CLIA's New IQCP Requirements Are in Effect, or Are They?:

Implementing Laboratory Risk Management Now to Ensure Success

Jack Zakowski, PhD, FACB

Director, Scientific Affairs and Professional Relations Beckman Coulter, Inc. and President-Elect Clinical and Laboratory Standards Institute (CLSI)

Executive War College

April 29, 2014

CLINICAL AND LABORATORY STANDARDS INSTITUTE®

BECKMAN COULTER

Learning Objectives

At the end of this session, participants will be able to:

- List the new Clinical Laboratory Improvement Amendment (CLIA) certification requirements for laboratories in the area of risk management.
- Incorporate risk management into the laboratory's broader quality management system (QMS).
- Implement use of the CLSI document EP23 as a key tool for an Individualized Quality Control Plan (IQCP).
- List the resources available to laboratories in creating an IQCP.

IQCP – The Short Version (Part 1 of 2)

- CLIA's New IQCP Requirements Are in Effect:
  - **Yes.**
  - They are effective as of **January 1, 2014.**

IQCP – The Short Version (Part 2 of 2)

- Or Are They?:
  - **January 1, 2014 – January 1, 2016:**
    - A transition and education period of two years
    - For both laboratories and inspectors
    - Laboratories may have their IQCPs assessed, but IQCPs will not cause an inspection failure
  - **January 1, 2016:**
    - Full implementation of IQCP
    - Laboratories will be failed for inadequate IQCPs
  - **Will your IQCP be adequate on its first draft?**

Centers for Medicare & Medicaid Services (26 pages)

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

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.

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

IQCP Is Applicable to CLIA-Certified Laboratories

The specialties/subspecialties **eligible** for IQCP are:

- Bacteriology
- Mycobacteriology
- Mycology
- Parasitology
- Virology
- Syphilis Serology
- General Immunology
- Routine Chemistry
- Urinalysis
- Endocrinology
- Toxicology
- Hematology
- Immunohematology
- Clinical Cytogenetics
- Radiobioassay
- Histocompatibility

The specialties/subspecialties ***not*** **eligible** for IQCP are:

- Pathology
- Histopathology
- Oral Pathology
- Cytology

Ref: CMS Memo S&C: 13-54-CLIA

What Is an IQCP?

Individualized Quality Control Plan

Risk Assessment

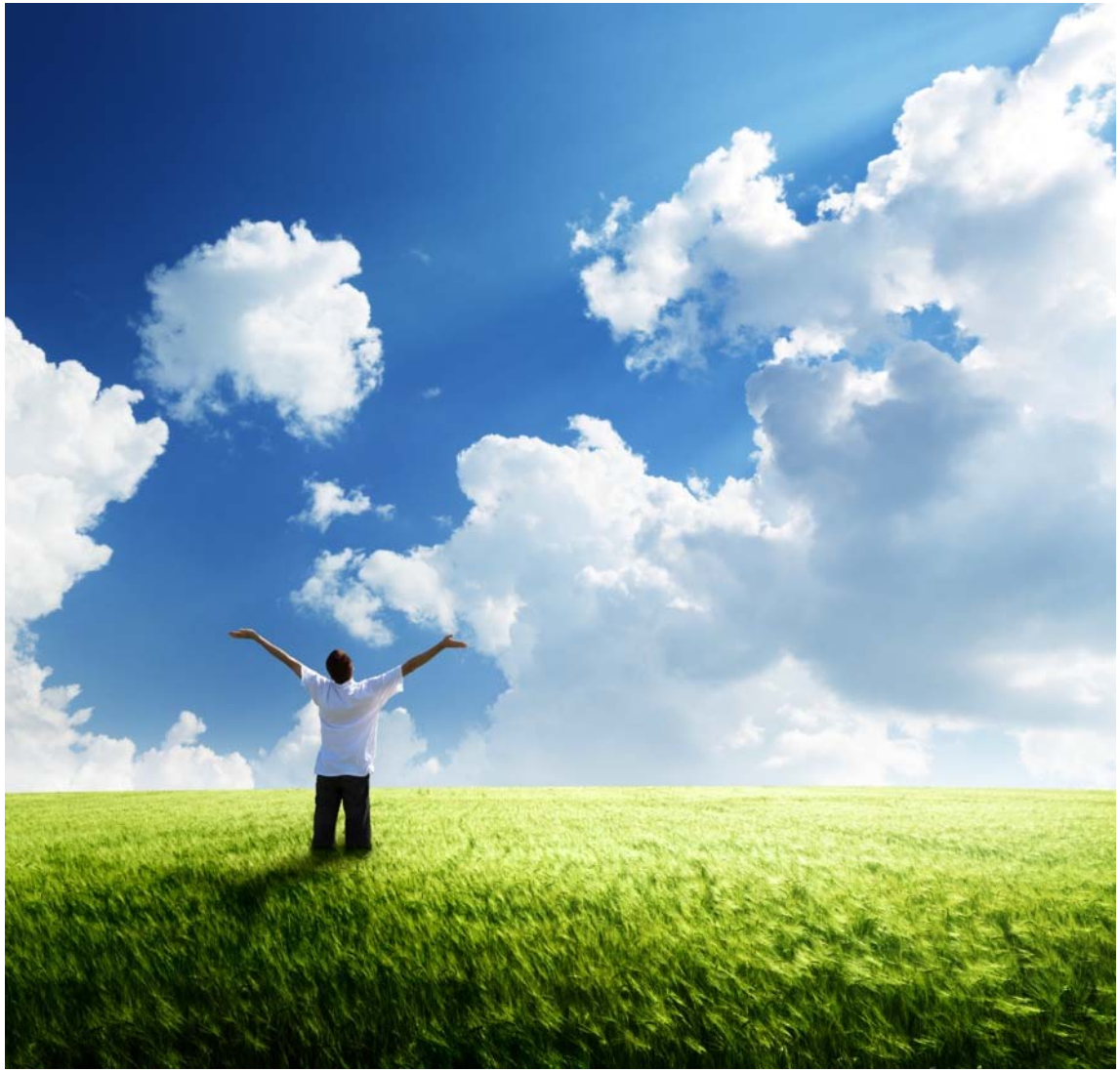
Quality Control Plan

Quality Assurance

Risk Assessment

- "Risk assessment is the identification and evaluation of potential failures and sources of errors in a testing process." *(CMS Interpretive Guidelines, Risk Assessment Section)*
  - Identify and evaluate risks.
  - Risks are potential failures and sources of error that can impact the accuracy and precision of test results.
  - Risk assessment is the first step in risk management.

Risk Assessment – High or Low?



Risk Assessment – High or Low?

