IQCPs: Get Started - Now!

Thursday, October 22, 2015

The following information in this presentation is intended as an aid in the development of your facility's IQCPs. Specific requirements for IQCPs can be found from CMS and your accreditation organization.

Your Speaker

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Technical Consultant II, FL. and S. Georgia

- Board Certified ASCP
- Co-Chair and Co Founder Central Florida POC Network
- POCC of the Year 2006
- Clinical Laboratory Consultant

Objectives

Describe the latest information on IQCP

Produce simple drafts of the three components of an IQCP: Risk Assessments, Quality Control Plans and Quality Assurance Plans

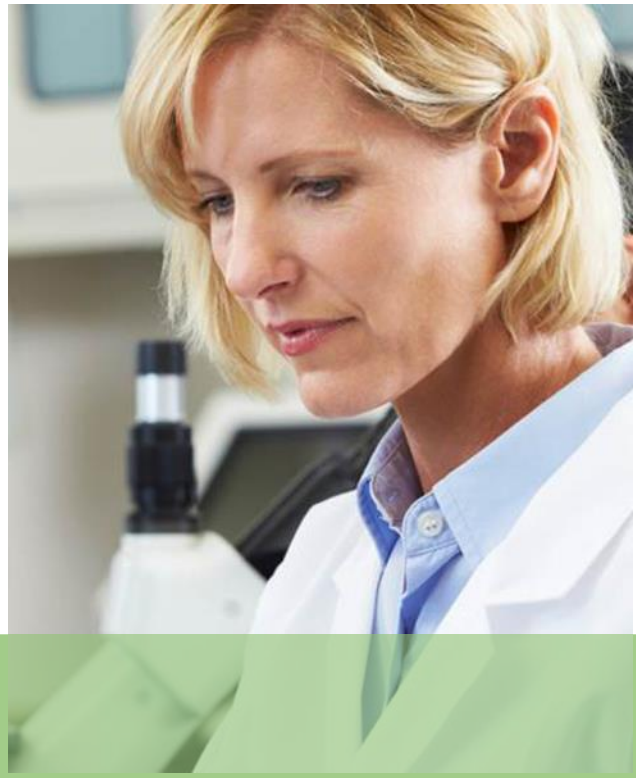
Identify many IQCP helpful hints to ease the IQCP process

Participate in a general IQCP question and answer session

Agenda

1. Where are we right now?
2. What to expect from the Inspectors
3. Pen to Paper suggestions - What you can do right away
   - Risk Assessment
   - Quality Control Plan
   - Quality Assurance Plan
4. Let’s do a practice IQCP
5. IQCP Helpful Hints

Our goal is to get you started on your IQCPs!



Where are we right now?

CLIA QC Options

	Now	**Jan. 1, 2016**
Default (2-3 levels external QC/day)	☑	☑
EQC (Equivalent QC)	☑	☒
IQCP	☑	☑

COLA ☑	CAP ☑	Joint Commission ☑

What to Expect from Inspectors

Not the Conclusions

The Process

Was the IQCP developed with input from the right personnel?

Were the data used in the RA of reasonable quantity and quality? Is your data summarize in an easy to read format?

Is there a process to monitor and review quality performance and linked back to RA?

An IQCP SOP is not required by CMS but should be considered as good laboratory practice and may be required by local, state or other accrediting groups.

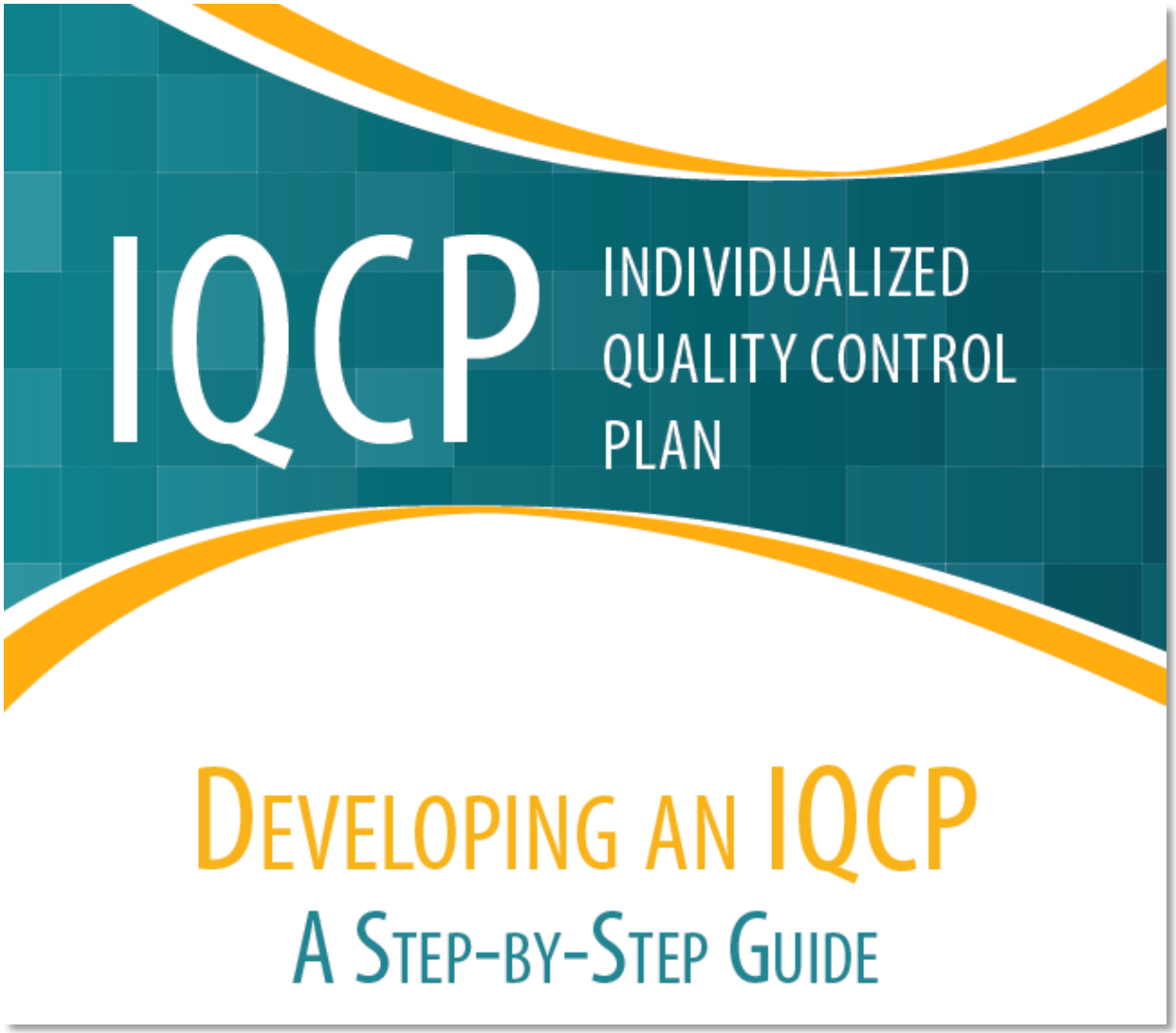
Analysis of identical devices used in various locations

Review of the Quality Control Plan elements

- Routine
- Failure investigations
- Corrective and Preventive Action (CAPA) including return to the Risk Assessment

Annual review of the Quality Control Plan

62 Pages Worth Reading….



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

What We're Hearing from Joint Commission

CLIA Laboratory Director Responsibilities

Accurate and reliable test results that are appropriate for patient care…no matter what QC method they use

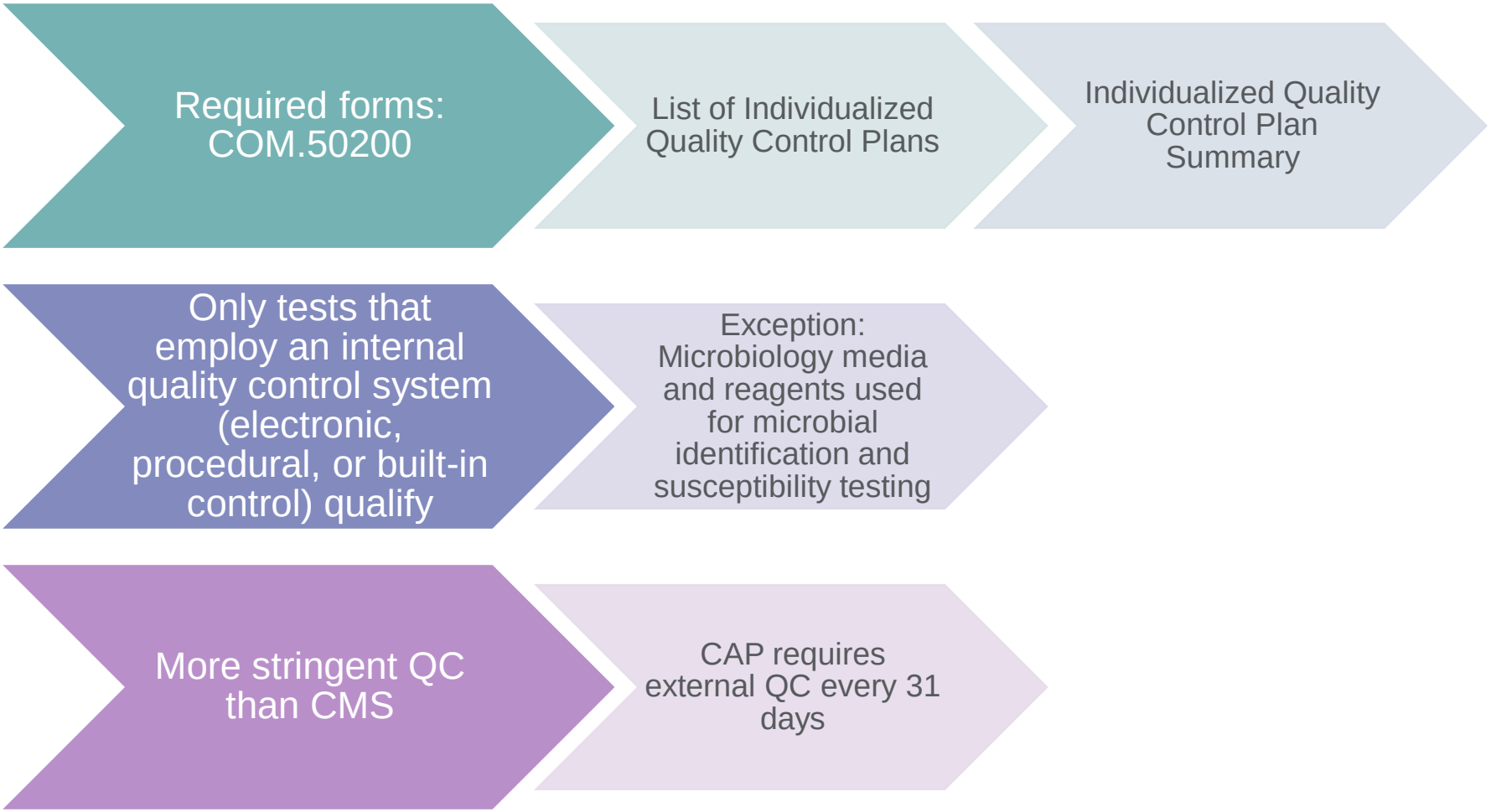
Ensuring that IQCP meets the requirements as set forth in IQCP Interpretive Guidelines (S&C-13-54-CLIA, Attachment 1)

