

Individualized Quality Control Plan(IQCP) & Quality Management Systems: Where do we begin?

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COLA Resources Inc. (CRIA®)
Non-Profit Subsidiary

CRIA® Mission Statement

“Provide educational and consultative services aimed at improving laboratory medicine and patient care”

COLA Resources Inc. (CRI®)

Goal: instructing and training healthcare professionals in improving their skills and, ultimately, to perform higher quality services for the communities they serve.

Goal: improve laboratory medicine and the quality of patient care associated with the day-to-day operations of laboratory medicine.

“Establish Continuous Quality standards through the Individualized Quality Control Plan (IQCP) Program”

Session Learning Objectives

- ✓ History & evolution of Quality Control
- ✓ Provide an Overview of Quality Management Systems (QMS)
- ✓ Provide an Overview of Individualized Quality Control Plan (IQCP)
- ✓ Describe the Relationship that exists between QMS & IQCP
- ✓ Prepare to implement Individualized Quality Control Plan(IQCP)

Did You Know?

“While diagnostics comprise less than 5% of hospital costs and about 1.6% of all Medicare costs, their findings influence as much as 60-70% of health care decision-making.”

Why is the laboratory an afterthought for managed care organizations? Forsman RW, Clin Chem 1996; 42: 813-816

Percentage of Errors in Clinical Testing

Pre-analytical Phase → 46%-68.2%

Inappropriate test request

Order entry errors

Misidentification of patient

Container inappropriate

Sample collection and transport inadequate

Inadequate sample/anticoagulant volume ratio

Insufficient sample volume

Sorting and routing errors

Labeling errors

<http://labmed.ascpjournals.org/content/43/2/41/T1.expansion.html>

Analytical Phase → 7% -13%

Equipment malfunction

Sample mix-ups/interference

Undetected failure in quality control

Procedure not followed

<http://labmed.ascpjournals.org/content/43/2/41/T1.expansion.html>

Post-analytical Phase → 18.5% - 47%

Failure in reporting

Erroneous validation of analytical data

Improper data entry

<http://labmed.ascpjournals.org/content/43/2/41/T1.expansion.html>

Evolution of Quality Control



Continues to evolve.....2014



Defining ISO 15189

- ✓ Specifies the quality management system requirements particular to medical laboratories
- ✓ Includes provisions on:
 - collection of patient samples
 - interpretation of test results
 - acceptable turnaround times
 - how testing is to be provided in a medical emergency
 - the lab's role in the education and training of health care staff.

What is IQCP?

- A) Inquiring Quality Control Process
- B) Inquisitive Query of Control Programming
- C) Individualized Quality Control Plan**
- D) A & B But NOT C
- E) All of the above
- F) None of the above

Total Quality Management

**Individual
Quality
Control
Plan(IQCP)**

**Quality
Management
System(QMS)
ISO15189**

**Quality
Laboratory
Medicine +
Quality
Patient Care**

Consider the following definitions...

Risk Assessment: identification and evaluation of potential failures and sources of errors in a testing process, impacting the accuracy and precision of test results. *First step in risk management*

Quality Assurance: focused on providing confidence that quality requirements will be fulfilled

Quality Control: testing materials that have a known concentration of the substance being measured prior to or concurrent with patient testing

(Interpretive Guidelines, Risk Assessment Section)

Consider the following definitions...

Quality Control Plan: (QCP) is a document that describes the practices, resources, and procedures to control the quality of a particular test process

- ✓ Monitors the accuracy and precision of a test performance over time
- ✓ Includes the number, type, and frequency of QC
- ✓ Defines criteria for acceptability of QC
- ✓ Referred to as IQCP

Interpretive Guidelines, Quality Control Plan Section)

