Example: Worksheet **to** Document RA Process/findings

Risk Assessment Component	Potential failure/error	Potential Cause	Mitigated/ Detected? Yes/no For yes, How?	Changes needed to detect/eliminate unmitigated failure
Specimen				
Test System				
Operator				
Environment				
Reagents				

Are Identified Errors/Risks Eliminated?

Review your instrument/manufacturer's information

- Requires in-depth analysis of requirements and features

Review site's SOPs for adequacy and adherence

Determine if training and competency assessment are adequate

Document your actions as you go!

Review Performance Data Collected on the Device

- In-house collected method performance data
  - Performance specification verification
    - ✓ Accuracy
    - ✓ Precision
    - ✓ Reportable range
  - QC
  - Proficiency testing
  - EQC evaluation data
- Published studies/information
- Quality assessment information
  - QA Monitor data
  - Complaints
  - Corrective actions

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Device's Features are Important
Some Considerations

- Operator ID lockout?
- System controls?
- Function checks?
- Reagent controls?
  - ✓ Reagent dating check
  - ✓ Built-in internal, procedural, and/or electronic controls
  - ✓ External or internal liquid QC (frequency – discrete or continuous)
- Error detection and elimination?
  - ✓ Systematic and/or transient error detection
  - ✓ Corrective actions initiated automatically based upon error
  - ✓ Confirmation of error mitigation prior to sample testing
- Documentation/report generation?

Review Device's Features for Post-analytical Risks

Some Considerations

- Positive Patient Identification?
- Interface mitigation features?
- Sample result range alerts?
- Patient History?
- Post-analytical reports?
  - ✓ Sample handling → monitor competency
  - ✓ Turn-around time
  - ✓ Exception → monitor sample integrity
  - ✓ Notification → monitor doctor receipt

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What about “Leftover” (unmitigated) Identified Risks?

“Turkey again, soon November will be here…how big was that flaming bird?”

“Leftover,” Residual, Identified Risks?

For those identified in the RA, but NOT detected or eliminated with *current* practices and testing device features—

determine which are ***significant***

but how?

Identification of significant risks?

Bottom line
It is a judgment!

You decide how to judge!

One Example: RM table to judge significance of leftover identified risks*

- For each leftover (residual) risk, determine the impact of an incorrect, delayed or no result due to the risk
  - Assess the probability of harm for each
    - Frequent to improbable
  - Assess the severity of harm
    - Negligible to catastrophic
- Significance depends on the combination of the probability of harm and severity

*ISO 14971:2007 Medical devices- Application of risk management to medical devices, www.iso.org

Risk Management Table to Judge Significance*

Severity of Harm

Probability	Negligible	Minor	Serious	Critical	Catastrophic
Frequent	**Not OK**	**Not OK**	**Not OK**	**Not OK**	**Not OK**
Probable	OK	**Not OK**	**Not OK**	**Not OK**	**Not OK**
Occasional	OK	OK	OK	**Not OK**	**Not OK**
Remote	OK	OK	OK	OK	**Not OK**
Inconceivable	OK	OK	OK	OK	OK

Frequent = once/week
Probable = once/month
Occasional = once/year
Remote = once every few years
Inconceivable = once in the life of the measuring system

Negligible = inconvenience or temporary discomfort
Minor = temporary injury or impairment not requiring professional medical intervention
Serious = injury or impairment requiring professional medical intervention
Critical = permanent impairment or life-threatening injury
Catastrophic = results in patient death

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*ISO 14971:2007 Medical devices- Application of risk management to medical devices. www.iso.org

Risk Assessment (RA)
3. Determine residual risk

Pre-analytical | Analytical | Post-analytical

Modify practices to accommodate elimination/detection of significant risks

For those risks identified as significant:

- Decide how to detect/eliminate the residual failure/error
- Modify and/or add additional policies and practices
- Modify training and competency assessment activities to accommodate changes