Quality Control Plan

- Delegate in writing to qualified personnel the development and implementation of the QCPs
- Review, sign and date the QCPs before patient testing begins and results are reported (This cannot be delegated)

Data sourced from: Developing a Successful IQCP: Let's Keep it Simple Slide 15 Elia Mears, MHA MT(ASCP)SM Field Surveyor The Joint Commission Stacy Olea, MBA, MT(ASCP), FACHE Executive Director Laboratory Accreditation The Joint Commission AACC July 2015

What We're Hearing from CAP



Data sourced from CAP All Common Checklist July 28, 2015 Permission granted by College of American Pathologists.

COM.50400 and COM.50500

Quality Control Plan

- Contain criteria to determine acceptable QC results
- Specify the number, type, and frequency of testing QC material(s)
- Provide for immediate detection of errors for each phase of the testing process
- Must meet regulatory and CAP accreditation requirements
- Follow manufacturer's instructions and recommendations for QC at minimum
- Indicate that your laboratory director reviewed, signed and dated the QCP document

Data sourced from CAP All Common Checklist July 28, 2015 Permission granted by College of American Pathologists.

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:		**Laboratory Section/Department:**		**CAP Number:**	

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
				Click here to enter a date.	Click here to enter a date.	Click here to enter a date.

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

The form is intended to be used for developing an IQCP or the performance for a risk assessment. The form is to be completed by laboratories preparing for a CAP inspection. Inspectors will use this form and IQCP List as tools for audit the IQCPs in use during a CAP onsite inspection.
Permission granted to use this form by College of American Pathologists.

COM.50600

Quality Assessment

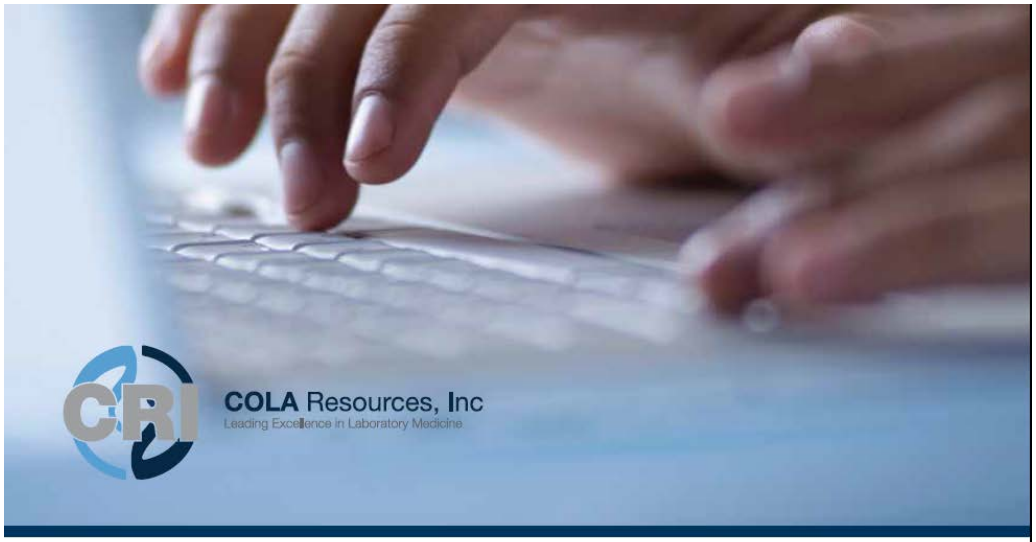
Monitoring to include the following:

- Reagents
- Specimen
- Environment
- Test system
- Testing personnel

Ongoing assessments may include, but are not limited to, the review of the following records:

- Quality control
- Proficiency testing
- Patient results review
- Specimen rejection logs
- Turn around time reports
- Error/corrective action logs
- Personnel/competency
- Instrument maintenance logs

What We're Hearing from COLA



Individualized Quality Control Plan (IQCP)

IMPLEMENTATION GUIDE

CAREPOINT SOLUTIONS

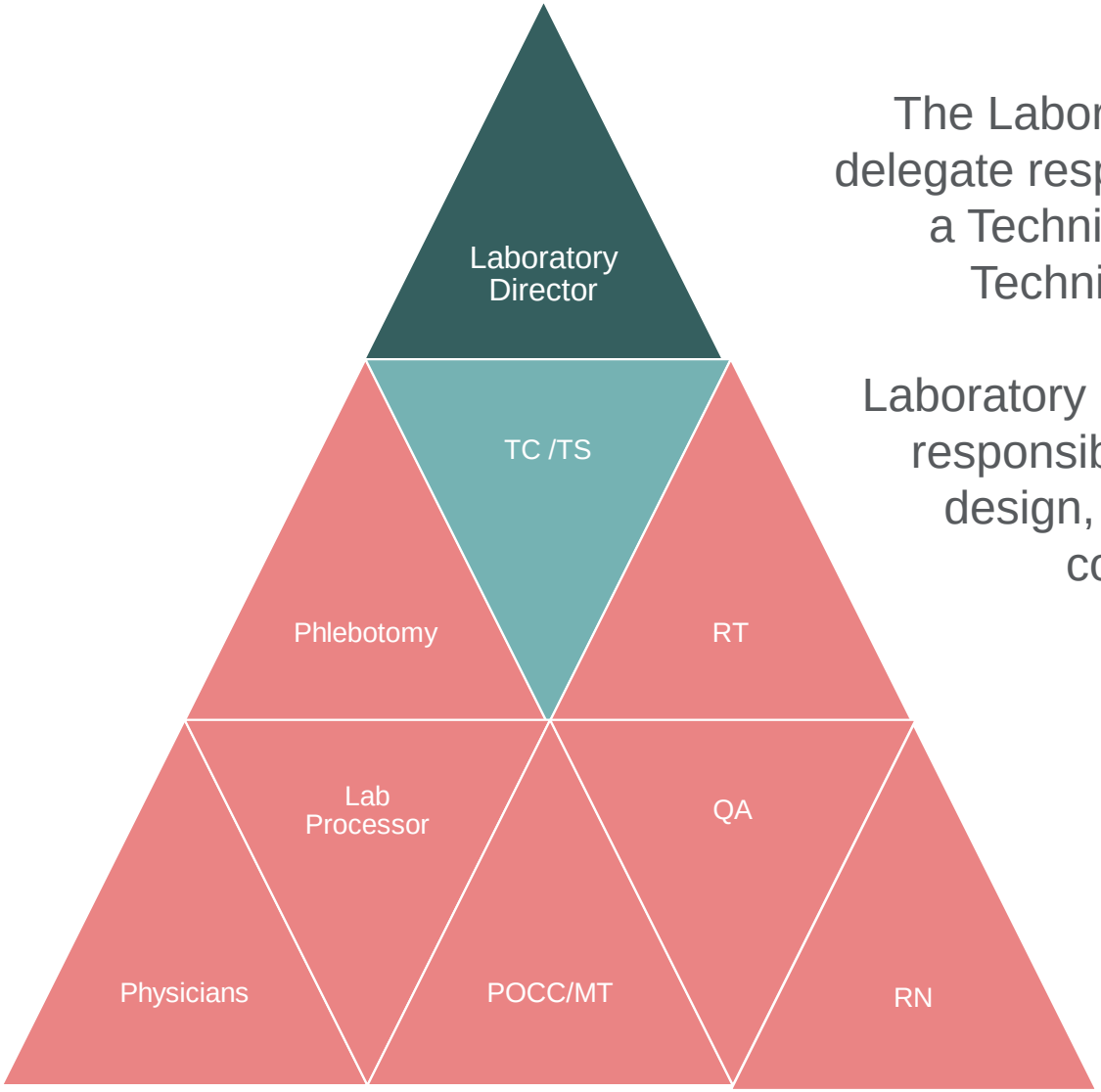
For More Information

CMS	IQCP@cms.hhs.org
CAP	accred@cap.org
Joint Commission	qualitylabs@jointcommission.org Go to the Leading Practice Library
COLA	info@cola.org
Alere	IQCP@alere.com www.alere.com/IQCP