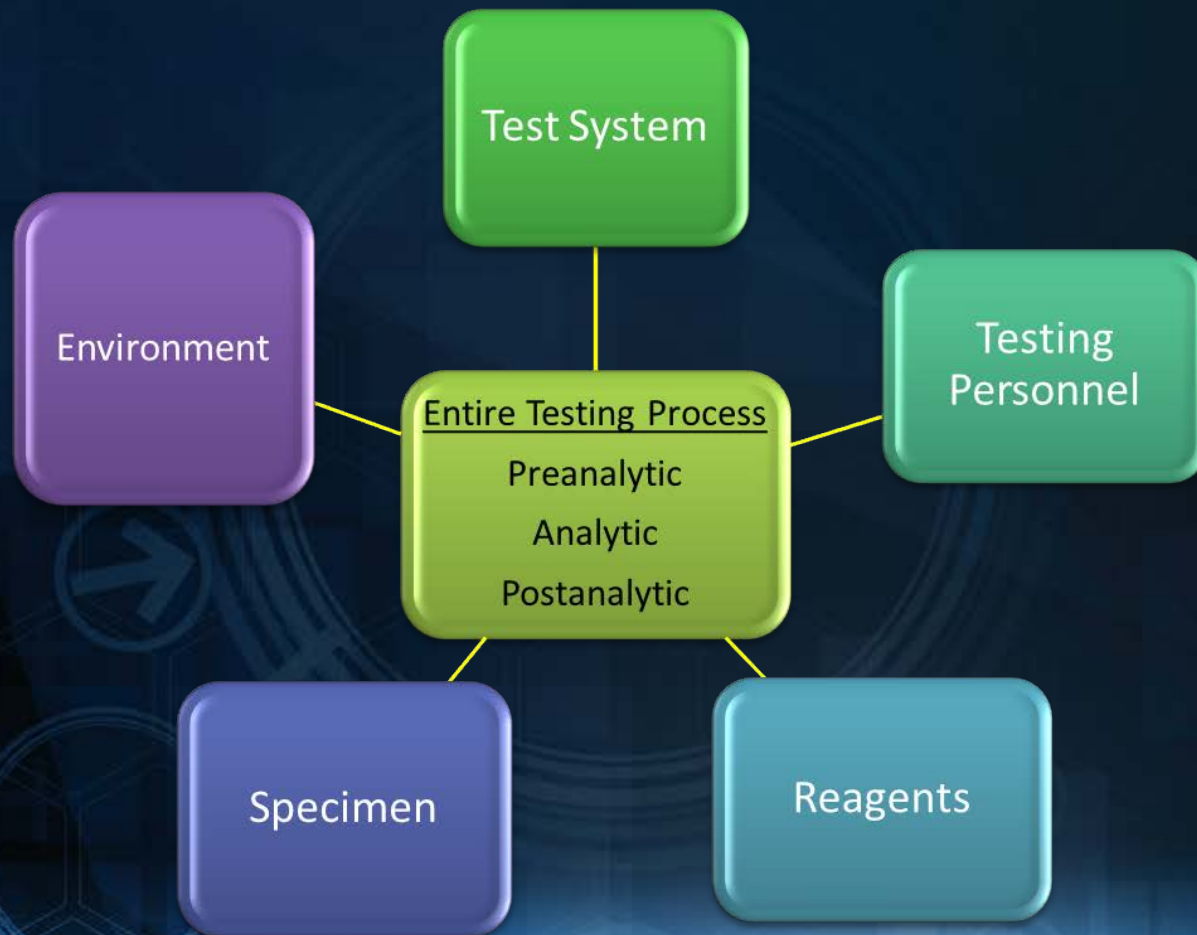
Consider the entire testing process in conjunction with the 5 components:

- ✓ Pre-analytic Systems
- ✓ Analytic Systems
- ✓ Post-analytic Systems

Follows QMS Path of Workflow & CLIA



Five Components of IQCP



Where Do we Begin.....

- ✓ Evaluate the risks specific to your laboratory
- ✓ Provide documented evidence of the risk assessment

“IQCP does not mandate any specific method of risk evaluation”

Defining the Data requirements to support the lab's assessment and decision:

- ✓ Laboratory's own data required
- ✓ Can be new data and/or historical
- ✓ Data used to meet other CLIA requirements
- ✓ CMS doesn't prescribe quantity or type of data

- ✓ Identified the sources of potential failures and errors
- ✓ Evaluated the frequency and impact of those failures and errors

THEN.....

