Evolving Clinical Laboratory Management Through Implementation of a Risk Assessment Plan

SEDEF YENICE

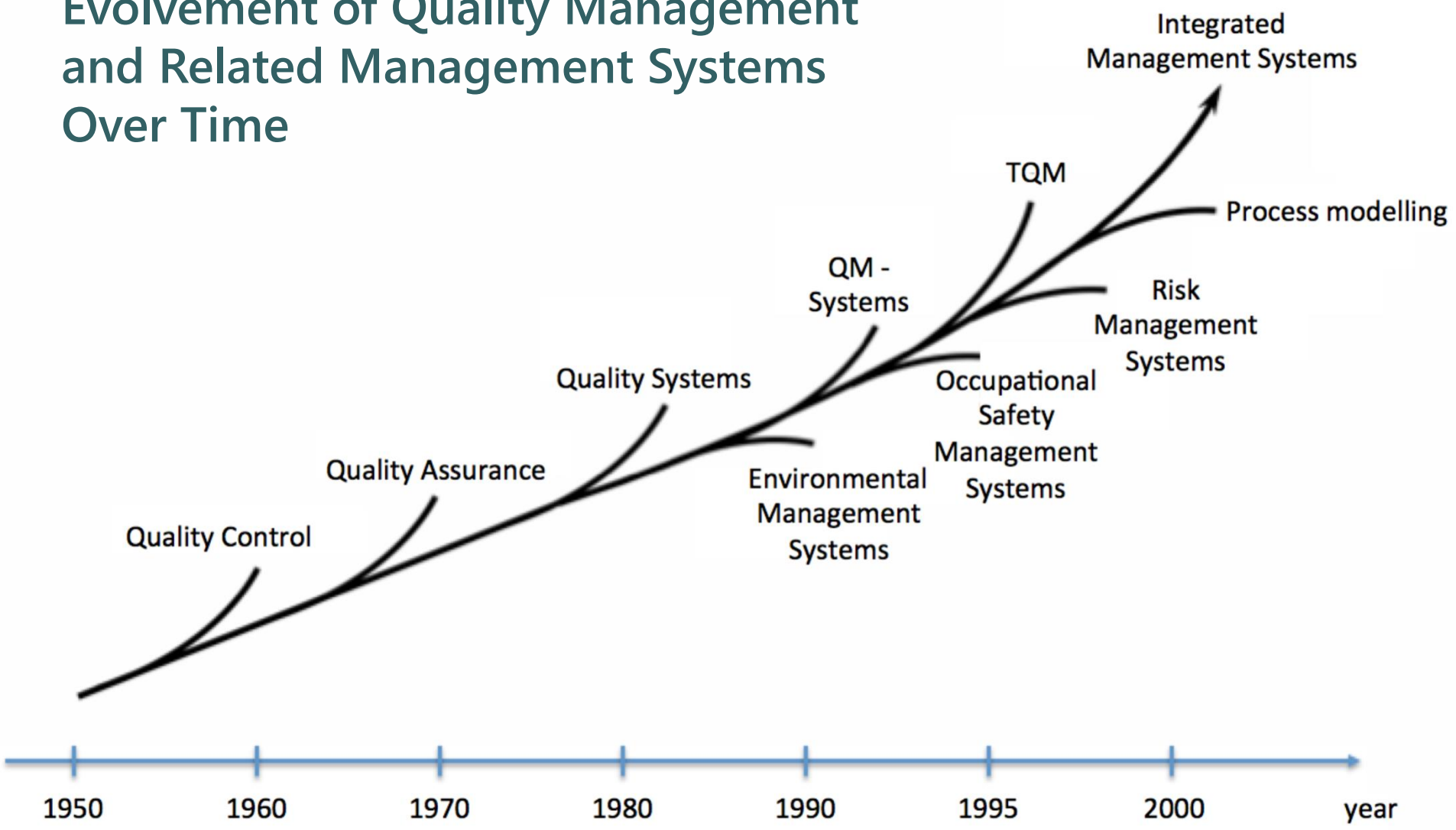
Session: Laboratory Management

analytica conference 2016
May 10 - 12, 2016, Munich

Objectives

- Review the milestones on risk management and quality control
- Identify the risk and risk management definitions
- Describe the sources of laboratory error
- Describe the implementation a quality control strategy
- Describe the stepwise approach to risk management
- Identify the quality control based on risk management and IQCP
- Perspectives for the future