- **Make sure that modifications/changes are documented in the IQCP**

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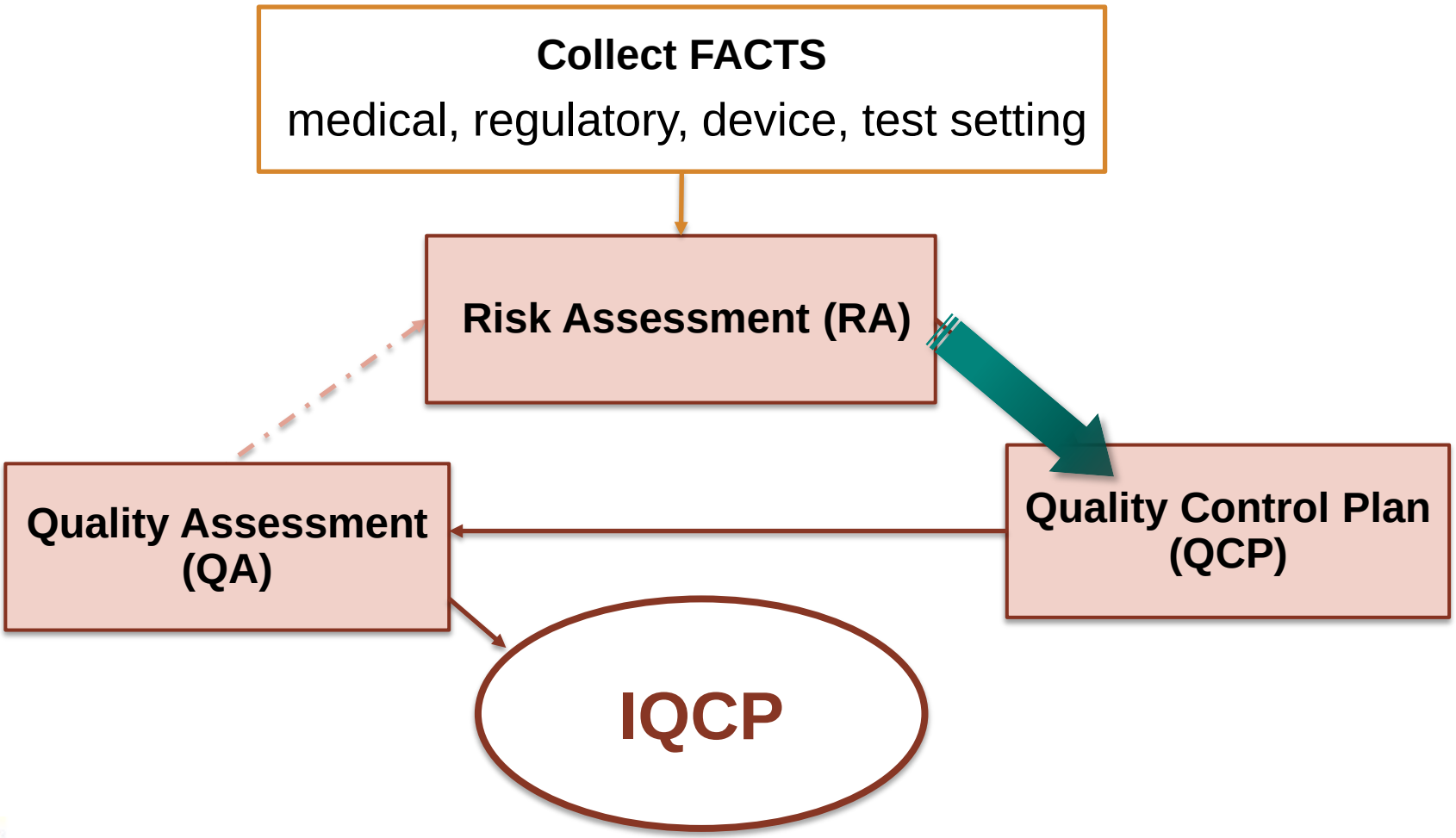

www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-54.pdf

CMS §493.1256d: QCP

- Documented strategy that is device and site specific for (analytical) quality test results
  - Practices, resources and procedures to control quality
    - Ensures accuracy/reliability and appropriate quality for patient care
    - Provides for immediate error detection due to:
      - Test system failure, adverse environment conditions, operator performance
    - Monitors performance accuracy and precision influenced by changes in test system, environment, and operators

www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-54.pdf

CMS says the QCP…

***Must** at least include the number, type, frequency of testing and criteria for acceptable result(s) of the quality control(s).*

Note: …labs are <u>not</u> permitted to establish QC procedures that are less stringent than those specified by the manufacturer…