Risk Assessment – Go to Work or Stay Home

CMS Risk Assessment

- Risk assessments for IQCPs must include, at a minimum, an evaluation of the following five components:
  - Specimen
  - Environment
  - Reagent
  - Test systems
  - Testing personnel

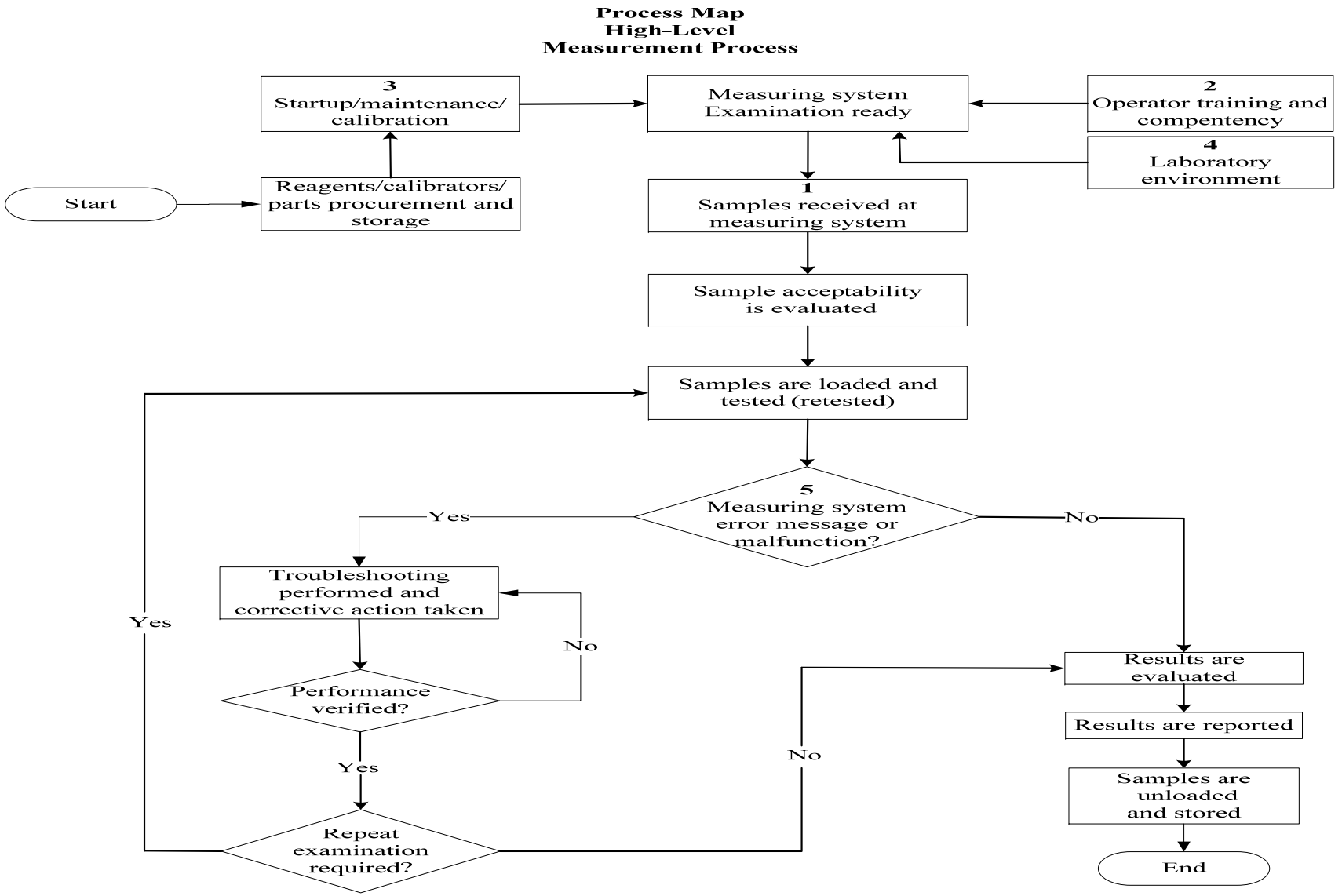
Ref: CMS Memo S&C: 13-54-CLIA

CMS Risk Assessment

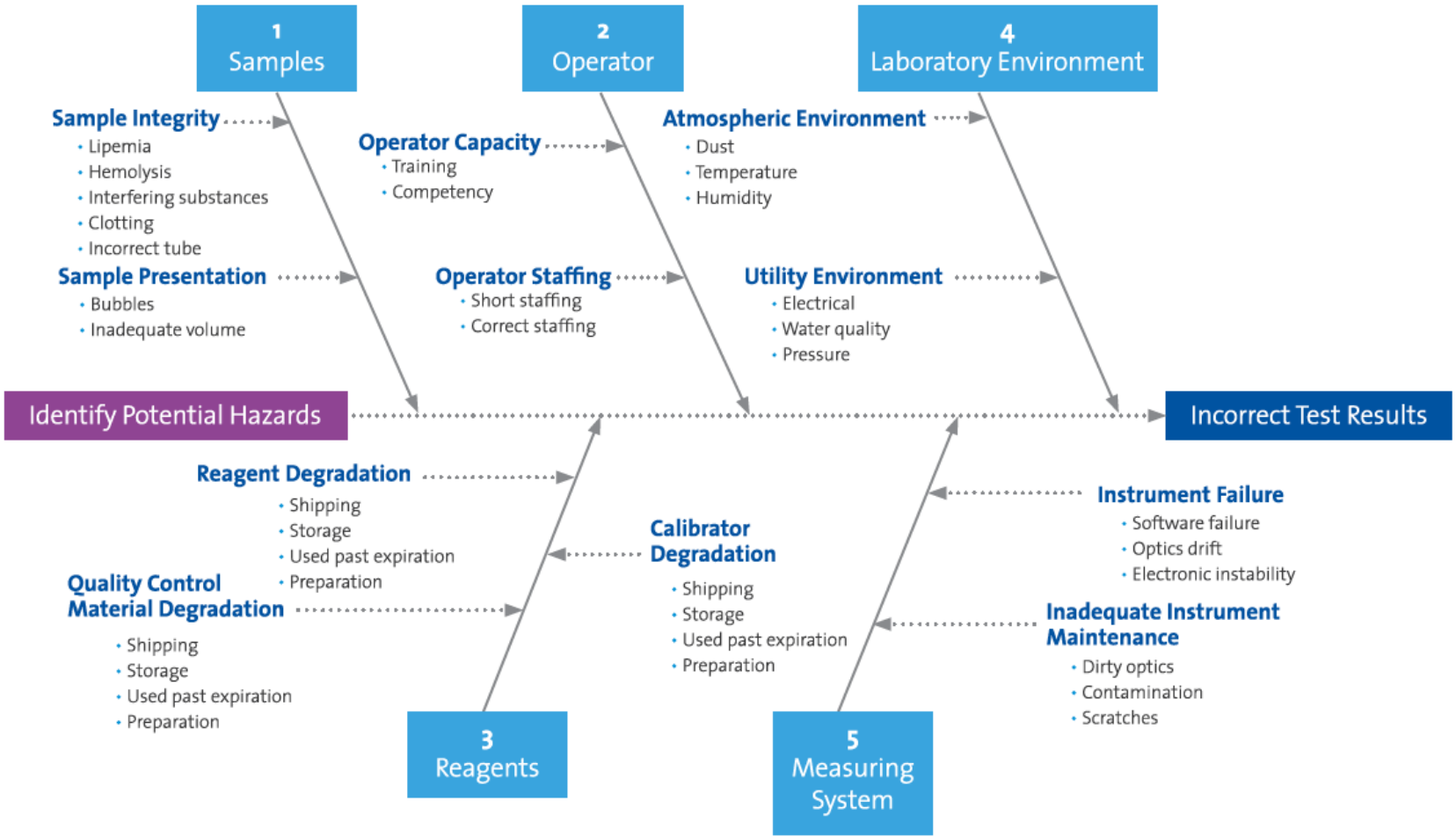
- The scope of risk assessments must encompass the entire testing process:
  - Preexamination (preanalytical)
  - Examination (analytical)
  - Postexamination (postanalytical) phases and include, at a minimum, the evaluation of the five risk assessment components listed on the previous slide.
- It includes:
  - Multiple laboratories/locations
  - Point-of-care devices
  - Multiple units