- ✓ Resulting RA is used to develop the Individualized Quality Control Plan (IQCP)

(Interpretive Guidelines, Risk Assessment Section)

- ✓ Based upon Risk Management
- ✓ IQCP is not EP-23 *“Laboratory Quality Control Based on Risk Management”*
- ✓ Labs are not required to incorporate EP-23
- ✓ IQCP is not a regulation
- ✓ EQC will no longer be acceptable
- ✓ IQCP is voluntary for laboratories
- ✓ Applies to moderate and high complexity testing

- ✓ IQCP will be an enforceable procedure for equivalent quality testing as per Appendix C of the State Operations Manual
- ✓ Existing CLIA QC & quality system concepts won't change
- ✓ No regulations will change!
- ✓ State and local regulations still apply
- ✓ Lab director will continue to have overall responsibility for QCP

EQC Vs IQCP

EQC	IQCP
Transitional	Updated Solution
Standardized	Customizable
Rigid	Flexible
Narrow Scope Limited regulations Limited Specialties	Broader Scope More Regulations (Excludes Pathology)
Analytic Phase Only	Pre Analytic/Analytic/Post Analytic Phases
Requires Internal QC	Does not Require Internal QC
Decreases External QC	May/May Not decrease QC

The LD is responsible for:

- ✓ Accurate and reliable test results that are appropriate for patient care
- ✓ Ensuring that IQCP meets the requirements as set forth in IQCP Interpretive Guidelines
- ✓ Signing and dating the IQCP when implemented and updated
- ✓ The LD may assign in writing:
 - The responsibility for establishing IQCP as part of the laboratory's overall QC program to the TC/TS
 - Specific portions of IQCP tasks to other qualified laboratory employees

Before you begin consider...

- ✓ If the manufacturer QC protocol is *less stringent* than the regulatory requirement, then you will need to do the IQCP in order to follow the manufacturer QC protocol.
- ✓ Historical data may be used in the risk assessment, such as EQC qualifying data, QC reports, and PT
- ✓ If you have used EQC in the past, it is likely that the test systems for which you chose EQC will be the same test systems for which you will choose IQCP
- ✓ IQCP is NOT new, simply a way to integrate all your current processes and procedures in one main document
- ✓ Tools are available!

Before you begin consider...



All CLIA specialties/subspecialties will be included in IQCP, except...

Pathology

Histopathology

Oral Pathology

Cytology

Before you begin consider...

- ✓ All CLIA regulations remain in force and must be followed
- ✓ Only the eligible regulations identified in the following table(s) may be considered with IQCP
- ✓ Any IQCP eligible regulation that the lab chooses to replace with IQCP must be supported in the RA

Table 1: Eligibility for IQCP

CLIA Specialty/ Subspecialty	Eligible for IQCP?	General Regulations Eligible for IQCP	Specialty/Subspecialty Regulations Eligible for IQCP	Specialty/ Subspecialty Regulations NOT Eligible for IQCP
Bacteriology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	§493.1261	N/A
Mycobacteriology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	§493.1262	N/A
Mycology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	§493.1263	N/A
Parasitology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	§493.1264	N/A
Virology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	§493.1265	N/A
Syphilis Serology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	N/A	N/A
General Immunology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	N/A	N/A

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Routine Chemistry	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	§493.1267(b),(c)	§493.1267(a), (d)
Urinalysis	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	N/A	N/A
Endocrinology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	N/A	N/A
Toxicology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	N/A	N/A
Hematology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	§493.1269	N/A
Immunohematology	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	N/A	§493.1271
Clinical Cytogenetics	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	N/A	§493.1276

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Radiobioassay	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	N/A	N/A
Histocompatibility	Yes	§493.1256(d)(3)-(5) §493.1256(e)(1)-(4)	§493.1278(b)(6), (c), (d)(6), (e)(3)	§493.1278(a), (b)(1-5),(d)(1- 5), (d)(7), (e)(1-2), (f),(g)
Pathology	No	None (Not eligible for IQCP)	N/A	N/A
Histopathology	No	None (Not eligible for IQCP)	N/A	N/A
Oral Pathology	No	None (Not eligible for IQCP)	N/A	N/A
Cytology	No	None (Not eligible for IQCP)	N/A	N/A

Individualized Quality Control Plan



Education & transition period for labs before IQCP is fully effective

Begins: January 1, 2014

Ends: January 1, 2016

Our journey begins now.....

- ✓ Follow the CLIA regulatory QC requirements as written
- ✓ Continue to follow the EQC procedures as described in the current Interpretive Guidelines
- ✓ Implement IQCP

Education, Education, Education!



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Leading Excellence in Laboratory Medicine

Creating an IQCP...

Where do I begin???



What Information Do I need?

The first step in developing your IQCP for a test is to gather as much information as possible about all phases of the testing process (pre-analytic, analytic and post-analytic). This information will be used to identify and evaluate potential risks (i.e., errors with the potential to cause harm) associated with:

- ✓ Specimens
- ✓ Testing Personnel
- ✓ Reagents
- ✓ Laboratory Environment
- ✓ Test System



Consider the following.....