Pen-to-paper suggestions

What you can do right away

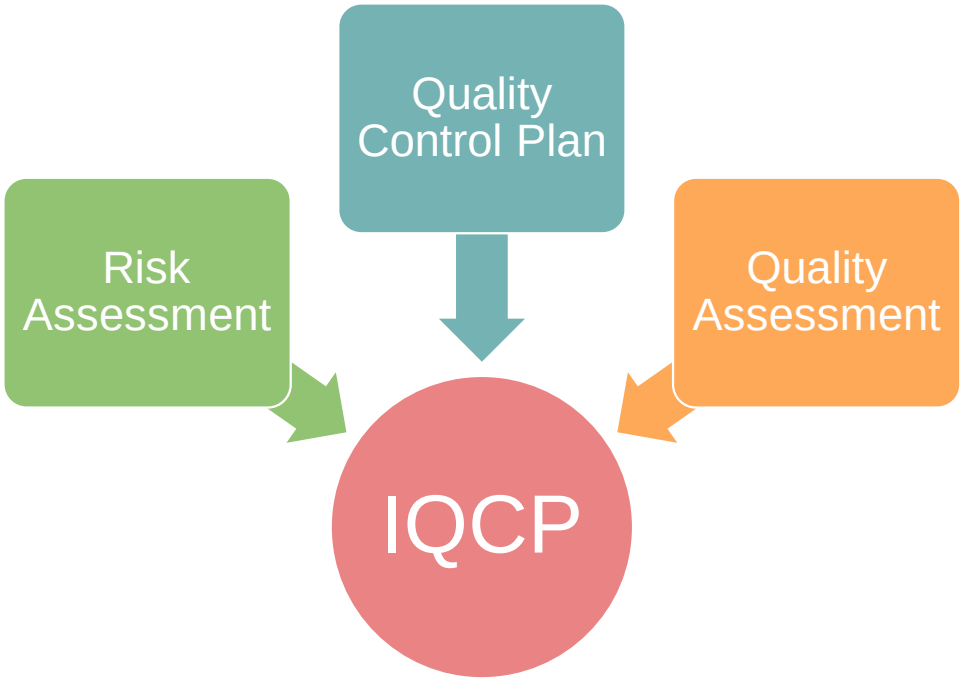
Create the Team



The Laboratory Director may delegate responsibility in writing to a Technical Consultant or Technical Supervisor.

Laboratory Director is ultimately responsible for the plan, its design, its approval and compliance.