Ref: CMS Memo S&C: 13-54-CLIA

Start With Process Maps (plural)

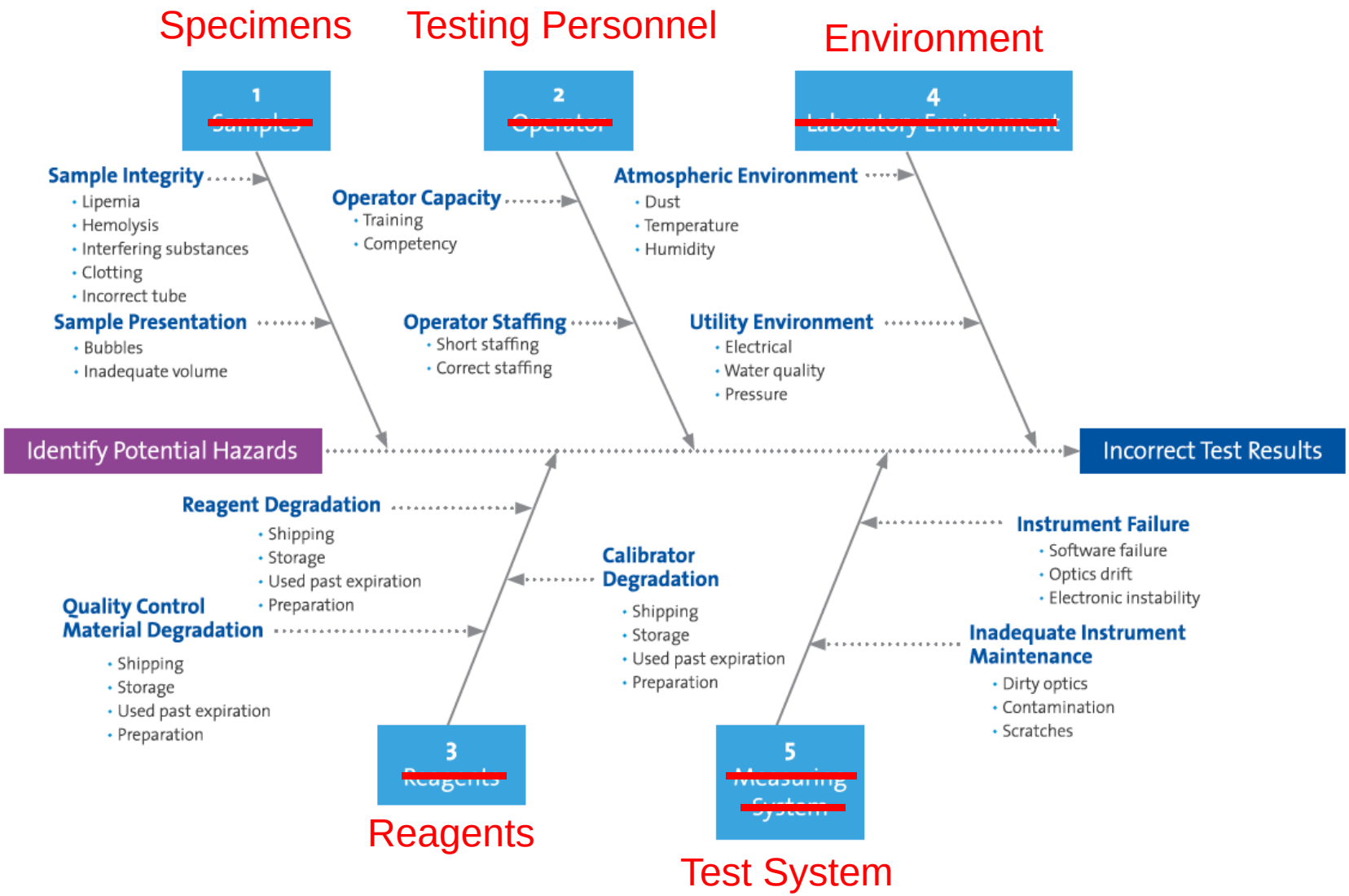


Risk Assessment Fishbone per CLSI EP-23



Ref: Figure 4, EP23-A™, Laboratory Quality Control Based on Risk Assessment, Approved Guideline

Risk Assessment Fishbone per CMS Components



Ref: CMS Memo S&C: 13-54-CLIA

CMS Frequently Asked Questions

CMS FAQ #22

- Q: “Will laboratories be required to use a process map, fishbone diagrams, formal risk assessment charts and protocols, etc. in their IQCPs?”
  - A: “No, CLIA will not require the use of these tools in the development of an IQCP.”

Ref: CMS Memo S&C: 13-54-CLIA

CMS Frequently Asked Questions

CMS FAQ #23

- Q: “Must the laboratory have data to support its decisions for the RA and QCP, and must they be documented?”
  - A: “Yes, the laboratory must have sufficient data to support its decisions, and all IQCP activities must be documented per Attachment 1-IQCP.”

CMS Frequently Asked Questions

CMS FAQ #27

- Q: “I have always followed manufacturer’s instructions for Quality Control (QC) in my lab. Why do I need to do anything differently?”
  - A (paraphrased): Following manufacturers instructions is *Necessary but Not Sufficient*.

What Is an IQCP?

Individualized Quality Control Plan

Risk Assessment

Quality Control Plan

Quality Assurance

Quality Control Plan (QCP)

"A QCP is a document that describes the **practices, resources, and procedures** to control the quality of a particular test process. The QCP must ensure the accuracy and reliability of test results, and that test result quality is appropriate for patient care."

"The QCP must provide for **the immediate detection of errors** that occur due to test system failure, adverse environmental conditions, and operator performance. It must also **monitor, over time**, the accuracy and precision of test performance that may be influenced by changes in the test system, environmental conditions, or variance in operator performance. Use D5441."

Ref: CMS Memo S&C: 13-54-CLIA

Quality Control Plan (cont'd)

"The QCP must at least include the number, type, and frequency of testing and criteria for acceptable result(s) of the quality control(s). "

"If indicated by the evaluation of the risk assessment, the QCP may also include:

- Electronic controls
- Procedural controls
- Training and competency assessment
- Other specified QC activities"

Ref: CMS Memo S&C: 13-54-CLIA

What Is an IQCP?