If indicated by…the evaluation of the RA, the QCP <u>may</u> also include:

- *Electronic controls*
- *Procedural controls*
- *Training and competency assessment*
- *Equipment maintenance, calibrations*
- *Other specified quality control activities*

CMS Survey & Certification Letter 13-54, August 16, 2013: http://www.cms.gov/Regulations-andGuidance/Legislation/CLIA/Individualized_Quality_Control_Plan_IQCP.html

Quality Control Plan (QCP)

CMS Inspector Probes: QCP

- Does the lab have a written QCP for each test system, as applicable?
- Does the QCP specify:
  - Number and type of controls?
  - Frequency of testing?
  - Criteria for acceptable results?
- Does the QCP require the lab to perform QC as specified by manufacturer instructions?
  - Remember, labs can always do more, but never less
- Is there documented evidence of lab director approval of the QCP before it was put into use?

www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-54.pdf

Example CMS QCP

http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/IQCP-Workbook.pdf

Laboratory Director's Approval (signature) is mandatory

1 Type of Quality Control	2 Frequency	3 Criteria for Acceptability (Range of Acceptable Values)
Temperature Checks Room Refrigerator Freezer A	Record room temperature daily, in the morning and afternoon. Record refrigerator and freezer each day of patient testing.	20°C – 25°C (Room) 2°C – 8°C (Refrigerator) -10°C – -20°C (Freezer) Recorded on temperature log sheets
Verify specimen collection tubes for acceptability upon receipt in the laboratory.	With each specimen	Refer to Specimen Rejection Policy and record all improperly collected tubes on specimen rejection log sheet.
Verify specimen collection time and time received by the laboratory.	With each specimen	If the time lapse for specimen collection and receipt is greater than 60 minutes, aliquot and store according to manufacturer's instructions (2°C – 8°C for 48 hrs or freeze at -10° C up to 5 weeks).
Internal Quality Control	Performed with each reagent disc.	Must be documented as acceptable on quality control log sheet prior to reporting results.
External Quality Control Normal value Abnormal value	Assay normal and abnormal quality control every 30 days or the first day of patient testing each month. In addition to the above, external quality control will be ran when: • laboratory conditions have changed significantly • training or retraining of personnel is indicated • test results do not match patient symptoms or clinical findings	Acceptable range printed in the manufacturer's package insert. Results must be recorded on quality control log sheet prior to reporting results.
Reagent Disc Storage	With each reagent disc	Document date and time on reagent discs when removed from refrigerator. Do not use reagent discs that are at room temperature beyond 48 hours.
Training	With each new testing personnel and when indicated.	Successful demonstration of test performance. Document training activities.
Competency Assessment	Six months and one year after initial training, annually thereafter.	All testing personnel must successfully meet all six CLIA elements for competency assessment.

Laboratory Director's Signature_____

Date

CAP Requirements for the QCP

Quality Control Plan Elements – COM.50500

COM.50500 Quality Control Plan Elements Phase II

The individualized quality control plan must define all aspects monitored based on the potential errors identified during the risk assessment, including the following parameters as applicable:

- **The number, type (external and internal quality control systems), and frequency of quality control**
- **Criteria for acceptable performance**
- **Monitoring of the testing environment and reagents**
- **Specimen quality**
- **Instrument calibration, maintenance, and function checks**
- **Training and competency of testing personnel**
- **Provisions for multiple identical devices and variation for uses covered under one IQCP**