Parts of an IQCP



Risk Assessment

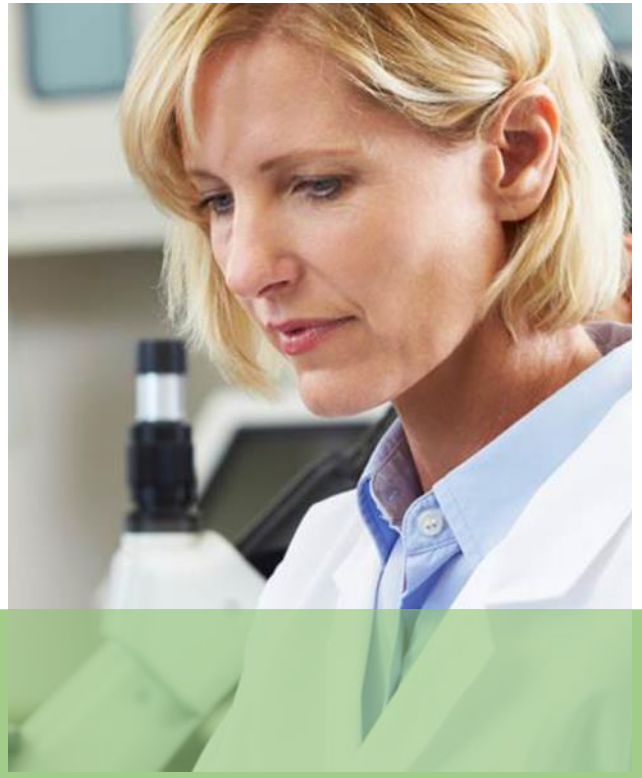
- Process to identify risks

Quality Control Plan

- List of errors and actions to mitigate the risks

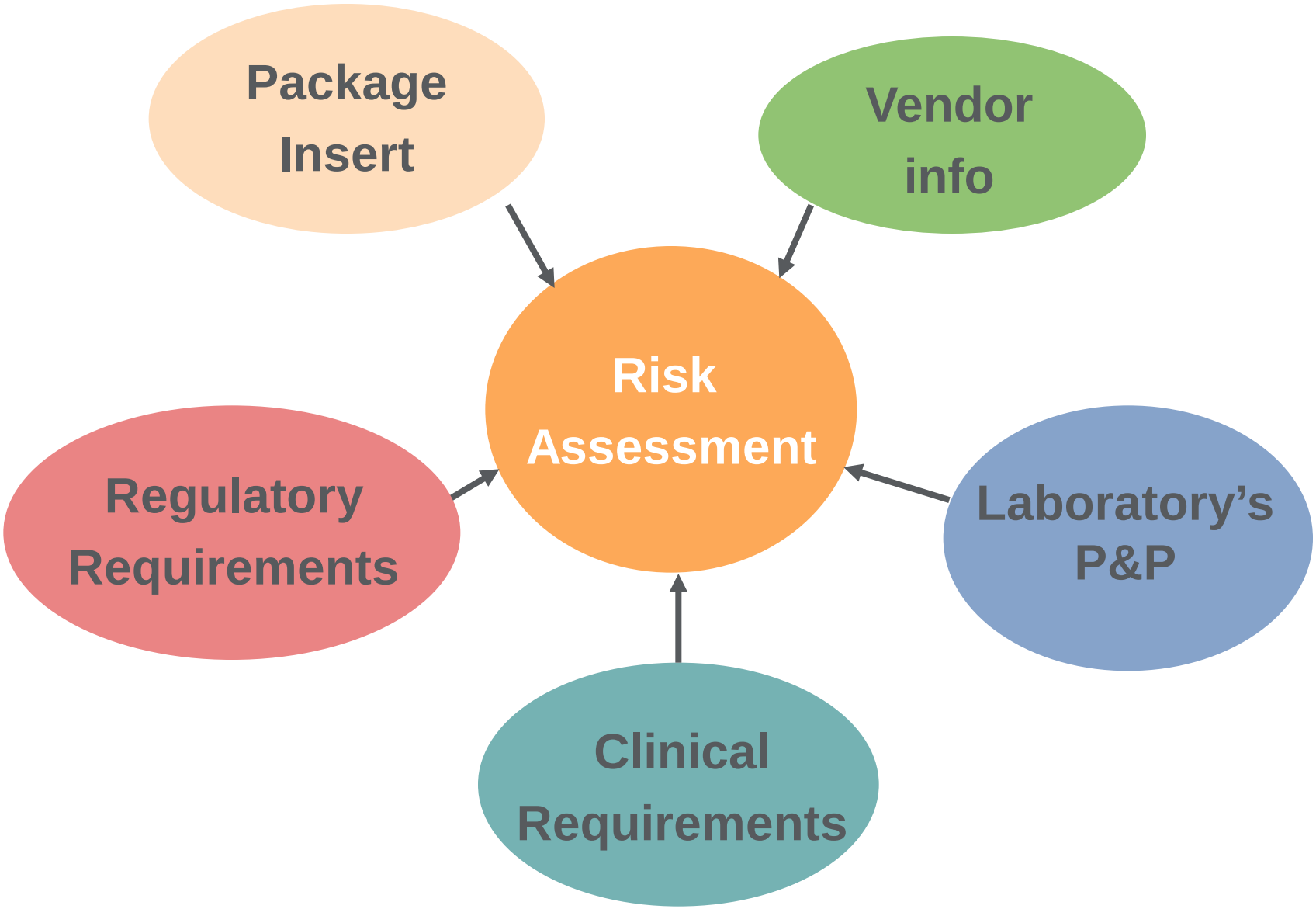
Quality Assessment

- Monitoring of that plan



Component 1- Risk Assessment

Collect Necessary Documents



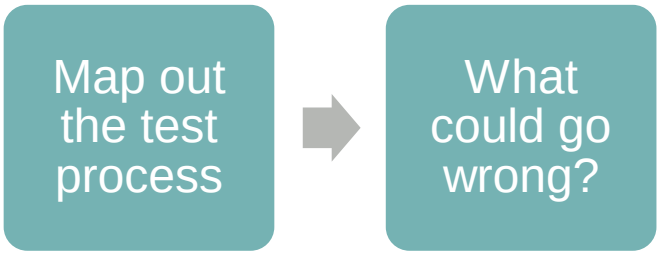
A Simple Approach to Risk Assessments

Ask…

Map out the test process

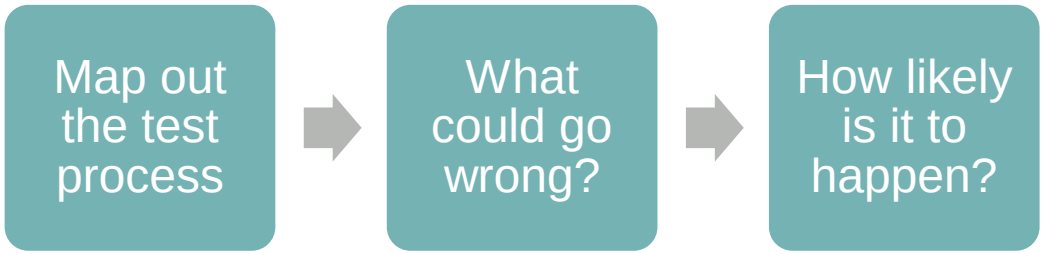
A Simple Approach to Risk Assessments

Ask…



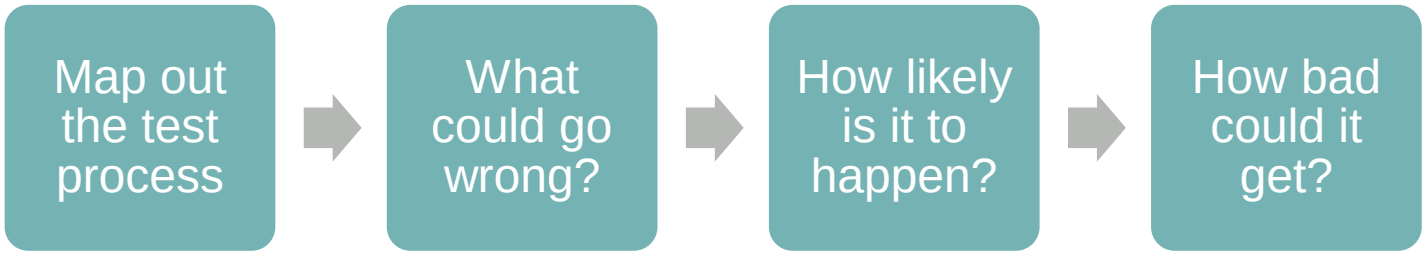
A Simple Approach to Risk Assessments

Ask…



A Simple Approach to Risk Assessments

Ask…



A Simple Approach to Risk Assessments

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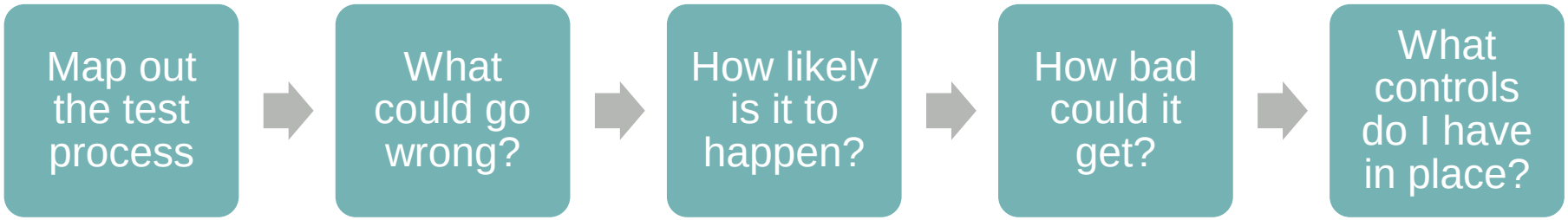
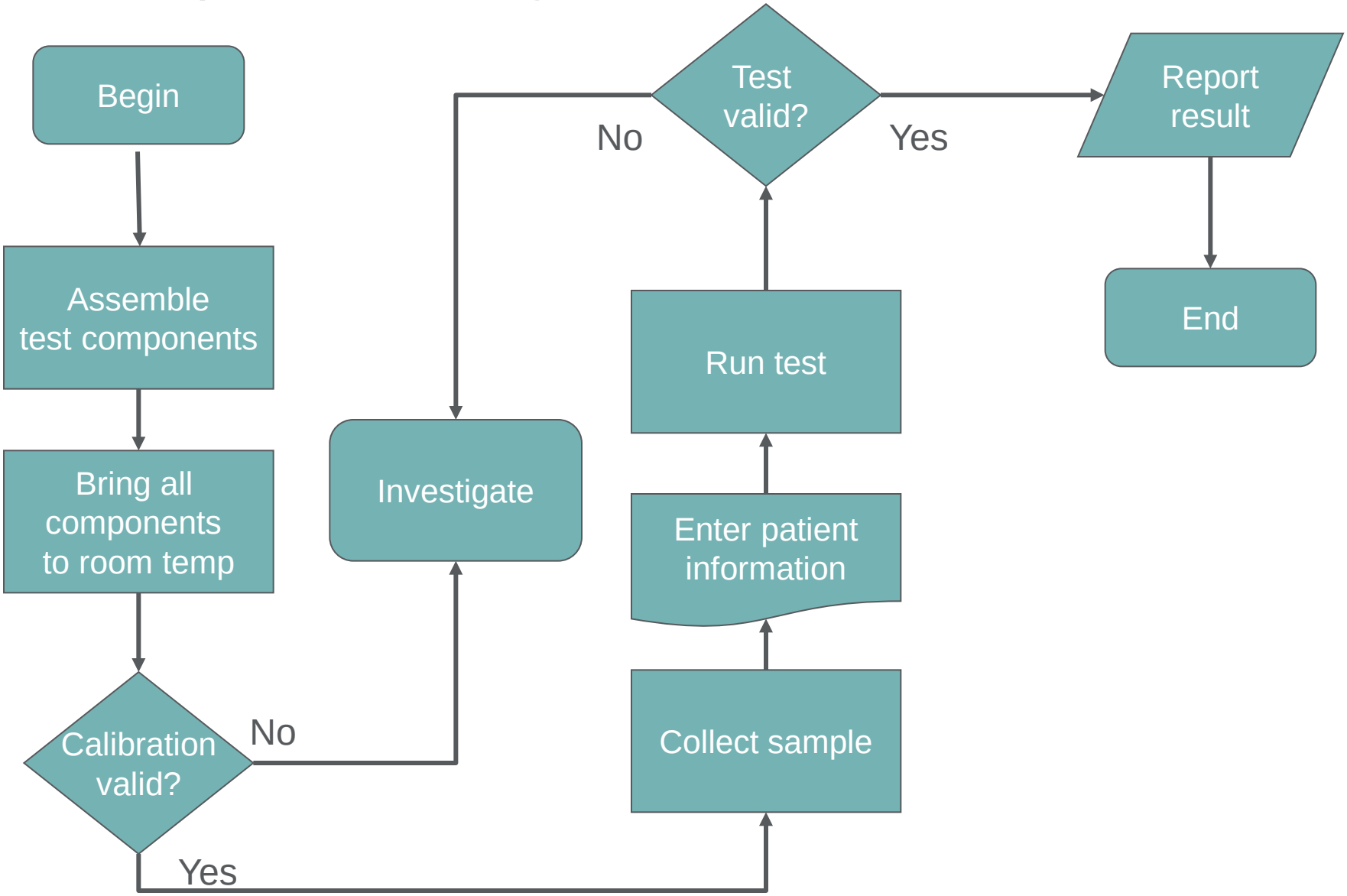
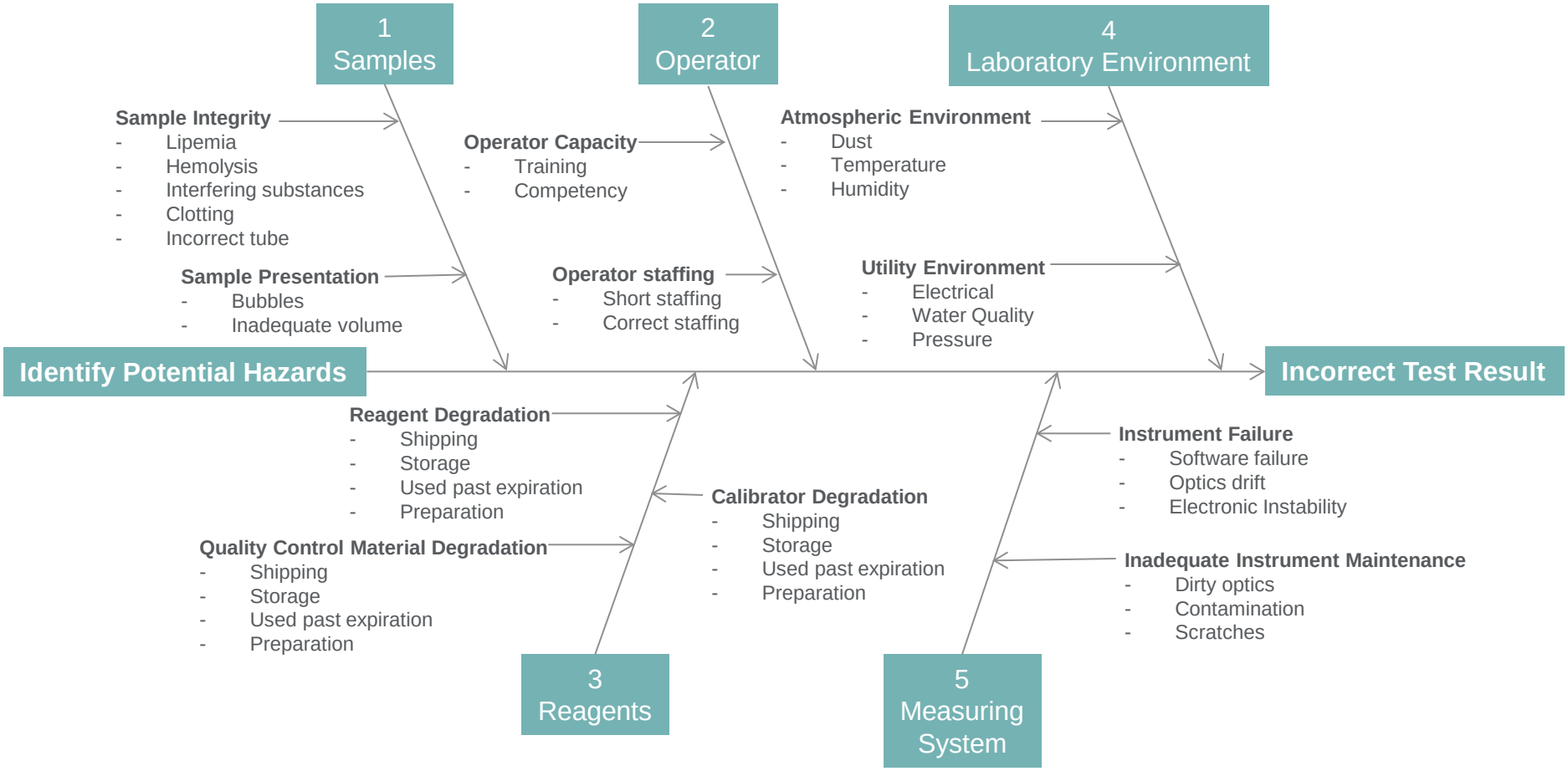