Evolvement of Quality Management and Related Management Systems Over Time



Milestones - Evolvement of Quality Risk Management Over Time

YEAR	
in the 1970s	United States manufacturers moved beyond statistical quality control in the 1970s to focus on total quality concepts, following the example of Japanese industry.
By the 1990s	quality management systems and risk management had taken hold in the United States as the preferred approach. Risk as used here is the combination of severity of harm and the probability of that harm occurring.
U.S. Department of Health and Human Services. Medicare, Medicaid and CLIA programs: Regulations implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Final rule. Fed Regist 1992; 57:7002-186	While the trend in the medical device manufacturing industry has been away from prescriptive regulation, clinical laboratory regulations in the 1990s prescribed the number of QC tests that must be performed daily regardless of the clinical significance of an erroneous result or the likelihood of occurrence, thus removing an incentive to seek inherently safer IVD medical devices. The revised CLIA regulations retained the prescriptive requirements. (CLIA regulations, 42 CFR Part 493 www.hcfa.gov/medicaid/clia/cliahome.htm)
in 1996	Revamped FDA regulations gave in vitro diagnostic (IVD) and other medical device manufacturers the responsibility to decide the appropriate amount of quality control testing based on risk assessment.

Milestones - Evolvement of Quality Risk Management Over Time

YEAR	
1998	• Quality System Regulation, US Code of Federal Regulations, 21 CFR Part 820. • Council Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices," Official Journal of the European Union L331 (December 7, 1998). • Australia, Canada, Japan, and the Global Harmonization Task Force have also embraced or are embracing risk management as part of the quality system. Global Harmonization Task Force, Risk Management as an Integral Part of the Quality Management System, Proposed Draft SG3/N15R6.
2000	ISO 14971:2000 (2007, 2012) Medical Devices – Application of risk management to medical devices
January 1, 2014	the Center for Medicare and Medicaid Services (CMS) www.cms.gov adopted an alternative Quality Control (QC) procedure that would allow laboratories – after appropriate assessment – the choice to implement a more flexible and customized QC procedure that is better adapted to the needs of their institution
Effective 1/1/16	EQC will no longer be available and laboratories will be required to follow either CLIA or IQCP. Also after 1/1/16, laboratories began to be cited for deficiencies under IQCP.

Published International Standards & Guides on Risk Management

	GUIDE
IVD	ISO 14971:2007 and 2012 International Organization for Standardization. Medical devices – Application of risk management to medical devices ISO 14971:2007. Geneva: International Organization for Standardization, 2007.
LABORATORY	CLSI Guideline C24 – A3 Clinical and Laboratory Standards Institute. Statistical quality control for quantitative measurements procedures: principles and definitions. Approved guideline - 3rd ed. C24 – A3. Wayne, PA: Clinical and Laboratory Standards Institute, 2006.
	ISO 22367:2008 Medical Laboratories – Reduction of error through risk management and continual improvement International Organization for Standardization. ISO 22367:2008. Geneva: International Organization for Standardization, 2008.
	ISO 31000:2009 Risk management -- Principles and guidelines
	ISO/IEC 31010:2009 Risk management – Risk assessment techniques
	ISO Guide 73:2009 Risk management — Vocabulary
	CLSI Guideline EP18 - A2 Clinical and Laboratory Standards Institute (CLSI). Risk Management Techniques to identify and control laboratory error sources: Approved guideline - second edition. CLSI Document EP18 – A2 (ISBN 1-56238-712-X). Clinical and Laboratory Standards Institute . 940 West Valley Road, Suite 1400, Wayne, Pennyslvania 19087-1898 USA, 2009.
	CLSI Guideline EP23 – A Clinical and Laboratory Standards Institute. Laboratory quality control based on risk management. Approved guideline - 1st edition. EP23 – A. Wayne, PA: Clinical and Laboratory Standards Institute, 2011.
	ISO/TR 31004:2013 Risk management -- Guidance for the implementation of ISO 31000
	ISO/IEC Guide 51:2014 Safety aspects — Guidelines for their inclusion in standards
	ICH Guideline Q9 on quality risk management 2015 European Medicines Agency/CHMP/ICH/24235/2006 Committee for Human Medicinal Products London, UK
	IQCP 2015 – 2016 Individual Quality Control Plan ISO 15189 + ISO 22367 + CLSI EP23-A CMS-CDC