- Records for all types of QC in use for the test, including external control results and graphs, electronic, procedural/built-in
- Package inserts and/or operators manuals for the test system/device, including the manufacturer's QC requirements
- Package inserts for all reagents, including controls and calibrators
- Previous EQC qualifying study for the test, if performed
- Records of calibration, maintenance, function checks and service records for the instrument
- Relevant literature about the test
- Proficiency testing records
- Applicable regulatory or accreditation criteria requirements
- Personnel qualification, training and competency records
- Environmental monitoring records
- Information about how the test is used in your laboratory (screening, diagnosis, treatment decisions such as medication adjustments)
- Problem logs, complaints or incidents related to the test
- Any comparisons of results with another method
- Policies for repeat testing & result review before reporting
- Relevant Quality Assessment reviews and activities
- Any other information that is relevant to how the test is performed in YOUR laboratory

You want to evaluate:

- ✓ How the test performs in your lab
- ✓ If, and how often relevant errors or undesirable conditions occur in your lab
- ✓ The potential impact of those errors
- ✓ What control activities your laboratory already has in place to detect or prevent those errors

“CONSIDER ALL PHASES OF TESTING...”



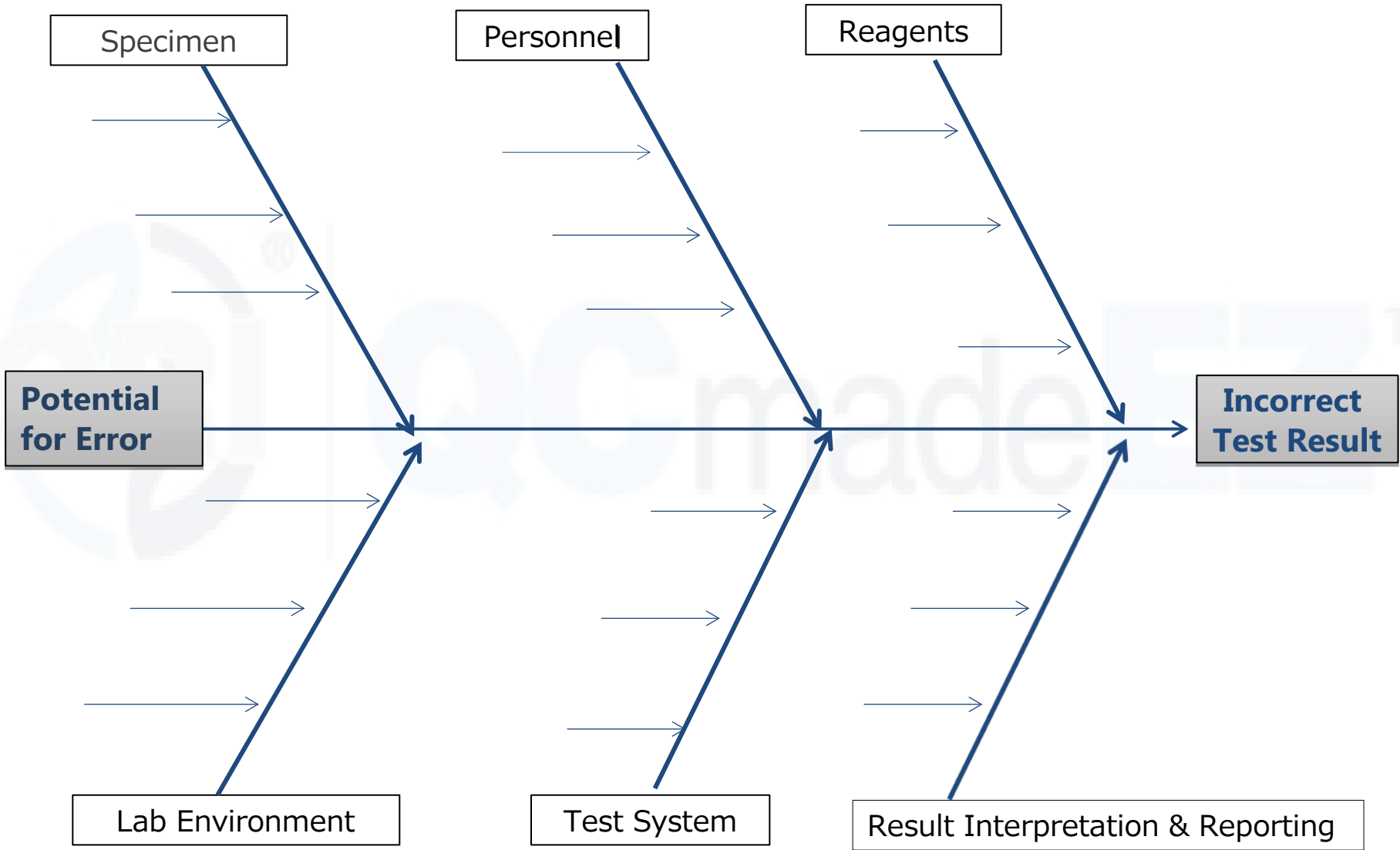
- ✓ Gather and compile information
- ✓ Perform the analysis
- ✓ Determine the optimum QC for this test in your lab
- ✓ Train to the QCP
- ✓ Continuous monitoring the effectiveness of the QCP and make changes if necessary