Map Your Testing Processes

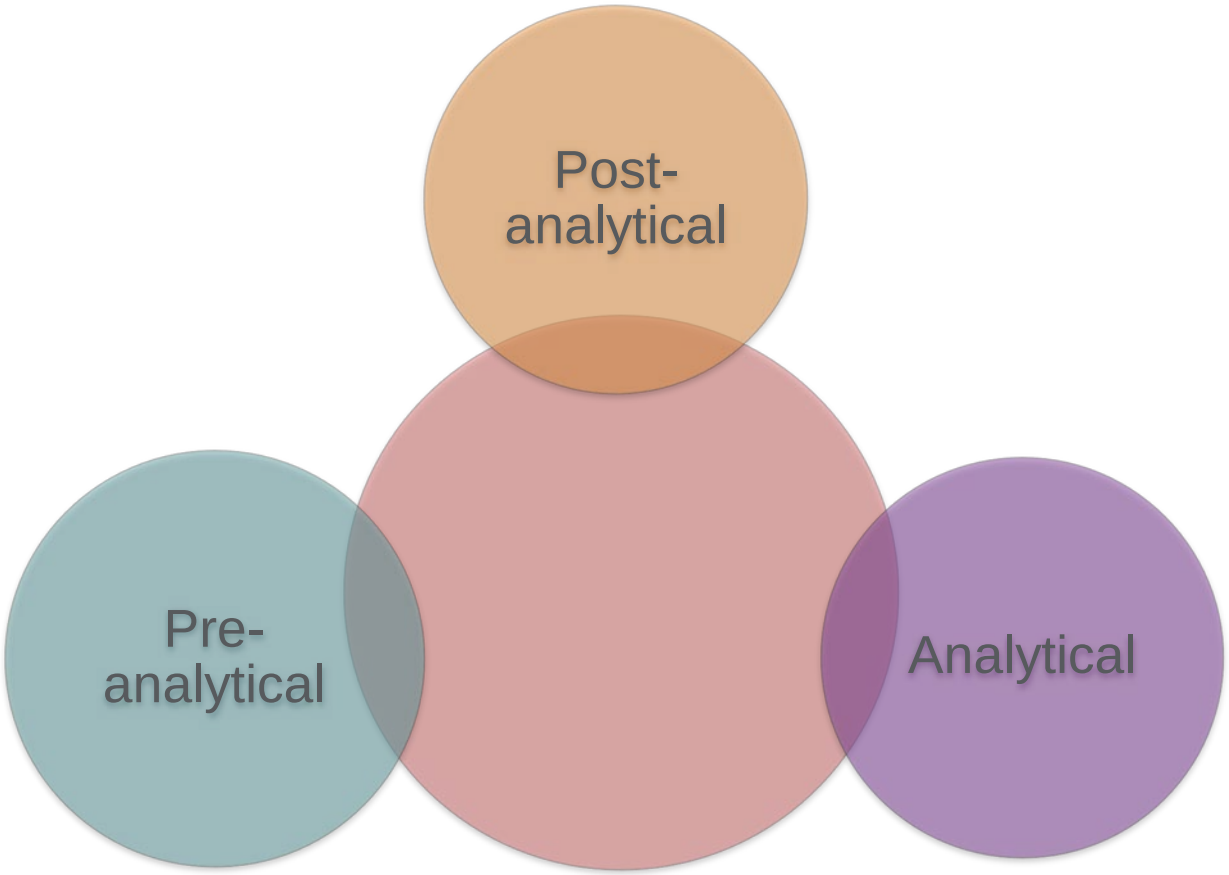


Map Your Testing Process

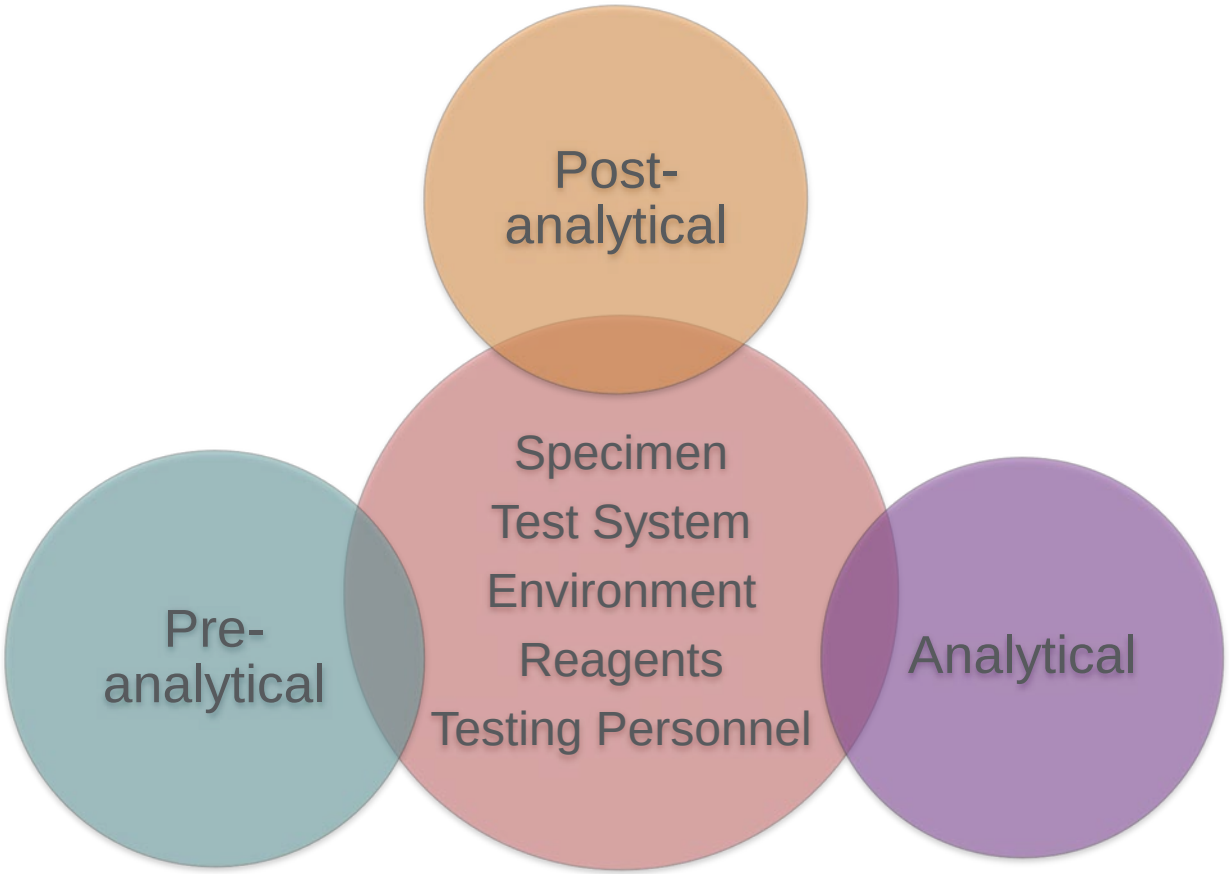


Permission granted from: Laboratory Quality Control Based on Risk Management; Approved Guideline. CLSI document EP23-A. pg. 22 Wayne, PA: Clinical and Laboratory Standards Institute; 2011.

Categorize the Process Steps



Categorize the Process Steps



Collect Data and Provide a Data Summary

Things to Include in Historical Quality Summary Statistics

Specify time period used to review data

Internal/external QC review

Maintenance and performance checks

Corrected reports and physician complaints

Ranking Severity of Failure and Probability of Harm

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

Frequent
- Once per week

Probable
- Once per month

Occasional
- Once per year

Remote
- Once every few years

Improbable
- Once in the life of the test system

Risk Acceptability Matrix

	Severity of Harm				
Probability of harm	Negligible	Minor	Serious	Critical	Catastrophic
Frequent	X	X	X	X	X
Probable	OK	X	X	X	X
Occasional	OK	OK	OK	X	X
Remote	OK	OK	OK	OK	X
Improbable	OK	OK	OK	OK	OK

Permission granted from: Laboratory Quality Control Based on Risk Management; Approved Guideline. CLSI document EP23-A. pg. 27 Wayne, PA: Clinical and Laboratory Standards Institute; 2011.