Risk Definition

ISO/IEC Guide 51:2014:

- **combination of the probability of occurrence of harm (3.1) and the severity of that harm**
- **The probability of occurrence includes the exposure to a hazardous situation (3.4), the occurrence of a hazardous event (3.3) and the possibility to avoid or limit the harm.**

ISO 31000:2009:

- **effect of uncertainty on objectives**
- **An effect is a deviation from the expected — positive and/or negative.**
- **Risk is often characterized by reference to potential events (2.17) and consequences (2.18), or a combination of these.**
- **Risk is often expressed in terms of a combination of the consequences of an event (including changes in circumstances) and the associated likelihood (2.19) of occurrence.**
- **Uncertainty is the state, even partial, of deficiency of information related to, understanding or knowledge of an event, its consequence, or likelihood.**

Risk Management Definition

ISO 31000:2009: Risk management -- Principles and guidelines

- coordinated activities to direct and control an organization with regard to risk

ISO 14971:2007: Medical devices -- Application of risk management to medical devices

- systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating, controlling and monitoring risk

RISK MANAGEMENT DEFINITION

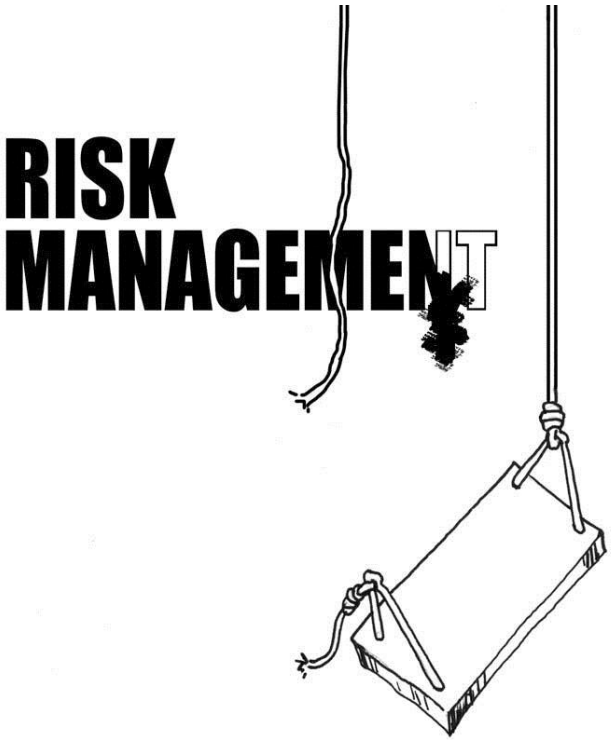
The stepwise risk management process for medical device manufacturers is described in an international standard, ISO 14971.

Risk management according to ISO 14971 is a product "life-cycle" process, which means it continues as long as the product is being produced and is still in active use.

www.iso.org/ISO 14971:2012

Risk management is not a new concept for laboratories to date

1970s - Healthcare
2000 - Patient Safety Programs
2003 - Medical Laboratories



- Evaluate the performance of new instruments.
- Troubleshoot instrument problems.
- Respond to physician and patient complaints.
- Estimate harm to a patient from incorrect results.
- Take actions to correct and prevent errors.