www.cap.org

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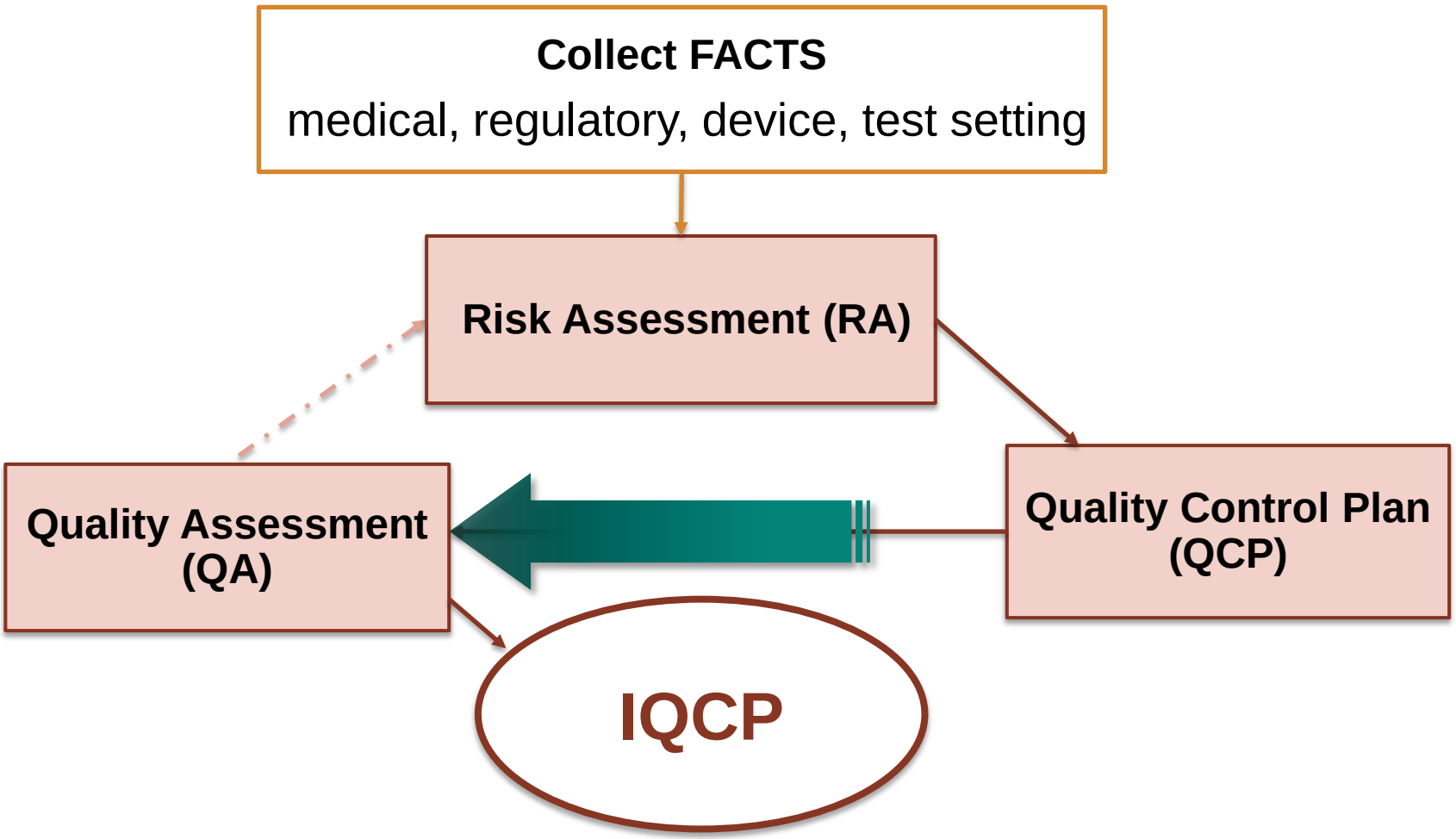
CAP – Example QCP Plan

Laboratory Name: Northfield Laboratory CAP#:11111-11

Type of Control	Frequency	Criteria for Acceptability
Internal QC every time a test is performed	Each time of use	Within manufacturer's limits using automated lockout
Two level of external quality controls from the manufacturer	Each new lot and shipment of reagents Every 31 days Monthly supervisory review	Within defined QC limits
Monitoring of reagent storage areas	Daily Monthly supervisory review	Within 2-8°C
Record and monitor open expiration dates	Each day of use	In date reagents used
Staff training and competency on specimen collecting and testing process	Initial training, 6-month competency for new personnel, ongoing annual competency	Complete training checklist and procedure review. Pass competency assessment with minimum score of 90%.
Monitoring of room temperature		Within 20-24°C
ETC…		