Individualized Quality Control Plan

Risk Assessment

Quality Control Plan

Quality Assurance

Quality Assurance per CMS

- "The laboratory must establish a review system for the **ongoing monitoring** of the effectiveness of its IQCP."
- 'The monitoring should **include, but is not limited to**, the following components: testing personnel, environment, specimens, reagents, and test system."
- "**Reevaluation** of the QCP should be considered when changes occur in any of the above components."

Ref: CMS Memo S&C: 13-54-CLIA

Current Practices vs CLIA Requirements

- Most laboratories today do most elements of Risk Assessment, QC plans, and QA today.
- CLIA now requires a more formal ongoing process, including defining key important steps, and documentation.
- Currently allowed EQC (Equivalent Quality Control) will be eliminated January 1, 2016.
- CLIA QC default is:
  - Manufacturer's instructions, or
  - CLIA-defined two levels of liquid control once per day
  - **Is that adequate?**

General Dwight D. Eisenhower and the D-Day Invasion of Normandy

Q: "How important was the Battle Plan in the D-Day Invasion of Normandy?"

A: "The Battle Plan was nothing. No Battle Plan survives the first contact with the enemy."

"The ***Planning Process*** was everything."


Clinical and Laboratory
Standards Institute
(CLSI)

Clinical and Laboratory Standards Institute

A not-for-profit standards development organization founded in 1968

www.CLSI.org

Vision:

Quality practices for better health.

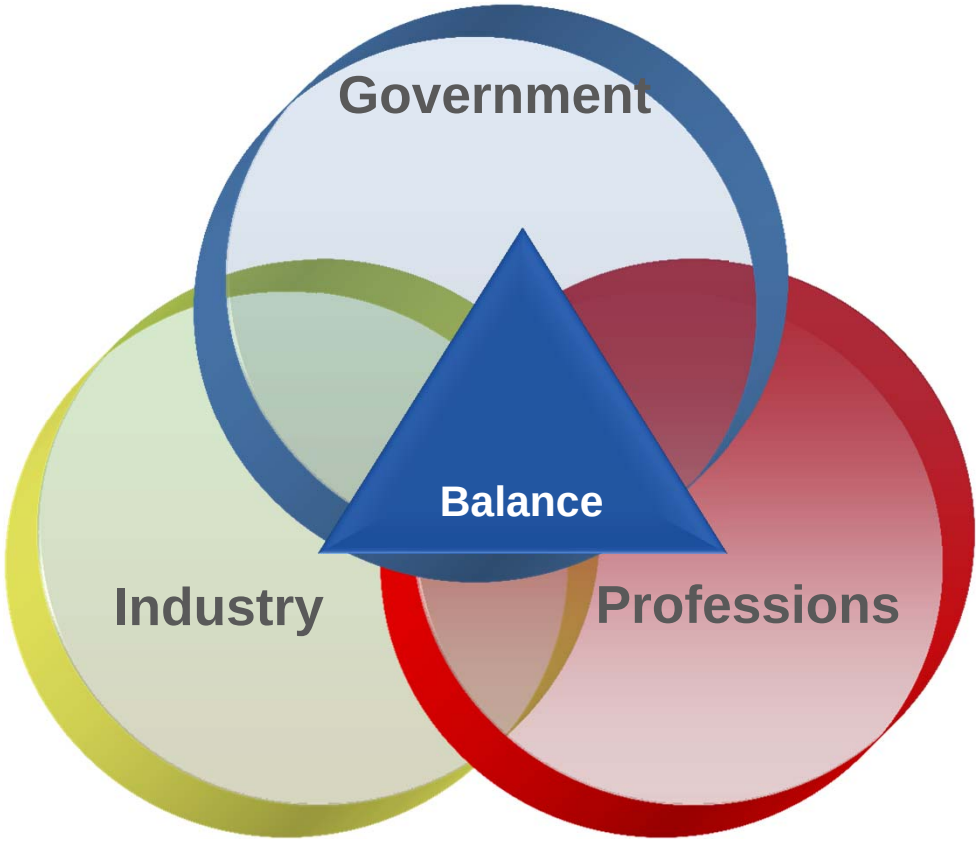
Mission:

Develop clinical and laboratory practices and promote their use worldwide.

Members and Volunteers

1800+ members from over
70 countries…and growing!

CLSI's Consensus Process



Industry	Government	Professions
IVD Manufacturers	Public Health Agencies	Hospitals and Laboratories
LIS Vendors	Regulatory Bodies	Health Care Delivery Systems
Startup Companies	Accrediting Organizations	Educational Institutions
Suppliers	Others	Professional Societies
Trade Organizations		

Products and Services

Standards Workshops

Guidelines Toolkits

Software Reports

Webinars ISO documents

eM100
from the Clinical and Laboratory Standards Institute (CLSI)

eCLIPSE™
Ultimate Access

Worldwide Recognition

- CLSI standards and guidelines are recognized worldwide by:
  - US Food and Drug Administration
  - College of American Pathologists
  - The Joint Commission
  - Many international accreditors
  - Manufacturers
  - Scientific societies
  - National governments
- CLSI is also the Secretariat for ISO Technical Committee 212 on *In Vitro* Diagnostic Products
  - ISO 15189, Medical laboratories – *Requirements for quality and competence*

Number	Product Area	Title of Standard or Guideline	Reference Number	CLSI Code or Edition Changes	FDA Publication Date
7-203	*In Vitro*	*Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens; Approved Standard—Sixth Edition*	H04-A6	GP42-A6*	9/8/2009
7-142	*In Vitro*	*Procedures for the Collection of Arterial Blood Specimens; Approved Standard—Fourth Edition*	H11-A4	GP43-A4*	9/9/2008
7-213	*In Vitro*	*Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests; Approved Guideline—Fourth Edition*	H18-A4	GP44-A4*	8/20/2012
Hematology					
7-71	*In Vitro*	*Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood; Approved Standard—Third Edition*	H15-A3		3/18/2009
7-165	*In Vitro*	*Reference Leukocyte (WBC) Differential Count (Proportional) and Evaluation of Instrumental Methods; Approved Standard—Second Edition*	H20-A2		9/9/2008
7-159	*In Vitro*	*Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assays; Approved Guideline—Fifth Edition*	H21-A5		3/16/2012
7-210	*In Vitro*	*Validation, Verification, and Quality Assurance of Automated Hematology Analyzers; Approved Standard—Second Edition*	H26-A2		10/4/2010
7-145	*In Vitro*	*Enumeration of Immunologically Defined Cell Populations by Flow Cytometry; Approved Guideline—Second Edition*	H42-A2		3/18/2008
7-150	*In Vitro*	*Clinical Flow Cytometric Analysis of Neoplastic Hematolymphoid Cells; Approved Guideline—Second Edition*	H43-A2		9/9/2008
7-135	*In Vitro*	*Methods for Reticulocyte Counting (Automated Blood Cell Counters, Flow Cytometry, and Supravital Dyes); Approved Guideline—Second Edition*	H44-A2		9/9/2008
7-205	*In Vitro*	*One-Stage Prothrombin Time (PT) Test and Activated Partial Thromboplastin Time (APTT) Test; Approved Guideline—Second Edition*	H47-A2		5/5/2010
7-163	*In Vitro*	*Body Fluid Analysis for Cellular Composition; Approved Guideline*	H56-A		9/9/2008
7-220	*In Vitro*	*Quantitative D-dimer for the Exclusion of Venous Thromboembolic Disease; Approved Guideline*	H59-A		8/2/2012
Immunology and Ligand Assay					
7-136	*In Vitro*	*Quality Assurance of Laboratory Tests for Autoantibodies to Nuclear Antigens: (1) Indirect Fluorescence Assay for Microscopy and (2) Microtiter Enzyme Immunoassay Methods; Approved Guideline—Second Edition*	I/LA02-A2		9/9/2008
7-131	*In Vitro*	*Specifications for Immunological Testing for Infectious Diseases; Approved Guideline—Second Edition*	I/LA18-A2		9/9/2008