HAZARD ANALYSIS

ISO 14971: IVD RISK MODEL, depicts a sequence of events that starts with a failure in a manufacturer's quality system that results in a defective device.

Manufacturer	Quality System Failure	Defective IVD Medical Device	Fault
Laboratory	Testing Process Failure	Incorrect Result	Hazard
Physician	Diagnostic Process Failure	Inappropriate Medical Treatment	Hazardous Situation
Patient		Injury or Death	Harm

www.iso.org/ISO 14971:2012

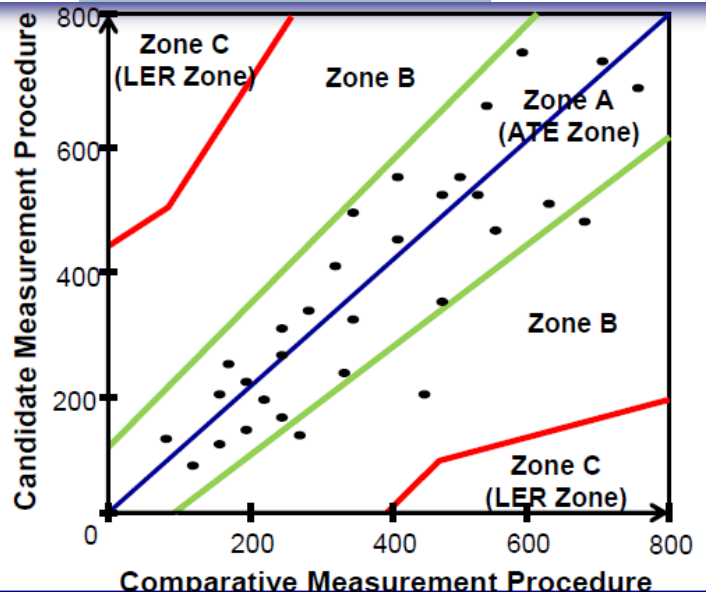
RISK ANALYSIS

Error grid analysis – developed by Clarke et al. (*Diabetes Care 1987*) to classify incorrect glucose results based on the degree of error and the physiological status of the patient.
Parkes et al. developed an error grid based on the consensus of a large number of medical practitioners. (*Diabetes Care 2000*)

An Error grid provides a logical basis for ranking the severity of harm on a scale of 1 (Zone A) to 5 (Zone E)

Ideally…

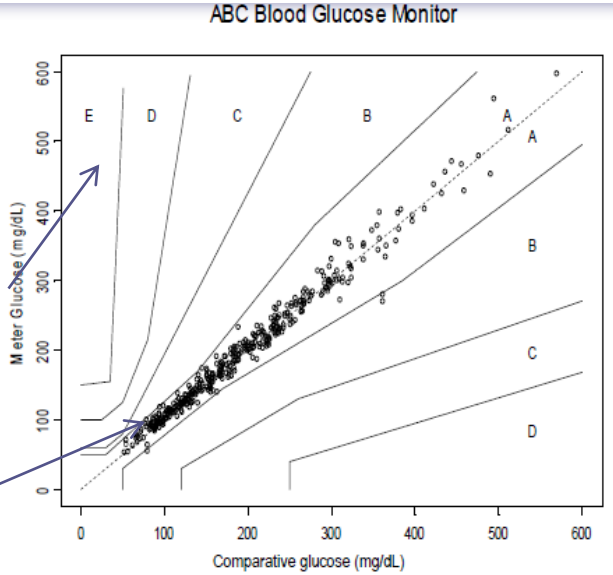
- Most of the data should be in Zone A (eg ≥ 95%)
- None of the data should be in Zone C



Zone	n	%
A	396	99.0
B	4	1.0

Dangerously incorrect treatment

Clinically acceptable performance



Nandagopalan S. CLSI

What could possibly go wrong?