Laboratory Director: Joan Smith, MD Date: 6/5/2015

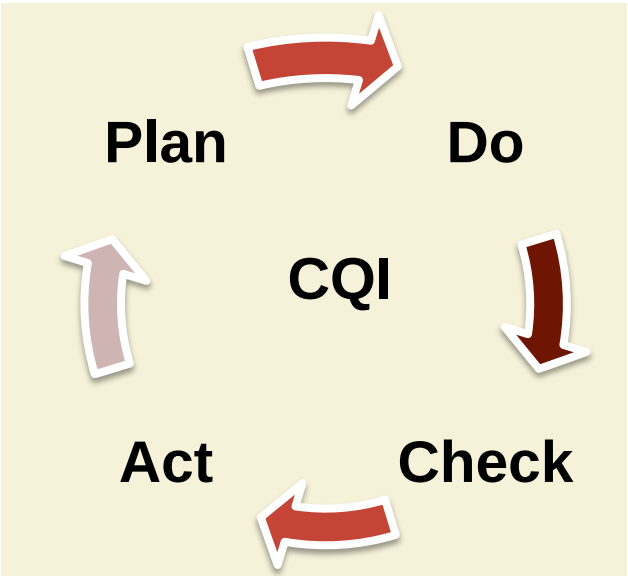


www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-54.pdf

Quality Assessment: Is the QCP/IQCP effective?

http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/IQCP-Workbook.pdf

QA is nothing new



Plan-Do-Check-Act for Continuous Quality Improvement (CQI)

- **Implement** the PLAN
- **Monitor, verify** and **improve** the PLAN, when needed

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CMS (CLIA): Does your QA?

- ✓ **Outline** the QA practices for your laboratory?
- ✓ **Monitor** continuously for effectiveness?
- ✓ **Revise** policies and procedures necessary to prevent recurrence of problems?
- ✓ **Discuss** QA reviews with appropriate staff?
- ✓ **Document** all QA activities?

http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/IQCP-Workbook.pdf

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Quality Assessment (QA)

CMS suggests useful documents for Quality Assessment

- QC review and PT performance
- Patient results review
- Specimen rejection logs
- Failure investigations
  - Corrective actions, reagent storage records, etc.
- Turnaround time reports
- Complaint logs
- Competency assessment records

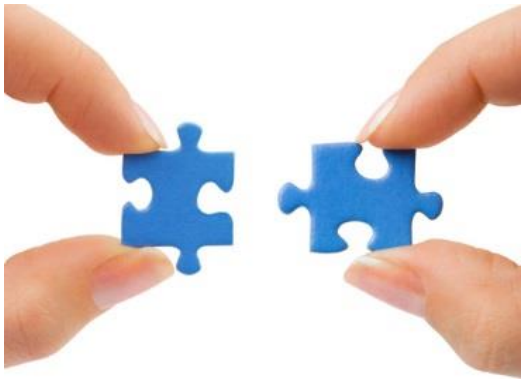
www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-54.pdf

Additional “Information” for QA

- Variance Forms,
- Quality Indicators,
- Corrected-Amended Reports (accept/reject feature, flags),
- Corrective action reports (trend clots, interfering substances),
- Clinician feedback

Problems?

QA leads to solutions



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OPTIONAL QA WORKSHEET

Take your identified sources of error from the **"Record Your Quality Assessment Questions/Findings"** section, and follow the steps taken by Kim to complete your laboratory's QCP worksheet below.

Laboratory Name_____ Test System Name _____

QA ACTIVITY (TO MONITOR)	FREQUENCY	ASSESSMENT OF QA ACTIVITY (Was there variation from established policy and procedures?)	CORRECTIVE ACTION (WHEN INDICATED)

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

CMS (CLIA) QA Example

1. Review all temperature logs monthly for room, refrigerator, and freezer to ensure temperatures were monitored according to the QCP, and appropriate corrective action(s) were taken for any temperatures that were out of range.

2. Review Specimen Receipt Log weekly for any unacceptable conditions, i.e. rejected samples, to ensure appropriate action(s) were taken. If the number of unacceptable specimens or occurrences exceeds a threshold established by the laboratory, conduct training, or another activity and monitor the effectiveness of the corrective action.

3. Review manufacturer's instructions with each new lot/shipment of reagent discs or software change. Ensure changes are incorporated into the standard operating procedures as well as monitor any quality control problems found regarding lot-to-lot variability.

4. Review Internal QC Logs monthly to ensure appropriate corrective action(s) were taken for any unacceptable values.

5. Update policy and procedures to outline steps for verbal reporting of patient test results.

6. Update policy and procedures for competency assessment and review personnel records/ documentations to ensure competency assessments meet the CLIA required elements.