**CLSI code changes refer to internal recategorization of CLSI documents. The standards and guidelines have remained the same and are still FDA recognized.*

And More ….

CLSI Documents Referenced to The Joint Commission Laboratory Accreditation Standards Chapters

CLINICAL AND LABORATORY STANDARDS INSTITUTE®

The Joint Commission

CLSI Reference Documents	QSA (Quality System Assessment for Nonwaived Testing) Chapter*			DC (Document and Process Control) Test Ordering and Reporting; Patient Identification; Specimen Collection, Handling, and Storage; Document Retention and Written Policies/Procedures	EC (Environment of Care) Safety; Facilities; Hazardous Materials; Laboratory Equipment/Instrumentation	EM (Emergency Management) Emergency Response and Disaster Preparedness	HR (Human Resources) Personnel Qualifications; Orientation and Training; Competency	IC (Infection Prevention and Control) Protection, Prevention, Communication, and Bench Precautions	IM (Information Management) LIS Requirements; Interruptions and Backup Plan; Information Security; Data Storage and Retrieval	LD (Leadership) Governance; Ethics; Licensure and Accreditation; Organizational Structure and Services; Laboratory Performance; Data and Information Review and Responsiveness; Complaints, Resolutions, and Communications	NPSG (National Patient Safety Goals) Patient ID; Critical Results Reporting; Hand Hygiene	PI (Performance Improvement) Data Collection; Analysis; Performance Review; Corrective Actions	WT (Waived Testing) CLIA; Oversight and Responsibility for Testing; Test Performance
	I. Proficiency Testing	II. Quality Control	III.–XXI. Technical Specialities										
Automation and Informatics (continued)													
LIS06-A				☑					☑	☑			
LIS07-A			☑	☑					☑	☑			
LIS08-A				☑					☑	☑			
LIS09-A				☑					☑	☑			
Clinical Chemistry and Toxicology													
C24-A3		☑	☑	☑	☑		☑			☑			
C29-A2		☑	☑	☑	☑		☑			☑			
C31-A2			☑	☑	☑		☑			☑	☑		
C34-A3	☑	☑	☑	☑	☑		☑			☑			
C37-A		☑	☑	☑	☑		☑			☑			
C38-A		☑	☑	☑	☑		☑			☑			
C39-A		☑	☑	☑	☑		☑			☑			
C40-A	☑	☑	☑	☑	☑		☑			☑			☑
C42-A	☑	☑	☑	☑	☑		☑			☑			
C43-A2	☑	☑	☑	☑	☑		☑			☑			
C44-A	☑	☑	☑	☑	☑		☑			☑			
C45-A	☑	☑	☑	☑	☑		☑			☑			

* Elements of the QSA Chapters: *PT; QC; record retention; verification; validation and calibration; reference and reportable ranges; sources of error; reagent handling.*

Abbreviations: CLIA, Clinical Laboratory Improvement Amendments; ID, identification; LIS, laboratory information system; PT, proficiency testing; QC, quality control.

And More ....

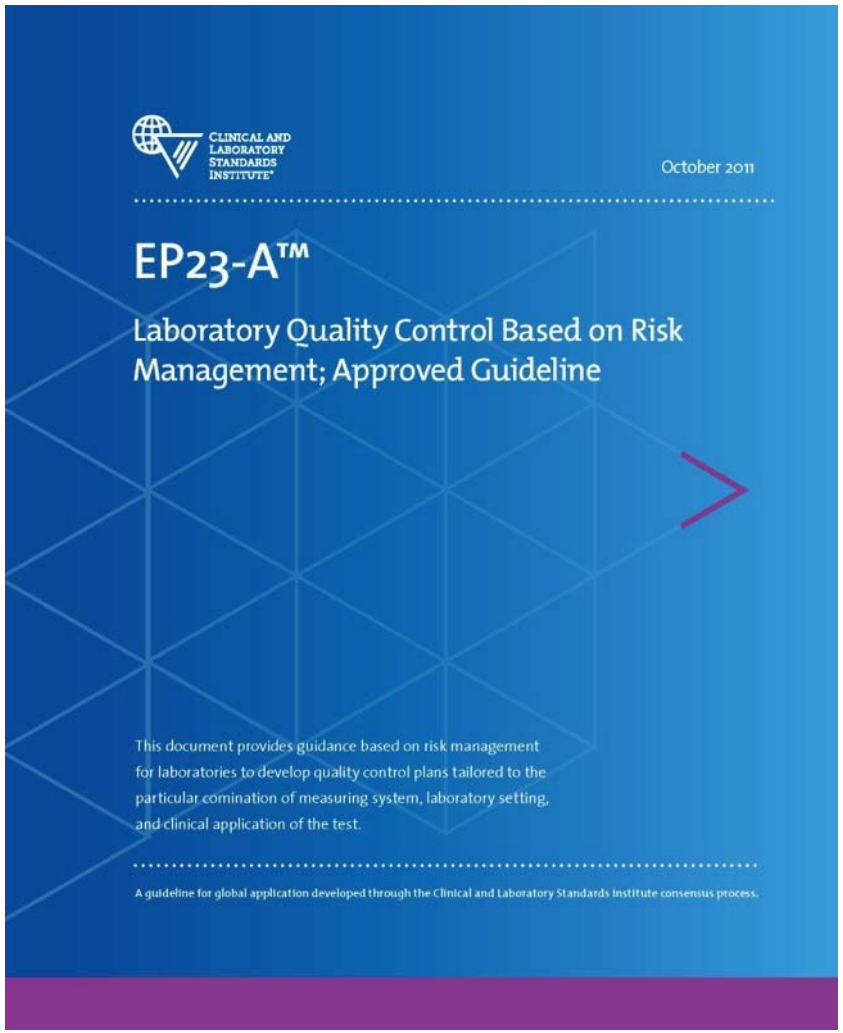
CLSI References in the CAP Accreditation Checklists