- ✓ How is the test used by the physician?
- ✓ Are decisions about medical procedures made quickly, based upon the results of this test?
- ✓ Consider patient population
- ✓ Volume of testing

- ✓ Fishbone Diagram
- ✓ Process Map
- ✓ Risk Identification Table
- ✓ Risk Assessment Table
- ✓ Risk Manageability Matrix



Fishbone Diagram for Test: _____ Phase: _____



Fishbone Diagram- All Phases

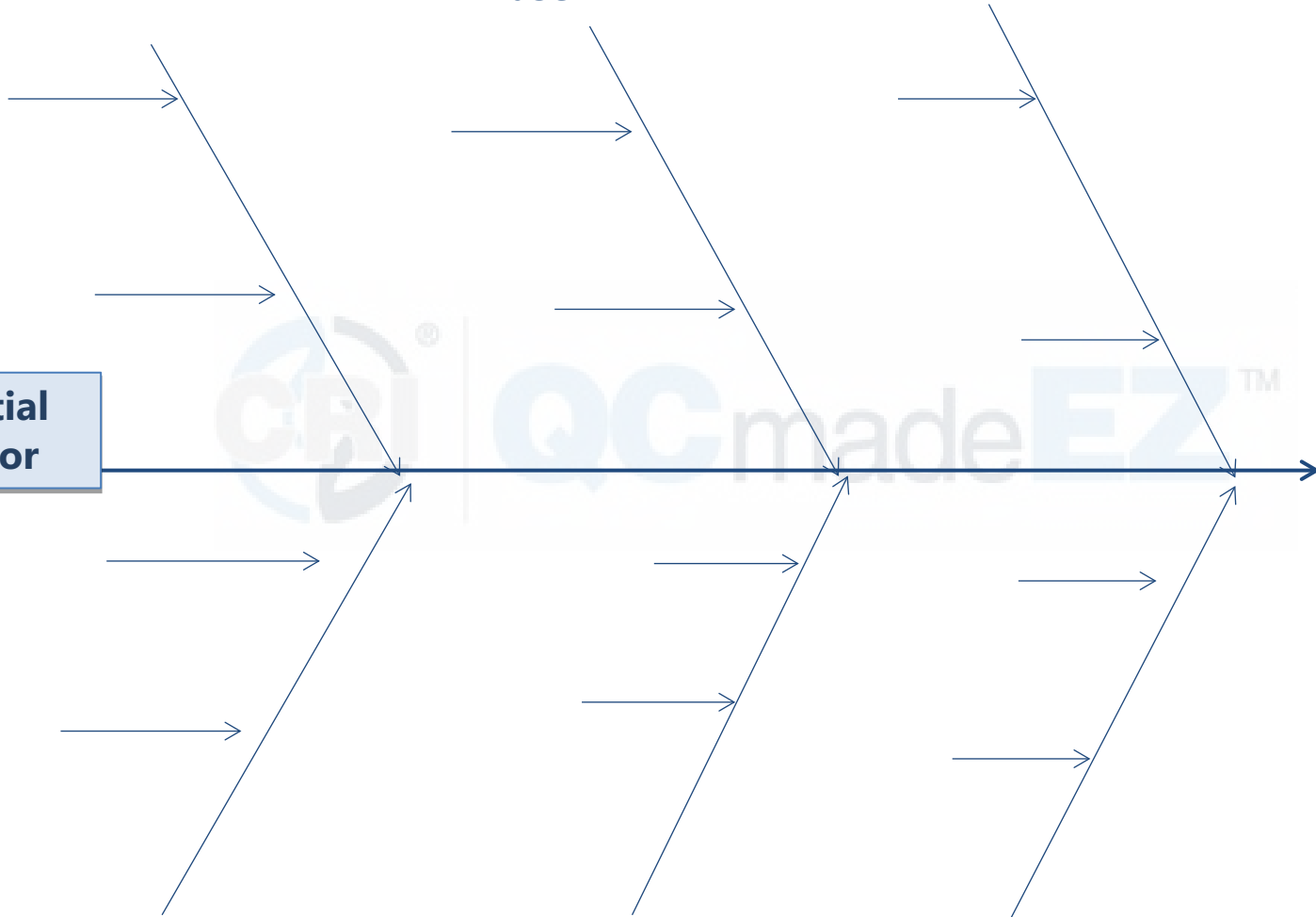