Achieving a 99% level of quality means accepting 1% an error rate

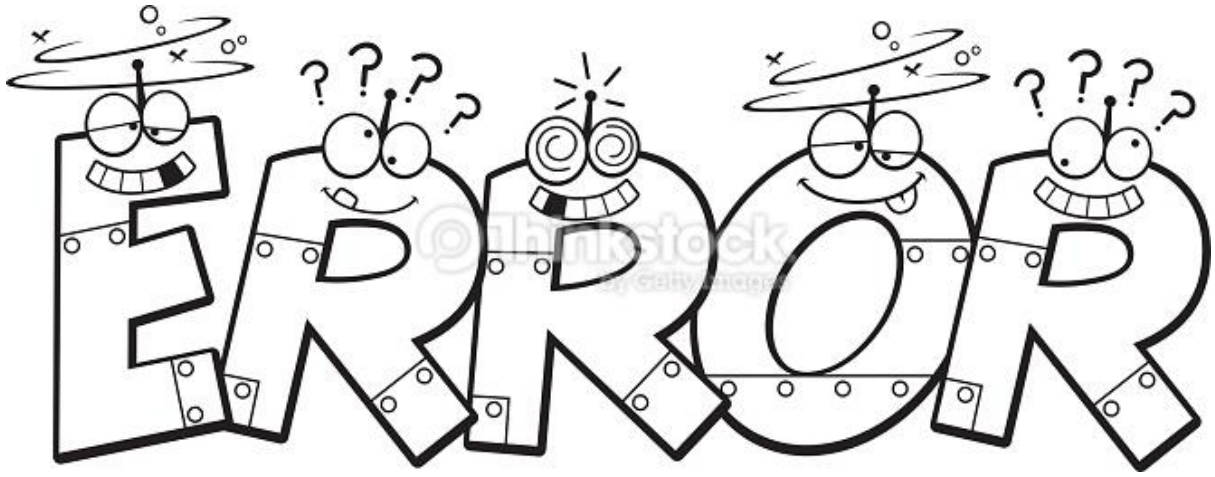
In France a 1% error rate would mean everyday

- 14 minutes without water or electricity
- 50,000 parcels lost by postal services
- 22 newborns falling from midwives' hands
- 600,000 lunches contaminated by bacteria
- 3 bad landings at Paris Orly airport

Result: 1% failure

Dr Kazunobu Kojima, WHO/HSE/IHR/Lyon Office

What are the Sources of Laboratory



?

Total Testing Process

Phases of the TTP	Definition	Examples of Activities in Phase	Estimated contribution to TTP errors
Pre-Pre Analytical	Activities associated with initial selection of the test	Inappropriate test request, order entry, patient/specimen misidentification, inappropriate sample collection, inappropriate container, handling, storage or transportation.	46–68%
Pre-Analytical	Pre-test laboratory activities	Errors in sorting, pipetting, labeling, centrifugation	3–5%
Analytical	Testing-associated activities	Equipment malfunction, sample mix-ups, assay interference, undetected failure in quality control	7–13%
Post-Analytical	Post-test laboratory activities	Erroneous validation of analytical data, excessive turn-around-time, improper data entry or manual transcription error, failure/delay in reporting critical values	13–20%
Post-Post Analytical	Activities associated with interpretation of test results by the clinician	Delayed/missed reaction to laboratory reporting, incorrect interpretation, inappropriate/inadequate follow-up plan, failure to order appropriate consultation	25–46%

COLA White Paper: Integrating Laboratories into the PCMH Model of Health Care Delivery. Accessed April 20, 2016

IFCC WG List of Highest Priority TTP Errors

Process Phase	Quality Indicator
Pre-pre analytical	Patient misidentification errors
	Test Transcription errors
	Incorrect sample type
	Incorrect fill level
	Unsuitable samples for transportation and storage
	Contaminated samples
	Hemolyzed samples
	Clotted samples
Analytical	Test with inappropriate internal QC
	Test performance error discovered with un-acceptable External Quality Assessment or Proficiency Control
	Unacceptable performance in an External Quality Assessment or Proficiency Testing
Post Analytical	Manual transcription data errors
Post-Post Analytical	Inappropriate TAT for STAT tests
	Incorrect laboratory reports
	Failure to notify of critical values