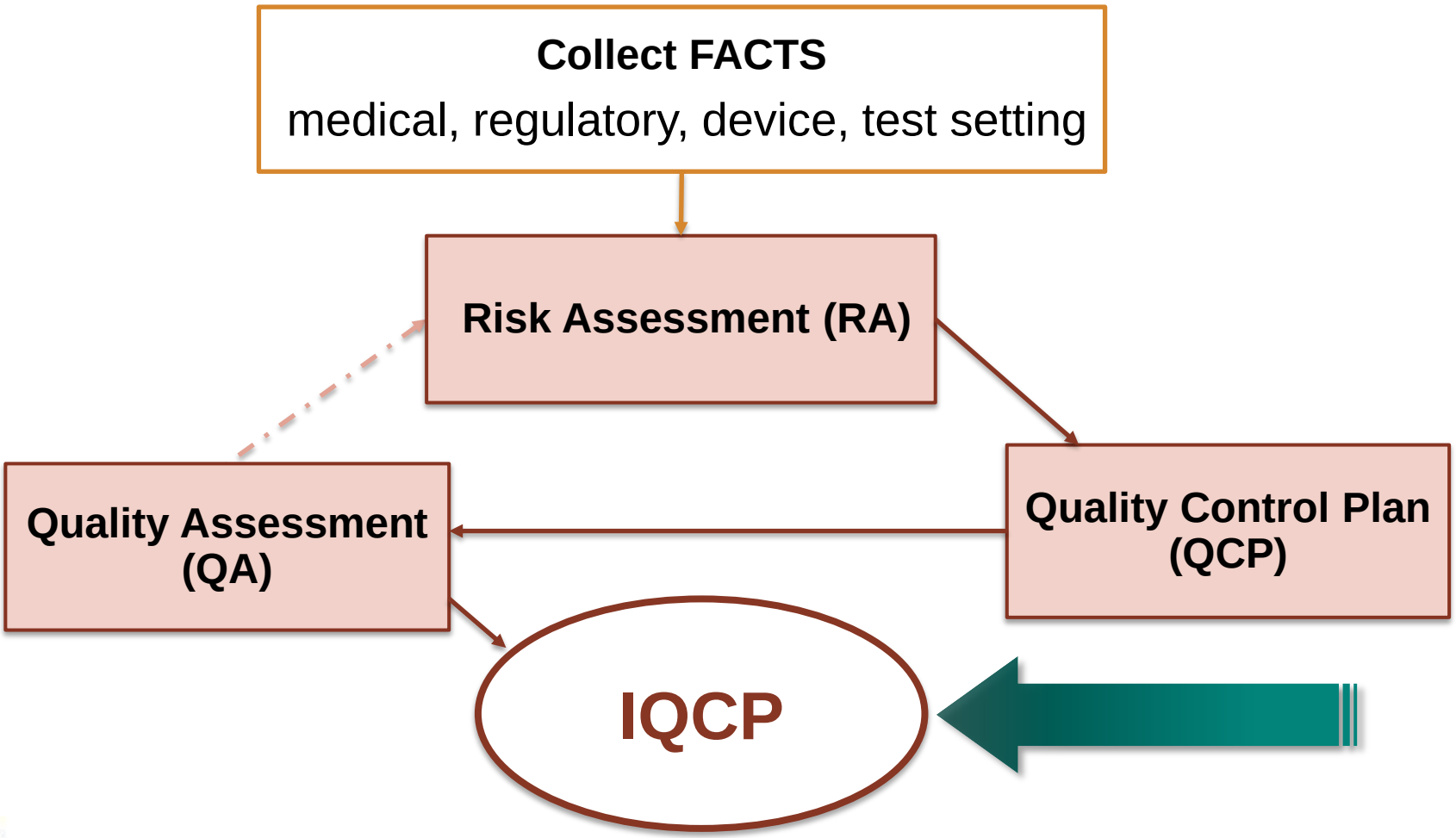
7. Review scheduled maintenance records/documentation for completeness for the test system(s) per laboratory policies and procedures.