**Pre-analytic
Phase**

**Analytic
Phase**

**Post-Analytic
Phase**

**Potential
for Error**

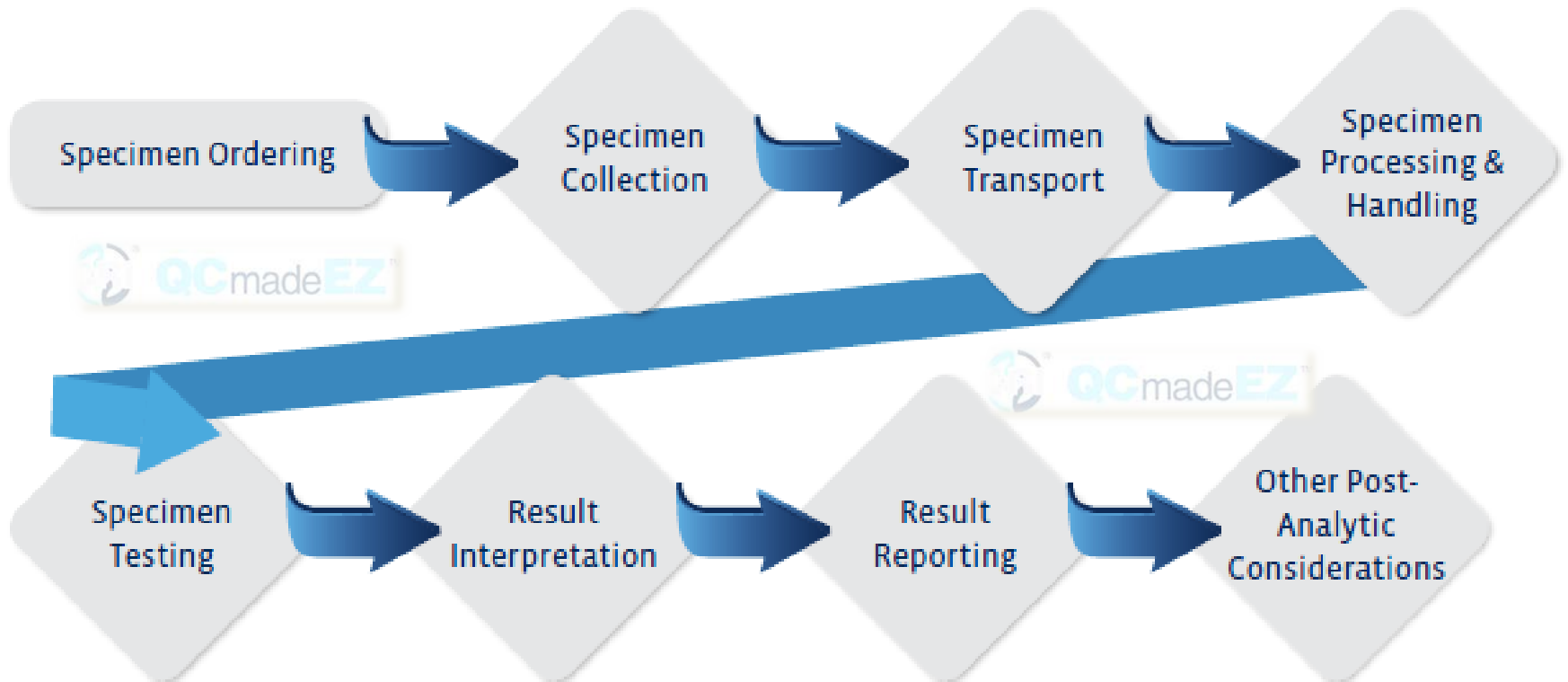
**Incorrect
Test Result**



Risk Identification Table

Component	Pre-Analytical Phase	Analytical Phase	Post-Analytical Phase (Result Interpretation and Reporting)
Specimen			
Personnel			
Laboratory Environment			
Test Systems			
Reagents			
Post-analytic Activities (Result Interpretation and Reporting)	X	X	