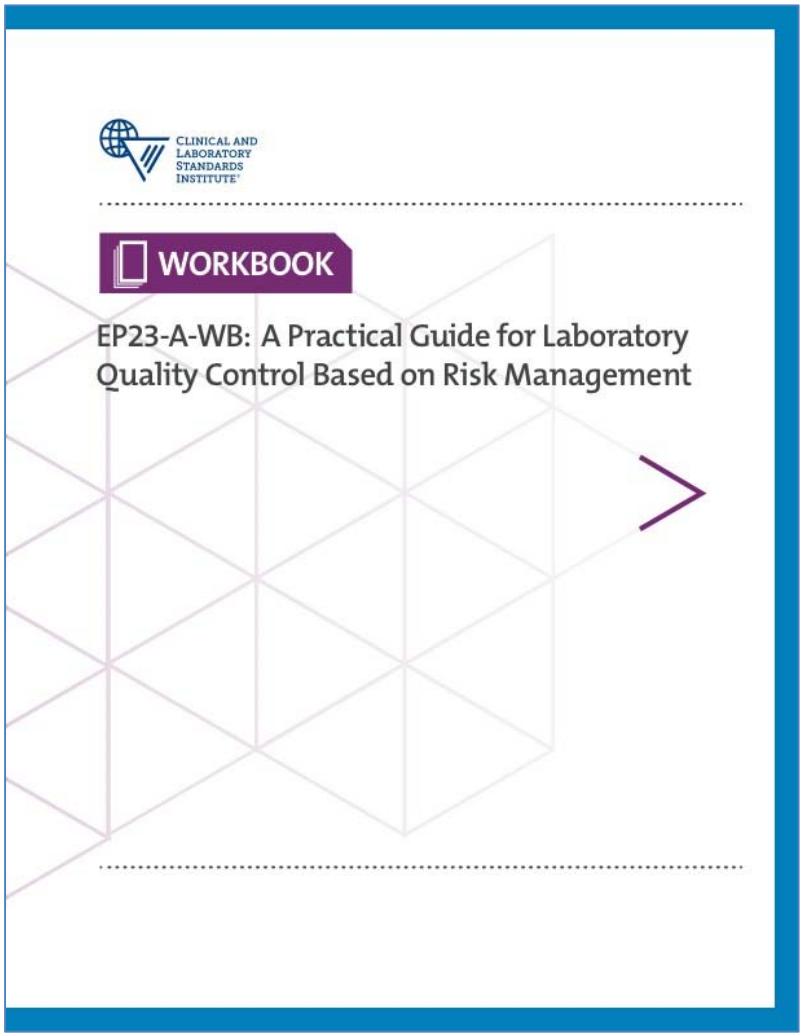
CLSI Document Referenced	Anatomic Pathology (ANP)	Biorepository (BAP)	Clinical Biochemical Genetics (CBG)	Chemistry and Toxicology (CHM)	All Common (COM)	Cytogenetics (CYG)	Cytopathology (CYP)	Forensic Drug Testing (FDT)	Flow Cytometry (FLO)	Laboratory General (GEN)	Hematology and Coagulation (HEM)	Histocompatibility (HSC)	Immunology (IMM)	Limited Service Laboratory (LSV)	Microbiology (MIC)	Molecular Pathology (MOL)	Point-of-Care-Testing (POC)	Reproductive Laboratory (RLM)	Team Leader Assessment of Director & Quality (TLC)	Transfusion Medicine (TRM)	Urinalysis (URN)
Automation and Informatics																					
AUTO02-A2										☑											
AUTO03-A2										☑											
AUTO08-A										☑											
AUTO10-A										☑											
AUTO12-A										☑							☑				
Clinical Chemistry and Toxicology																					
C24-A3	☑		☑	☑	☑						☑		☑	☑	☑	☑	☑	☑			
C34-A3				☑																	
C43-A2				☑				☑													
C46-A2				☑										☑			☑				
C49-A					☑																
C52-A2				☑				☑													
T/DM06-A (now C60-A)*				☑																	
General Laboratory																					
C03-A4 (now GP40-A4-AMD)										☑											
GP05-A3	☑		☑	☑			☑			☑					☑	☑					

*This document was either assigned a new document code or revised to a new edition after the publication of the CAP Accreditation Checklists. The text in parentheses indicates the new document code for the CLSI document, which is now available at www.clsi.org.

EP23-A—*Laboratory Quality Control Based on Risk Management; Approved Guideline*

CLSI Document EP23-A





Published October 2011

EP23-A Document Development Committee

Document Development Committee on Laboratory Quality Control Based on Risk Management

James H. Nichols, PhD, DABCC, FACB
Chairholder
Baystate Medical Center
Springfield, Massachusetts, USA

Greg Cooper, CLS, MHA
W. Gregory Cooper LLC
Denton, Texas, USA

Devery Howerton, PhD
Centers for Disease Control and Prevention
Atlanta, Georgia, USA

Ellis Jacobs, PhD, DABCC, FACB
New York City Health & Hospital Corporation
New York, New York, USA

W. Gregory Miller, PhD
Virginia Commonwealth University
Richmond, Virginia, USA

Valerie L. Ng, PhD, MD
Alameda County Medical Center/ Highland General Hospital
Oakland, California, USA

Nils B. Person, PhD, FACB
Siemens Healthcare Diagnostics
Flanders, New Jersey, USA

Arleen Pinkos, BS, MT(ASCP)
FDA Center for Devices and Radiological Health
Silver Spring, Maryland, USA

Ann E. Snyder, MT(ASCP)
Centers for Medicare & Medicaid Services
Baltimore, Maryland, USA