Laboratory Director Signature _____ *Dr. Martin*

Date _____ *mm/dd/yyyy*

http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/IQCP-Workbook.pdf

Finally, Putting “Everything” Together



www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-54.pdf

Put the IQCP (Information) Together

Keep it simple

Impress the inspector

- Show all the good work that was done
- It is essential for inspector “buy-in”

NO *official* format

- Document as appropriate for the situation
- No “wrong” way *if individualized*; RA covers all 5 areas; has supporting documentation; and signed by Medical Director

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CDC/CMS Workbook

http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/IQCP-Workbook.pdf

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.

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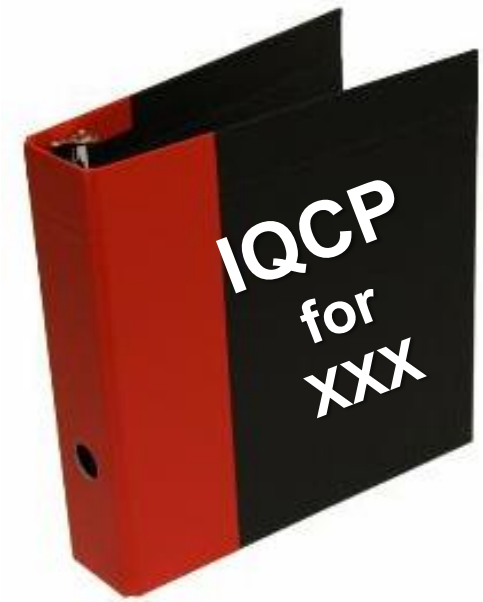
CDC/CMS Workbook Implies??

CONGRATULATIONS!!!

You have completed a Risk Assessment,
created a Quality Control Plan
and performed a Quality Assessment
for the test system being evaluated for an IQCP!!

51



Clearly organize facts, RA processes, findings, QCP and QA

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Putting the IQCP together

Keep it “short” – 1 – 2 pages: (think executive summary)

- Start with specifics - testing device/analytes, site’s name/address, effective date, CLIA number, director, other relevant information
- Summarize RA process - steps, staff, information collected, etc.
- Summarize changes in practice(s) for all 3 phases of testing
- Identify location of supporting documentation/data, SOPs, etc.
- Include QCP – must specify the CMS mandates for analytical QC
- Include QA approach - monitors, frequency, follow-up, inclusion into lab’s QA plan

Show director’s approval of the process and plan

Keep like all other documents (2 years after QCP is discontinued)

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www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-54.pdf

CAP –IQCP Test List

COM.50200 IQCP Test List Phase II

The laboratory has identified all tests using an IQCP and completed the CAP's forms for laboratories using an individualized quality control plan.

- **Required forms:**
  - **List of Individualized Quality Control Plans**
  - **Individualized Quality Control Plan Summary**
- **Forms may be downloaded from the CAP website (http://www.cap.org) through e-LAB Solutions Suite under CAP Accreditation Resources, Accreditation Forms and Instructions**

List of Individualized Quality Control Plans

Complete the fields below for each IQCP in use and present to the inspector during the on-site inspection. Fill out a separate Individualized Quality Control Plan Summary form for each IQCP listed.

Laboratory Name: Northfield Laboratory **CAP Number:** 11111-11

1) Laboratory Section/Department	2) Instrument/Device Include name, manufacturer, and model	3) Tests List all tests included under the IQCP
Point-of-Care Testing - Surgery	Brand A Coagulation Analyzer	ACT
Point of Care Testing – ER, CCU, ICU	Brand B Critical Care Analyzer	pH, PCO2, PO2, sodium, chloride, potassium, creatinine, BUN, glucose, lactate
Point of Care Testing Section - ER	Brand C Cardiac Analyzer	Troponin, CK-MB, myoglobin
Microbiology	Brand D Rapid Strep Test Kit	Strep A antigen
Respiratory Therapy	Brand E Blood Gas Ana	

COLLEGE of AMERICAN PATHOLOGISTS

Individualized Quality Control Plan Summary

Complete a separate form for each IQCP in use and present to the inspector during the on-site inspection.