Process Map



Risk Manageability Matrix

	<u>Severity of Harm</u>				
<u>Probability of Harm</u>	Negligible	Marginal	Significant	Severe	Catastrophic
Frequent	Unmanageable	Unmanageable	Unmanageable	Unmanageable	Unmanageable
Probable	Manageable	Unmanageable	Unmanageable	Unmanageable	Unmanageable
Possible	Manageable	Manageable	Manageable	Unmanageable	Unmanageable
Rare	Manageable	Manageable	Manageable	Manageable	Unmanageable
Improbable	Manageable	Manageable	Manageable	Manageable	Manageable

Probability of Harm

- **Frequent** = once per week
- **Probable** = once per month
- **Possible** = once per year
- **Rare** = once every few years
- **Improbable** = once in the life of the measuring system

Severity of Harm

- **Negligible** = inconvenience or temporary discomfort
- **Marginal** = temporary injury or impairment not requiring professional medical intervention
- **Significant** = injury or impairment requiring professional medical intervention
- **Severe** = permanent impairment or life-threatening injury
- **Catastrophic** = patient death

Risk Assessment Table

	Column A Potential Error	Column B How often has this error occurred or how likely is it to occur?	Column C Can this be detected by existing controls or current laboratory practices?	Column D Risk Level (See Risk Manageability Matrix)	Column E Cause of Error & Risk Mitigation (Add to QC Plan)
Specimens	<i>List all potential errors related to patient preparation, specimen collection, preparation, type, condition and storage of specimens. For example, if a test requires whole blood, a clotted specimen may be a source of error.</i>				

Ask the Questions.....

- ✓ Is the test system eligible for IQCP?
- ✓ Does the IQCP include all required elements?
- ✓ Does the lab's data support its IQCP?
- ✓ Does the IQCP include the number, type, frequency and acceptability criteria for QC?
- ✓ Is my lab, at a minimum, following the manufacturer QC requirements?
- ✓ Has the Lab Director reviewed and approved the IQCP?

Ask the Questions.....

- ✓ How is the test used by the physician?
- ✓ Are decisions about medical procedures made quickly, based upon the results of this test?
- ✓ Who is my patient population
- ✓ Are there any opportunities for improvement?

In Summary...

- ✓ Once effective, IQCP will supersede the current EQC policy
- ✓ Existing CLIA QC & QS concepts won't change
- ✓ No regulations will change!
- ✓ Minimally, labs must follow manufacturer's instructions
- ✓ Lab director has overall responsibility for IQCP

CRI E-Optimizer Platform

*This **software tool** offers laboratories a guide or roadmap on performing a risk assessment and develop an Individualized Quality Control Plan (IQCP)*

- *Easy to use*
- *Customizable*
- *Documented records /report*
- *Subscription model*

CRI Implementation Guide

- ✓ Manual offering an **overview** of Quality Control:
 - evolution
 - framework
 - definitions
- ✓ **Roadmap** to performing Risk Management:
 - Risk Assessment Plan → **Process Mapping, Fishbone, or a Risk Identification Table**

“Once IQCP is completed and reviewed what are next steps for my lab?”

- ✓ Review IQCP at regular intervals
- ✓ When quality failures occur– review of QC plan should be included in your investigation
- ✓ Re-evaluate and adjust IQCP if necessary

“IQCP is an ongoing process...”

Remember...

“IQCP is not intended to necessarily reduce QC requirements, but it is intended to ensure effective QC for each laboratory and the tests it performs”

IQCP Resources Available



www.cms.hhs.gov/clia/

S&C 13-54-CLIA

www.criedu.org

www.labuniversity.org

www.info@criedu.org

rcasados@criedu.org

1(800) 981-9883

Final Thought....

“Productivity and efficiency can be achieved only step by step with sustained hard work, relentless attention to details and insistence on the highest standards of quality and performance.” - J. R. D. Tata

Thank You....

Questions?