Component 2 - Quality Control Plan

Quality Control Plan

Nothing less than the manufacturer’s recommendations or local, state or AO requirements.

Quality Control Plan

Nothing less than the manufacturer's recommendations or local, state or AO requirements.

Lab Director approval, sign, and date.

Quality Control Plan

Identify the processes that need additional controls.

Link your existing and new QC processes
to the failures they prevent or detect.

Examine all your QC processes.
If you find a QC process that does not prevent or detect a failure, use the IQCP process to stop doing it.

Process and Procedure Controls

Electronic/Internal/ Procedural Controls

Equipment Maintenance and Temperature Records

Corrective Actions

Personnel Training and Competency Assessment

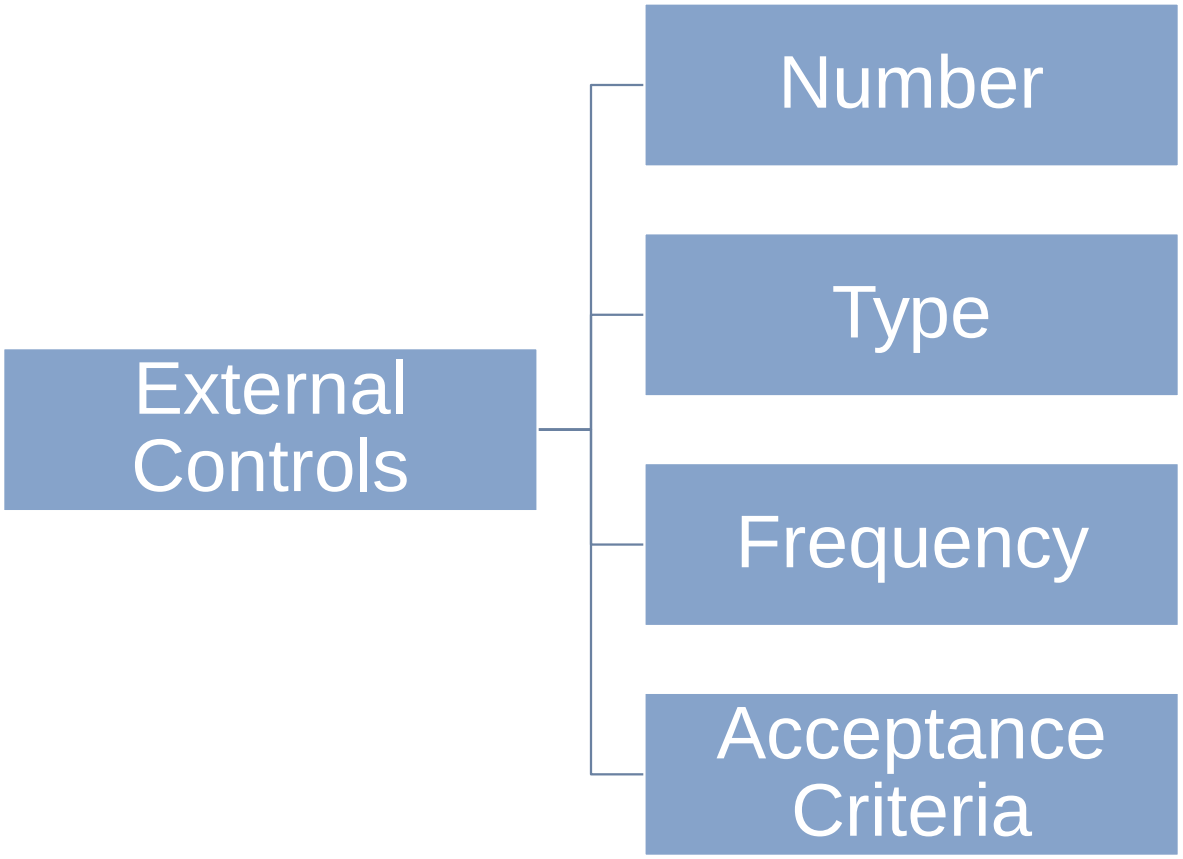
Equipment Calibration Records

Proficiency Testing Results

Verification Data or Establishment of Performance Specification Data

External Controls

When Using External Controls You Must Specify:



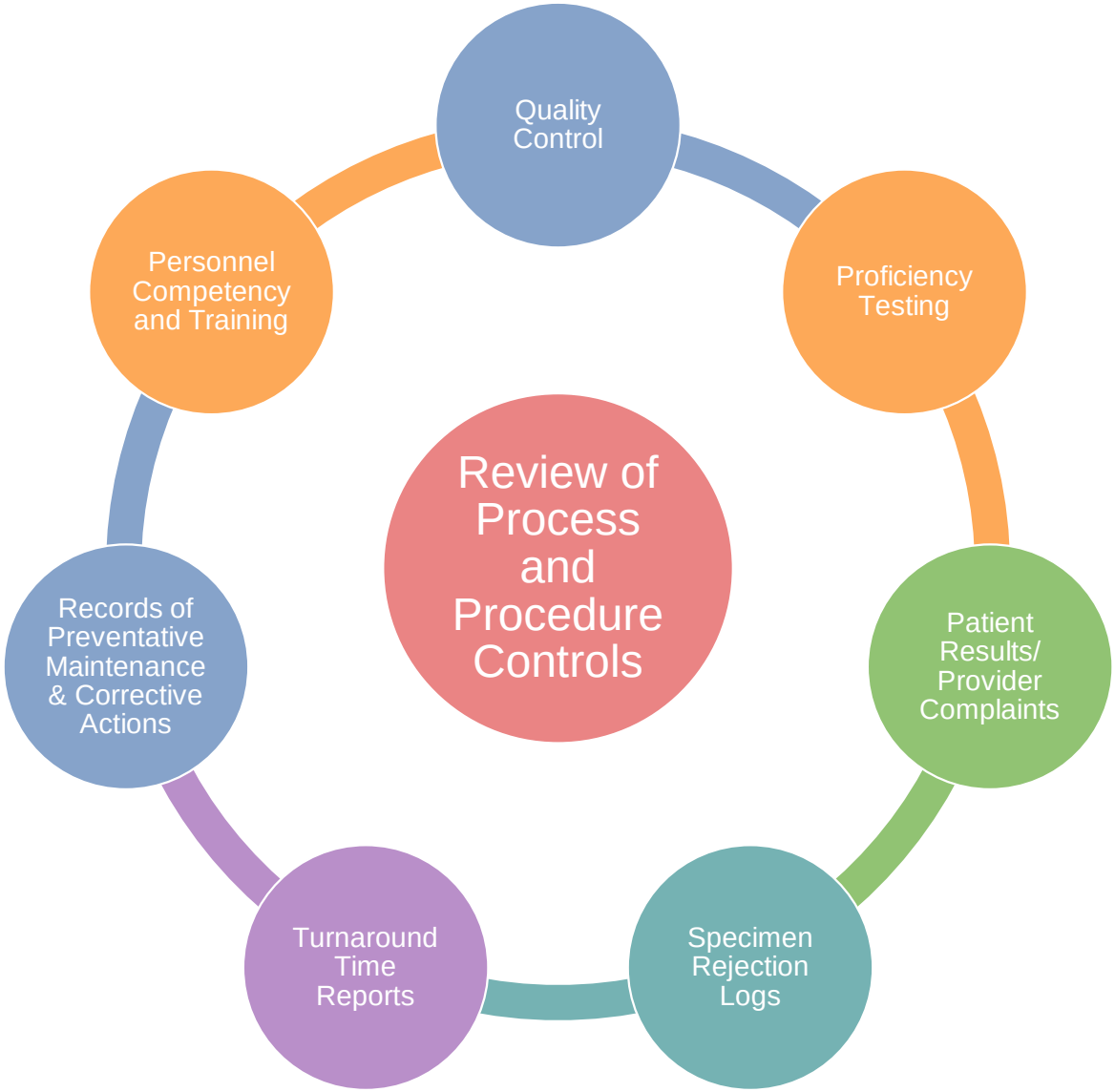
Component 3 - Quality Assessment

Quality Assessment (QA)

Monitoring must be part of the laboratory's overall Quality Assessment plan.

- The monitoring should include, but is not limited to: testing personnel, environment, specimens, reagents, and test system.
- Reevaluation of the QCP should be considered when changes occur in any of the above components or during a failure investigation.
- QA is used to determine if the quality activities are working according to your QCP.