Laboratory Name: Northfield Laboratory **Laboratory Section/Department:** Point-of-Care Testing - ER **CAP Number:** 11111-11

1) Instrument/Device Include name, manufacturer, and model	2) Tests List all tests included under the IQCP	3) Number of Devices In Use	4) List of Test Sites* If used in more than one area	Date of Director Approval	Date Implemented	Date Retired
Brand C Cardiac Analyzer	Troponin, CK-MB, Myoglobin	1	n/a	8/1/2015	8/1/2015	n/a

5) Process Used to Monitor Risk

List control processes put in place based on risk assessment – define the monitor and frequency evaluated.

Reagents	Environment	Specimen	Test System	Testing Personnel	Other
Two levels of external QC with new lots and shipments	Daily room temperature monitoring in testing area	Written specimen collection procedures with defined acceptability criteria	Internal controls each time a test is performed	Staff training and competency on specimen collection and testing process	
Record and monitor open expiration dates (14 days)	Instrument maintained on designated bench top away from the sink	Testing performed at the point-of-care with immediate testing after the specimen is collected	Two levels of external QC every 30 days	Assigned user ID codes with lock out for unauthorized users	

CAP IQCP Webinar, August 19, 2015

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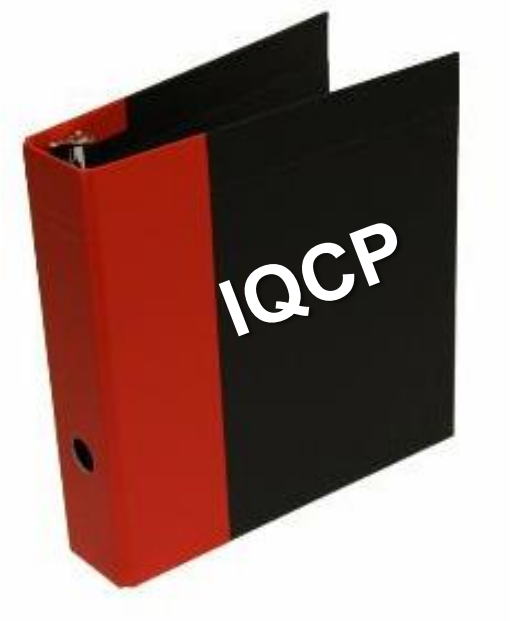

Whatever Approach Used: Make sure…
IQCP is controlled,
Ready for inspection,
Includes the "right" stuff -- RA, QCP and QA, signatures, etc.
And others understand and know where it is!


Quality Processes
for Quality Test Results
IQCP Matters!

References

- CMS Survey & Certification Letter 13-54, August 16, 2013: *Individualized Quality Control Plan (IQCP): A New Quality Control (QC) Option.* http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-54.pdf
- http://www.cms.gov/Regulations-andGuidance/Legislation/CLIA/Downloads/IQCPbenefits.pdf
- http://www.criedu.org/iqcp-2
- http://www.jointcommission.org/assets/1/18/LAB_IQCP_2016_Prepub.pdf
- http://www.jointcommission.org/assets/1/23/Lab_Focus_Two_2015.pdf
- http://www.cap.org/ShowProperty?nodePath=/UCMCon/Contribution%20Folders/WebContent/pdf/15189-risk-management-guideline.pdf
- http://www.jointcommission.org/assets/1/6/PSC_for_Web.pdf
- ISO 14971:2007 Medical devices- Application of risk management to medical devices. www.iso.org
- http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Individualized_Quality_Control_Plan_IQCP.html
- Email IQCP@cms.hhs.gov for questions relating to IQCPs
- http://www.cap.org/apps/docs/advocacy/comments/comments_cms_quality_strategy.pdf
- International Organization for Standardization. ISO 14971:2007 *Medical devices—application of risk management to medical devices.* www.iso.org
- Clinical Laboratory Standards Institute. *Laboratory Quality Control Based on Risk Management; Approved Guideline. CLSI Document EP23-A. Wayne, PA; 2011*
- CLSI FAQ Sources of Failure Template (Question #12) http://clsi.org/edu/workshops/ep23qa/
- *http://www.jointcommission.org/patient_safety_systems_chapter_for_the_hospital_program/*
- http://www.cap.org/web/home/lab/eAlerts/eAlert?contentID=11076452&_afrLoop=618964995331847#%40%3F_afrLoop%3D618964995331847%26contentID%3D11076452%26_adf.ctrl-state%3D3vhtqnud7_47
- http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/IQCP-Workbook.pdf

Thank you