Marcia L. Zucker, PhD
Consultant
Metuchen, New Jersey, USA

Staff

Clinical and Laboratory Standards Institute
Wayne, Pennsylvania, USA

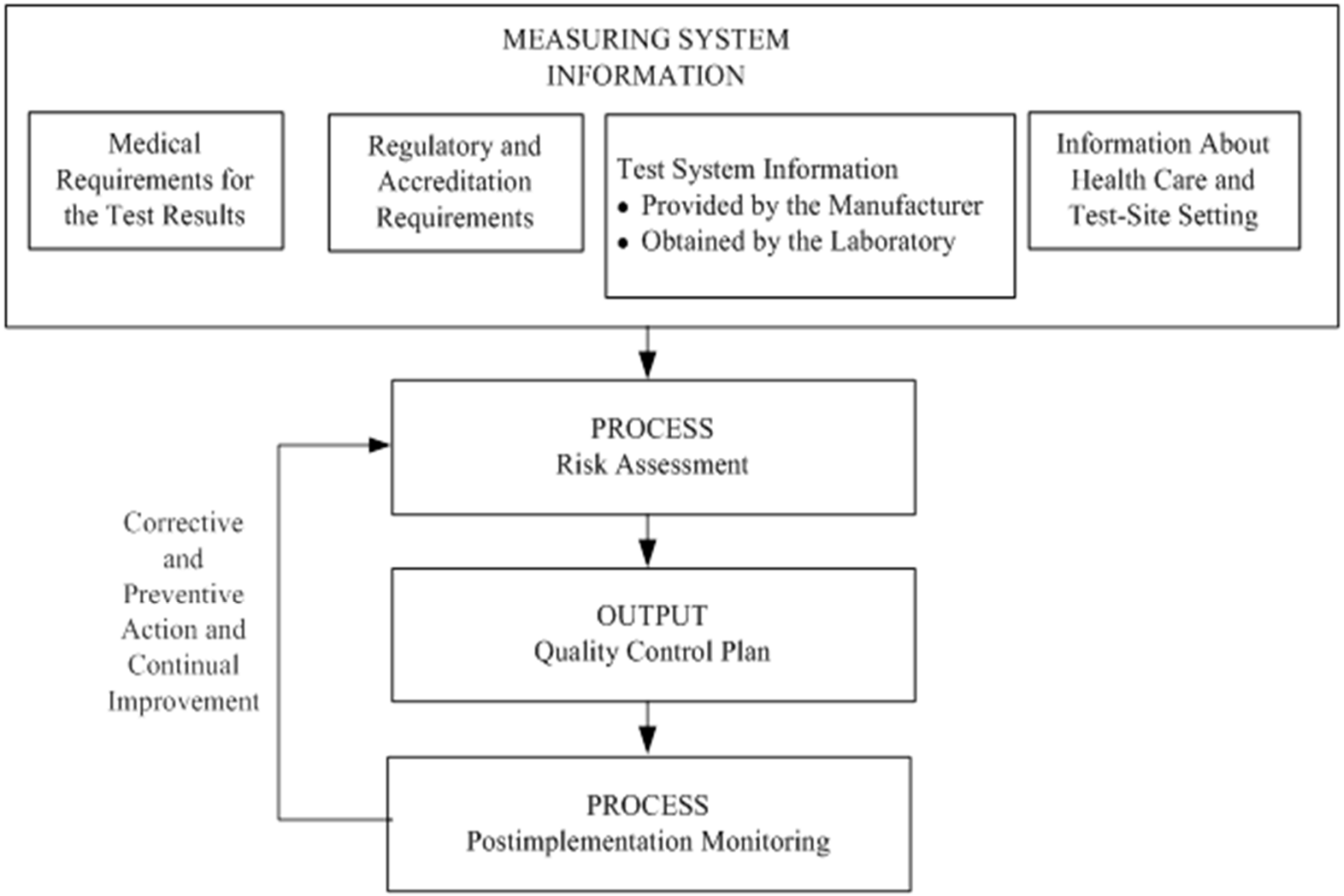
Luann Ochs, MS
Vice President, Standards Development

Ron S. Quicho
Staff Liaison

Megan P. Larrisey, MA
Assistant Editor

Ref: EP23-A, Committee Membership

Developing an IQCP



EP23-A Gathering Information

Table 1. Sources for Collecting Information for Risk Analysis

Information	Source
Regulatory and accreditation requirements • Mandated QC procedures • Required quality assurance activities • Regulatory agency recall and device failure notifications	Regulatory authorities; accreditation agencies
Measuring system information • Intended use (including limitations, warnings, and precautions) • Environmental requirements • Instructions for calibration, maintenance, use, and reagent storage • Calibrator traceability information • QC features • Risk mitigation recommendations	*In vitro* diagnostic (IVD) manufacturer
Laboratory information • Environmental conditions, including facilities and utilities, and existing controls • Installation/operational qualification reports • Operator training and competency • Internal performance evaluation/verification data • External performance data (eg, proficiency test results) • Process map covering the steps analyzed	Laboratory
Publications and reports from laboratory peers • Published performance evaluations • Published clinical studies • Other users (eg, user groups, listservs, forums)	Laboratory
Clinical information • Clinical applications for use of a test result • Biological reference intervals and clinical decision levels • Foreseeable medical errors that could result from incorrect, delayed, or no results • The severity of patient harm that would result from the hazardous situations	Laboratory, in consultation with medical users of the test results

Ref: EP23-A Document, Page 21

Risk Assessment Worksheet

Targeted Failure Mode (Hazard)	Measuring System Feature or Recommended Action	Known Limitations of Feature or Recommended Action	Frequency (1 – 5 scale)	Severity (1 - 5 scale)	Detectability (1 – 5 scale)	Criticality (Frequency X severity X detectability)	Control Process Effective?	The QCP Actions Required to Address Known Limitations	Residual Risk Acceptable? (Yes/No)
Manner in which the system could fail or error could occur.	*Are there manufacturer control checks or recommended actions to reduce or detect failure?*	*What are the known limitations to the control processes or recommended actions?*	*What is the frequency of failure?*	*How severe is impact of failure on patient?*	*Does the control process detect or prevent the failure? Low = 1 control can detect failure High = 5 control ineffective*	*A measure of laboratory risk and priority for laboratory to address failure mode Low <10 Mid= 10 - 20 High >20*	*The laboratory's assessment of residual risk with all manufacturer, external, and other control processes implemented.*	*The action required to address residual risk to include as an element of the QCP.*	*The laboratory's assessment of clinical acceptability of residual risk.*
Lipemia	No internal, manufacturer, or other control process available	Manufacturer verbally states that there is no interference from lipemia. Measurement system is not optical. Not stated in operator's manual or test cartridge package insert.	5 Lipemic samples occur more than one a week	1 Measurement system not affected by lipemia	1 Measurement system not affected by lipemia	5 Low risk and priority	If laboratory agrees with manufacturer- no further action If laboratory concerned or doubts information, can conduct own lipemia studies	No action required Conduct lipemia study	Yes Yes after lipemia study
Reagent degradation during shipping	No internal or manufacturer control process available	Use external QC to detect cartridge deterioration during shipping	4 New shipments arrive every 2 months	5 Compromised reagent can impact patient, wrong PT/INR results can lead to coumadin overdosing or underdosing	1 External QC will detect compromised reagent before patient testing	20 Moderate risk and priority for laboratory to address	External QC will detect compromised reagent before patient testing Laboratory should ensure QC viability and appropriate ranges set before use	Evaluate each shipment of reagent before use for patient testing	Yes

EP23 – Probability and Severity of Harm Analysis

Table 3. Risk Acceptability Matrix

	Severity of Harm				
Probability of Harm	**Negligible**	**Minor**	**Serious**	**Critical**	**Catastrophic**
Frequent	unacceptable	unacceptable	unacceptable	unacceptable	unacceptable
Probable	acceptable	unacceptable	unacceptable	unacceptable	unacceptable
Occasional	acceptable	acceptable	acceptable	unacceptable	unacceptable
Remote	acceptable	acceptable	acceptable	unacceptable	unacceptable
Improbable	acceptable	acceptable	acceptable	acceptable	acceptable