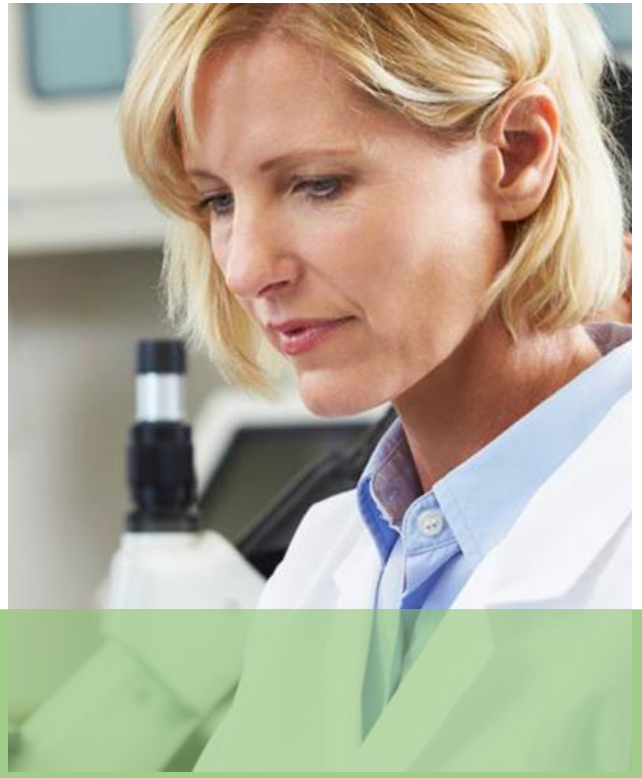
Quality Assessment Activities



Without Quality Assessment, You Don't Have a Complete IQCP

- **Implement** the PLAN with a review schedule for evaluating your QCP
- **Monitor, verify** and **improve** the PLAN, when needed
- **You must update any portion of the RA with new information and modify the QCP when needed**

http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/IQCP-Workbook.pdf Data sourced from pg.43



Let’s do a practice IQCP Risk Assessment

Things to consider if you want to do an IQCP on the Acme Company Lab Test

If Acme Company's Test instructions state to perform 2 levels of external QC each day of testing-you meet minimum CLIA QC requirements and IQCP is not required

If Acme Company's Test recommends QC frequency less than CLIA, you have to: perform 2 levels of external QC each day of testing OR perform an IQCP

Look at your Acme Company Test, if the QC protocols would be costly running external controls daily, then PRIORITIZE the development of an IQCP

Example of a Risk Analysis Worksheet from Alere

Failure	Cause	Failure Type	Potential Effect(s) of Failure	Alere Triage® System Risk Mitigation Features	Alere Triage® System Labeling Instructions, Warnings and Precautions	Laboratory Risk Mitigation	Severity	Frequency	Laboratory Documentation
All specific information here is taken from the Alere Triage® User Manual, revision B, Alere Triage® BNP Product Insert (PN: 26159en Rev. C), Alere Triage® Cardiac HS Product Insert (PN: 26161en Rev. D), Alere Triage® D-Dimer Product Insert (PN:26164en Rev. D) and Alere Triage® TOX Drug Screen Product Insert (PN:26171en Rev. A).									
Operator failure	Not following manufacturer instructions	Testing Personnel		Guided instructions are on the screen of the instrument.	Package Insert (PI) and Instrument User Manual (UM)				
Test Device Handling	Improper reagent shipping temperature	Environment		Alere shipping containers designed to appropriately control temperature	Quality Control and Warnings and Precautions sections of PI				
	Outdated test device-use of expired devices	Testing Personnel		Expiration date is embedded in the device barcode that is read by meter	Warnings and Precautions of PI Expiration dating is printed on every test device.				
	Outdated test device-use of expired devices beyond 14 day room temperature storage	Reagent		None	Reagents must be stored according to the PI and UM. Expiration date is based on reagent stability studies. Technical Bulletin Quality Control Features 10001645-01 07/13				
Test Device Failure	General Test Device Failure - error code	Reagent		Built-in Procedural controls will detect general reagent failures	Technical Bulletin Quality Control Features 10001645-01 07/13				

Step by Step Risk Analysis Assessment

Risk Assessment Components	Phases of Testing	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?
Specimen				
Environment				
Reagent				
Test Systems				
Testing Personnel				

Data sourced from: Developing a Successful IQCP: Let's Keep it Simple Slide 36 Elia Mears, MHA MT(ASCP)SM
Field Surveyor The Joint Commission Stacy Olea, MBA, MT(ASCP), FACHE Executive Director Laboratory Accreditation The Joint Commission AACC July 2015

RA –Acme C

The Step by Step Guide provides additional risk assessment questions in Appendix D that can help ask WHAT CAN GO WRONG!

Laboratory: Anywhere Mec
Test Location: NICU

Risk Assessment Components	Phases of Testing	What t… go wrong…	…urces of error be reduced?	How can we reduce the identified sources of error?
Specimen	Preanalytic	Wrong sample type, incorrect anticoagulant, inadequate fill of tube, patient misidentification and specimen labelling errors.	YES	Training and competency on collection technique, follow manufacturer's instructions for specimen requirements Policy and Procedures (P&P).
		Bubbles or air in sample	YES	Training and competency on collection technique removal of air
		Improper lancet and capillary collection plain plastic, Li Heparin, clots, and inadequate mixing.	YES	Direct observation, and (P&P).

Data sourced from: Developing a Successful IQCP: Let's Keep it Simple Slide 61 Elia Mears, MHA MT(ASCP)SM
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RA –Acme Company Test-Environment

Laboratory: Anywhere Medical Center Test System: Acme Company Test Location: NICU				
Risk Assessment Components	Phases of Testing	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?
Environment	Preanalytic, and Analytic	Temperature of testing area, humidity, and/or altitude out of range.	YES	Monitoring and documentation of temperature and humidity, competency, and P&P.
		Testing area not free of vibration and/or not level.	YES	Appropriate test area designation.
		Designated area not free of contamination (NICU in a dirty utility room)	YES	Appropriate test area designation, and site audits.

Data sourced from: Developing a Successful IQCP: Let's Keep it Simple Slide 64 Elia Mears, MHA MT(ASCP)SM
Field Surveyor The Joint Commission Stacy Olea, MBA, MT(ASCP), FACHE Executive Director Laboratory Accreditation The Joint Commission AACC July 2015

RA – Acme Company Test - Reagent

Laboratory: Anywhere Medical Center Test System: Acme Company Test Location: NICU				
Risk Assessment Components	Phases of Testing	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?
Reagent	Preanalytic and Analytic	Reagent degradation if improper temperature upon receipt.	YES	Record conditions on receipt, document temperatures, room temperature storage documentation and monitor storage areas.
		If test device has a changed exp date, new exp date not labelled on test device	YES	If test devices out of box expiration changes, new date on test device, and new expiration date on RT stored cart
		Test device not used immediately after out of pouch	YES	P&P, training, and competency.

Data sourced from: Developing a Successful IQCP: Let's Keep it Simple Slide 63 Elia Mears, MHA MT(ASCP)SM
Field Surveyor The Joint Commission Stacy Olea, MBA, MT(ASCP), FACHE Executive Director Laboratory Accreditation The Joint Commission AACC July 2015

Example of Cut and Paste IQCP Support Document

Laboratory: Anywhere Medical Center Test System: Acme Company Test Location: NICU				
Reagent	Preanalytic and Analytic	Reagent degradation if improper temperature upon receipt.	YES	Record conditions on receipt, document temperatures, room temperature storage documentation and monitor storage areas.
		If test device has a changed exp date, new exp date not labelled on test device	YES	If test devices out of box expiration changes, new date on test device, and new expiration date on RT stored cart
		Test device not used immediately after out of pouch	YES	P&P, training, and competency.
Reagent	Preanalytic	Outdated test device-use of expired devices beyond 14 day room temperature storage	YES	Reagents must be stored according to the PI and UM. Expiration date is based on reagent stability studies. Technical Bulletin Quality Control Features 10001645-01 07/13

Data sourced from: Developing a Successful IQCP: Let's Keep it Simple Slide 63 Elia Mears, MHA MT(ASCP)SM
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RA –Acme Company Test- Test System

Laboratory: Anywhere Medical Center -Test System **Test Location: NICU**				
Risk Assessment Components	Phases of Testing	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?
Test System	Preanalytic, and Postanalytic	Wrong User ID	YES	Training and competency
		Procedural control and external controls (what to do if fails)	YES	Understand how procedural control works, QC failures, P&P, and follow manufacturer's instructions
		Manual Reporting error	YES	P&P and verification of results before reporting, or adding a data manager system such as RALS® as an interface.

Data sourced from: Developing a Successful IQCP: Let's Keep it Simple Slide 62 Elia Mears, MHA MT(ASCP)SM
Field Surveyor The Joint Commission Stacy Olea, MBA, MT(ASCP), FACHE Executive Director Laboratory Accreditation The Joint Commission AACC July 2015

RA –Acme Company Test-Testing Personnel

Laboratory: Anywhere Medical Center- Testing Personnel **Test Location: NICU**				
Risk Assessment Components	Phases of Testing	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?
Testing Personnel	Preanalytic	Operator training, PRN's trained? How frequent do PRN's perform the test?	YES	Competency and training of all personnel required, P&P
		Testing personnel and qualifications inadequate, short staffed, or license requirements not verified.	YES	Documentation of education and qualifications at the time of hire, or when responsibility assigned.
		Low test volume and inadequate testing experience	YES	Test volume may drive frequency needed for QC

Data sourced from: Developing a Successful IQCP: Let's Keep it Simple Slide 65 Elia Mears, MHA MT(ASCP)SM
Field Surveyor The Joint Commission Stacy Olea, MBA, MT(ASCP), FACHE Executive Director Laboratory Accreditation The Joint Commission AACC July 2015

Let’s do a practice Quality Control Plan

Anywhere Medical Center Laboratory
Acme Company Test Example QCP Worksheet

Laboratory: Anywhere Medical Center- Acme Company test- Location: NICU		
Type of Quality Control	Frequency	Criteria for Acceptability (Range of Acceptable Values)
Procedural Control	With each specimen	Must be documented as acceptable according to package insert on the quality control log sheet prior to reporting results.

http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/IQCP-Workbook.pdf Data sourced from pgs. 37-38