Ref: EP23-A, Table 3

Risk Assessment Worksheet

Targeted Failure Mode (Hazard)	Measuring System Feature or Recommended Action	Known Limitations of Feature or Recommended Action	Frequency (1 – 5 scale)	Severity (1 - 5 scale)	Detectability (1 – 5 scale)	Criticality (Frequency X severity X detectability)	Control Process Effective?	The QCP Actions Required to Address Known Limitation	Residual Risk Acceptable? (Yes/No)
Manner in which the test system could fail or error could occur.	*Are there manufacturer control processes, checks or recommended actions to reduce or detect failure?*	*What are the known limitations to the control processes or recommended actions?*	*What is the frequency of failure?*	*How severe is impact of failure on patient?*	*Does the control process detect or prevent the failure? Low = 1 control can detect failure High = 5 control ineffective*	*Measure of laboratory risk and priority for laboratory to address failure mode Low <10 Mid= 10 - 20 High >20*	*The laboratory's assessment of residual risk with all manufacturer, external, and other control processes implemented.*	*The action required to address residual risk to include as an element of the QCP.*	*The laboratory's assessment of clinical acceptability of residual risk.*
Lipemia	No internal, manufacturer, or other control process available	Manufacturer verbally states that there is no interference from lipemia. Measurement system is not optical. Not stated in operator's manual or test cartridge package insert.	5 Lipemic samples occur more than one a week	1 Measurement system not affected by lipemia	1 Measurement system not affected by lipemia	5 Low risk and priority	If laboratory agrees with manufacturer- no further action If laboratory concerned or doubts information, can conduct own lipemia studies	No action required Conduct lipemia study	Yes Yes after lipemia study
Reagent degradation during shipping	No internal or manufacturer control process available	Use external QC to detect cartridge deterioration during shipping	4 New shipments arrive every 2 months	5 Compromised reagent can impact patient, wrong PT/INR results can lead to coumadin overdosing or underdosing	1 External QC will detect compromised reagent before patient testing	20 Moderate risk and priority for laboratory to address	External QC will detect compromised reagent before patient testing Laboratory should ensure QC viability and appropriate ranges set before use	Evaluate each shipment of reagent before use for patient testing	Yes

Risk Assessment Worksheet

Appendix C. (Continued)

These control strategies (ie, use bar code reader, implement procedural step to train staff to verify manual entries) are added to the Laboratory Risk Assessment table.

An Illustrative Example of a Glucose Measurement on an Automated Measuring System						
Row #	Targeted Failure Mode (Hazard)	Measuring System Feature or Recommended Action	Known Limitations of Feature or Recommended Action	Control Process Effective?	The QCP Actions Required to Address Known Limitations	Residual Risk Acceptable? (Yes/No)
3	Incorrect results due to sample data entry error	Bar code reader ensures correct data entry.	Bar code misread – rare event. Manual entry errors are more frequent than bar coded data entry errors.	Yes, unless manual entry.	**Manufacturer recommendations:** – Use bar codes for data entry. **Laboratory-implemented control processes:** – Train staff to verify manual data entries.	Yes

Ref: EP23-A, Appendix C pg 71

Quality Control Plan

Famous Hospital Laboratories

PT/INR Quality Control Plan
Effective date: October 1, 2011
Laboratory Director: Sarah Ryan, MD

1. **Electronic Controls:**
   a. Shall be run on each instrument once every eight hours.
2. **Liquid-based QC Samples:**
   a. Analyze two levels of QC samples before and after each change in reagent lot. Do not use QC that was shipped with the reagent being tested.
   b. Analyze two levels of QC after each calibration.
   c. Analyze two levels of QC samples at least weekly.
3. **Proficiency Testing:**
   a. Participate in proficiency testing program two times per year.
4. **Maintenance:**
   a. Clean the instruments after each use with alcohol wipes, following the instructions in the user's manual.
   b. Check the **laboratory** refrigerator monitors daily.
   c. Check the room temperature monitors in the **outpatient clinic** daily.
5. **Training:**
   a. Nurses and laboratory technicians – document proper training for:
      i. Sample collection
      ii. Sample placement on reagent test strip
      iii. Testing procedures
      iv. Cleaning procedures
      v. Documentation of results
   b. Receiving personnel – document proper training for:

From Risk Assessment

Which IQCP Do I Start With?

I have to do several IQCPs (each system, each process, each laboratory, each site).

Which IQCP do I start with?

- Suggestion #1:
  - Which system keeps you up at night?
  - Which process do you worry about the most?
- Suggestion #2:
  - Which system might be easiest to do?
  - Which process could serve as a model/template for other systems and their IQCPs?
- Suggestion #3:
  - Which system's QC will not meet CLIA minimum requirements on January 1, 2016?

Resources Available

Centers for Medicare & Medicaid Services (CMS)

- Educational materials for laboratories are under development. Materials will be released periodically before and during the IQCP Education and Transition Period.
- Laboratories are advised to check the CLIA website for updated information: http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Individualized_Quality_Control_Plan_IQCP.html.
- State agencies should expect to receive questions and inquiries from laboratories during and after the IQCP Education and Transition Period.
- Website: http://www.cms.hhs.gov/clia/
- E-mail questions to: IQCP@cms.hhs.gov

CMS.gov Website – IQCP

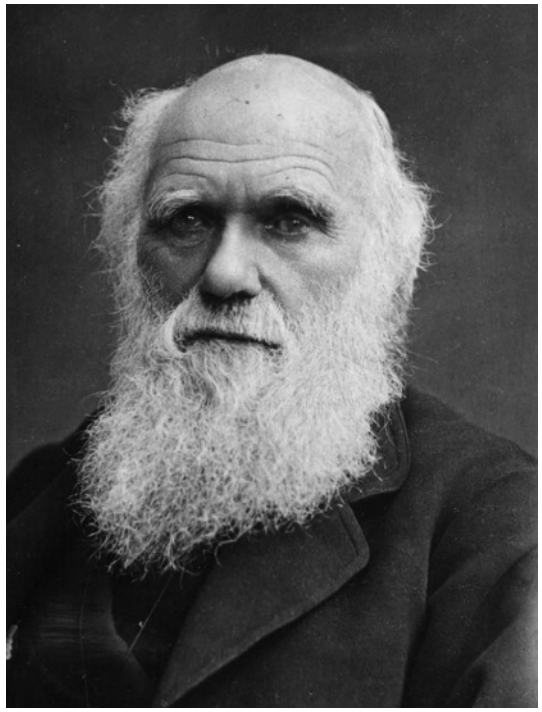
Additional Resources Available

- CLSI
  - www.clsi.org
  - EP23-A™—*Laboratory Quality Control Based on Risk Management; Approved Guideline*
  - EP23 Workbook
  - EP23 Worksheet
  - EP23 Online Webinars
    (Upcoming: EP23™ and POCT: Tackling Risk Management, May 14, 2014, 1:00–2:00 PM (EDT)
  - EP23™ Online Workshop: Risk-Based Tools to Meet IQCP Requirements
- Private consultants
- Contacting your manufacturer
  - Manufacturers can provide certain needed information.
  - Manufacturers may not complete IQCPs for laboratories.

A Parting Thought

"It is not the strongest of the species who survive, nor the most intelligent, but the ones most responsive to change."

Charles Darwin
The Origin of Species




Thank You