Anywhere Medical Center Laboratory
Acme Company Test Example QCP Worksheet

Laboratory: Anywhere Medical Center- Acme Company test- Location: NICU		
Type of Quality Control	**Frequency**	**Criteria for Acceptability (Range of Acceptable Values)**
Procedural Control	With each specimen	Must be documented as acceptable according to package insert on the quality control log sheet prior to reporting results.
Temperature Checks	Record room temperature daily, in the morning and afternoon. Record refrigerator and freezer each day.	List of all ranges as specified in the package insert for room, refrigerator and freezer. These ranges will be recorded on the temperature log sheets.

http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/IQCP-Workbook.pdf Data sourced from pgs. 37-38

Anywhere Medical Center Laboratory
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Temperature Checks	Record room temperature daily, in the morning and afternoon. Record refrigerator and freezer each day	List all range as specified in the package insert for room, refrigerator and freezer. These ranges will be recorded on the 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.

http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/IQCP-Workbook.pdf Data sourced from pgs. 37-38

Anywhere Medical Center Laboratory
Acme Company Test Example QCP Worksheet

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Temperature Checks	Record room temperature daily, in the morning and afternoon. Record refrigerator and freezer each day	List all range as specified in the package insert for room, refrigerator and freezer. These ranges will be recorded on the 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.
External Quality Control Normal and Abnormal Values	Assay normal and abnormal quality control no less than stated on package insert. Also see package insert for additional conditions to be run.	Acceptable external control values are within laboratory determined ranges. Results must be recorded on quality control log sheet prior to reporting results.

http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/IQCP-Workbook.pdf Data sourced from pgs. 37-38

Anywhere Medical Center Laboratory
Acme Company Test Example QCP Worksheet

Laboratory: Anywhere Medical Center- Acme Company test- Location: NICU		
Type of Quality Control	**Frequency**	**Criteria for Acceptability (Range of Acceptable Values)**
Procedural Control	With each specimen	Must be documented as acceptable according to package insert on the quality control log sheet prior to reporting results.
Temperature Checks	Record room temperature daily, in the morning and afternoon. Record refrigerator and freezer each day	List all range as specified in the package insert for room, refrigerator and freezer. These ranges will be recorded on the 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.
External Quality Control Normal and Abnormal Values	Assay normal and abnormal quality control no less than stated on package insert. Also see package insert for additional conditions to be run.	Acceptable external control values are within laboratory determined ranges. Results must be recorded on quality control log sheet prior to reporting results.
Reagent Device Storage	With each reagent device	Document date and time on reagent device when removed from the refrigerator. Follow package insert instructions for handling reagents.

http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/IQCP-Workbook.pdf Data sourced from pgs. 37-38

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Reagent Device Storage	With each reagent device	Document date and time on reagent device when removed from the refrigerator. Follow package insert instructions for handling reagents.
Training	With each new testing personnel and when indicated	Successful demonstration of test performance. Document training activities.

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These examples are not meant to be all inclusive of all possible QC procedures that may apply to your laboratory

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Temperature Checks	Record room temperature daily, in the morning and afternoon. Record refrigerator and freezer each day	List all range as specified in the package insert for room, refrigerator and freezer. These ranges will be recorded on the temperature log sheets.
Verify specimen collection tubes for acceptability upon receipt in the laboratory	With each patient specimen	Refer to Specimen Rejection Policy and record all improperly collected tubes on specimen rejection log sheet.
External Quality Control Normal and Abnormal Values	Assay normal and abnormal quality control no less than stated on package insert. Also see package insert for additional conditions to be run.	Acceptable external control values are within laboratory determined ranges. Results must be recorded on quality control log sheet prior to reporting results.
Reagent Device Storage	With each reagent device	Document date and time on reagent device when removed from the refrigerator. Follow package insert instructions for handling reagents.
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 Approval and Signature_____ Date_____		
Laboratory Director or Designee Review and Signature_____ Date_____		

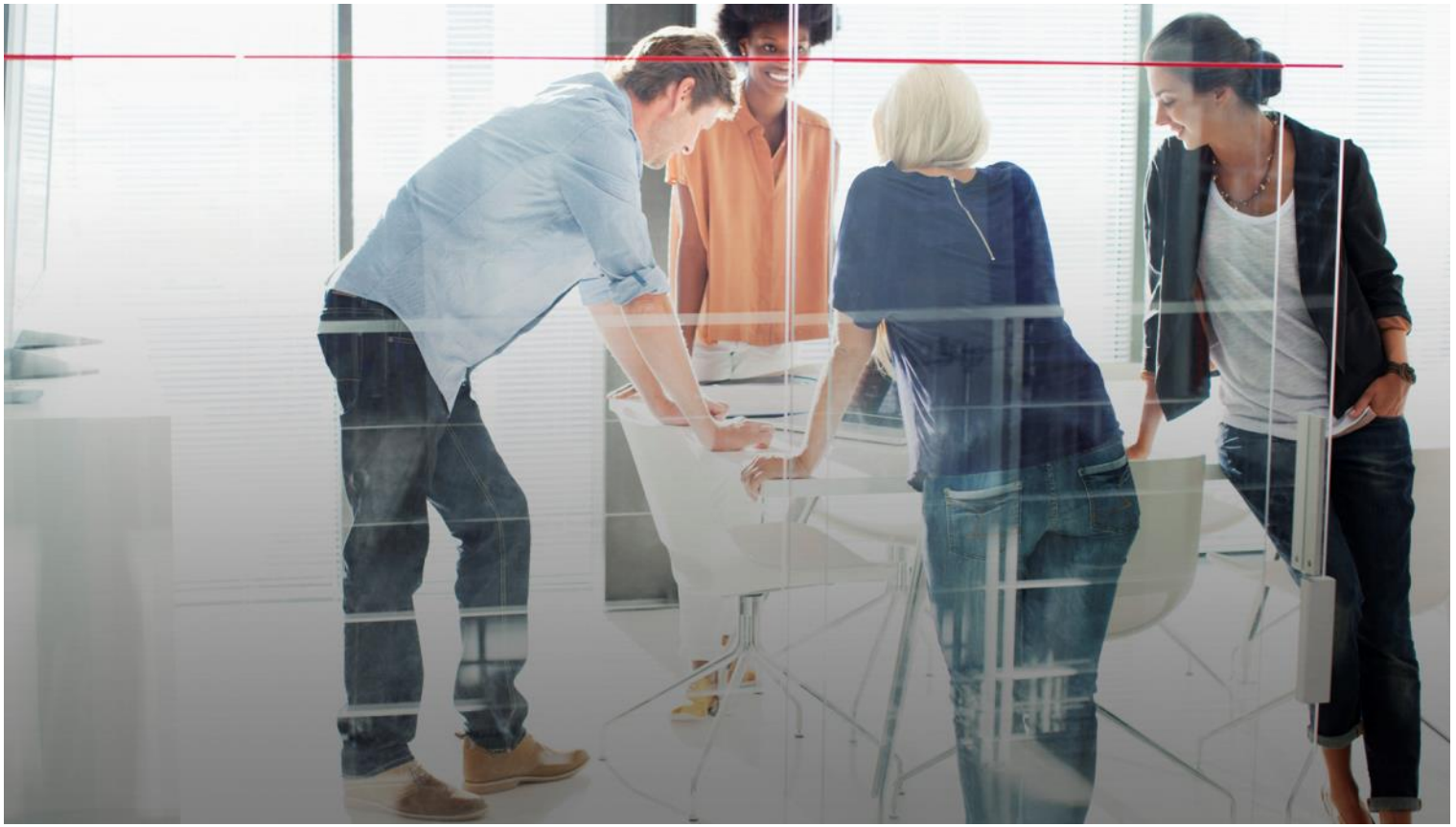
http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/IQCP-Workbook.pdf pg. 37-38

Anywhere Medical Center Laboratory
Acme Company Test Example QA Worksheet

Laboratory: Anywhere Medical Center- Acme Company test- Location: NICU			
QC Process to Monitor	Frequency	Assessment of QC Process (Was there variation from established policy and procedures?)	Corrective Action (When indicated)
Review all temperature logs	Monthly	Yes	Remedial training of testing personnel. Reassess testing personnel performance.
Review all specimen rejection logs	Monthly	Yes	Remedial training of processing personnel. Reassess processing personnel performance.
Review QC logs	Daily	No	
PT Records	Monthly	No	
FDA Alerts	As Needed	No	
Review training logs	As needed based on staffing	No	
Review personnel qualifications	As needed based on new hires.	No	
Review competency assessments	Annually	No	

Data sourced from: Developing a Successful IQCP: Let's Keep it Simple Slide 68 Elia Mears, MHA MT(ASCP)SM
Field Surveyor The Joint Commission Stacy Olea, MBA, MT(ASCP), FACHE Executive Director Laboratory Accreditation The Joint Commission AACC July 2015

Draft an IQCP Standard Operating Procedure



An IQCP SOP is not required by CMS, but should be considered as good laboratory practice and may be required by local, state or other accrediting groups.

IQCP Helpful Hints

Tips

DON’T go it alone!!!

Don’t just cram your existing QC procedures into your IQCP

- An IQCP links potential failures to QC procedures.
- If a QC procedure doesn’t link to an IQCP failure, STOP DOING IT

Multiple tests on a cartridge?
Devices in multiple locations?

The manufacturer RA spreadsheets could be a starting point.

- Feel free to modify them to work for you
- Don’t forget about the pre- and post- analytical failures

Tips

- Summarize your data for your inspectors
- Risk Analysis does not have to be complicated
- Laboratory Director cannot delegate initial approval of IQCP
- IQCP SOP may be incorporated into existing QCP and QA SOPs
- Best guide: Developing an IQCP A Step-by-Step Guide

In Closing…

If you haven’t started yet, get started tomorrow!

Thank You!

Questions?