COLA White Paper: Integrating Laboratories into the PCMH Model of Health Care Delivery. Accessed April 20, 2016

Sources of Post-analytical Error

- Transcription error
- Time to deliver the result to the clinician
- Error in transmitting the result over the phone (eg., was it BMP or BNP?)
- Failure to heed errors signaled by the instrument or the LIS/HIS/middleware

The pre-analytical, analytical, and post-analytical factors that are most likely to occur in a hospital setting are not the same as those that might typically occur during blood glucose testing in an outpatient setting. Plebani reported a series of hospital lab errors divided into pre-analytical, analytical, and post-analytical categories. The causes and distributions of that hospital's errors are as follows:

Table 1. Phases in Diagnostic Processing Leading to Missed Diagnoses

Phase	Example of Errors	Percentage of Missed Diagnoses
Preanalytical	• Failure to order appropriate diagnostic or laboratory tests • Adequate diagnostic or laboratory tests ordered but not performed	55
Analytical	• Diagnostic or laboratory test performed incorrectly	8
Postanalytical	• Incorrect interpretation of diagnostic or laboratory tests • Responsible provider did not receive diagnostic or laboratory test results	37

Adapted from Ref. 15.

Diabetes Spectrum Volume 27, Number 3, 2014

Klonoff DC. Diabetes Spectrum 27(3), 2014.

Pfützner A. et al. J Diabetes Sci Technol 7:1275-81, 2013.

The FDA has categorized the most common blood glucose monitor errors in terms of their potential sources (eg., errors caused by monitor design, production, or use). Six error source categories and examples of each are :

Table 2. Potential Sources of Error in Blood Glucose Monitors Based on FDA Experience

Category	Sources of Error or Failure
Operator	Failure to follow procedure correctly, including: • Sample contamination • Incorrect specimen collection (e.g., poor lancet technique and incorrect volume) • Application of an insufficient amount of blood to the strip or incorrect application of blood to the strip • Use of a sample from an alternate site not validated by the manufacturer • Application of blood specimen to the strip more than once (e.g., if the user believes not enough was added the first time) • Incorrect insertion of strip into meter • Inaccurate timing • Use of contaminated, outdated, or damaged strips or reagents, including calibrators or quality control materials • Failure to understand or respond to meter output • Errors in meter maintenance or cleaning • Errors in calibration or failure to calibrate or otherwise adjust the meter or check performance with quality control materials as directed by labeling • Incorrect saving or use of stored data • Improper storage or handling of the meter, calibrators, quality control materials, or test strips or improper maintenance of the meter • Inadvertent changes of parameter (such as units of measurement) • Failure to contact physician when necessary (OTC) • Incorrect incorporation of results into overall treatment plan (prescription POC) • Use of strips not validated for use on the monitor

Klonoff DC. Diabetes Spectrum 27(3), 2014.

Error sources categorised by FDA:

Reagent	• Expired strips or reagents • Damaged or contaminated strip • Failure of strips, calibrators, or quality control materials to perform adequately • Incorrect manufacturing; product fails to conform with specifications • Incorrect dimensions of reagent strip • Interference with chemical reaction on strip (e.g., reducing substances) • Inadequate design of container for strips or other reagents; failure to prevent deterioration; failure of desiccant used to keep strips dry
Environmental	Effects on the device, including: • Temperature • Humidity • Altitude, hyperbaric conditions • Electromagnetic radiation • Visibile light, sunlight Effects on humans, including: • Lighting, glare off meter surfaces • Distractions, visual and auditory • Stressful conditions • Limited manual dexterity
Software	• Confusing or obscure user prompts and feedback • Incorrect mathematical algorithm • Undetected or unrecognized signal errors • Timing failure • Incorrect storage of test results in memory, including matching result with correct patient or time of test • Other software failures

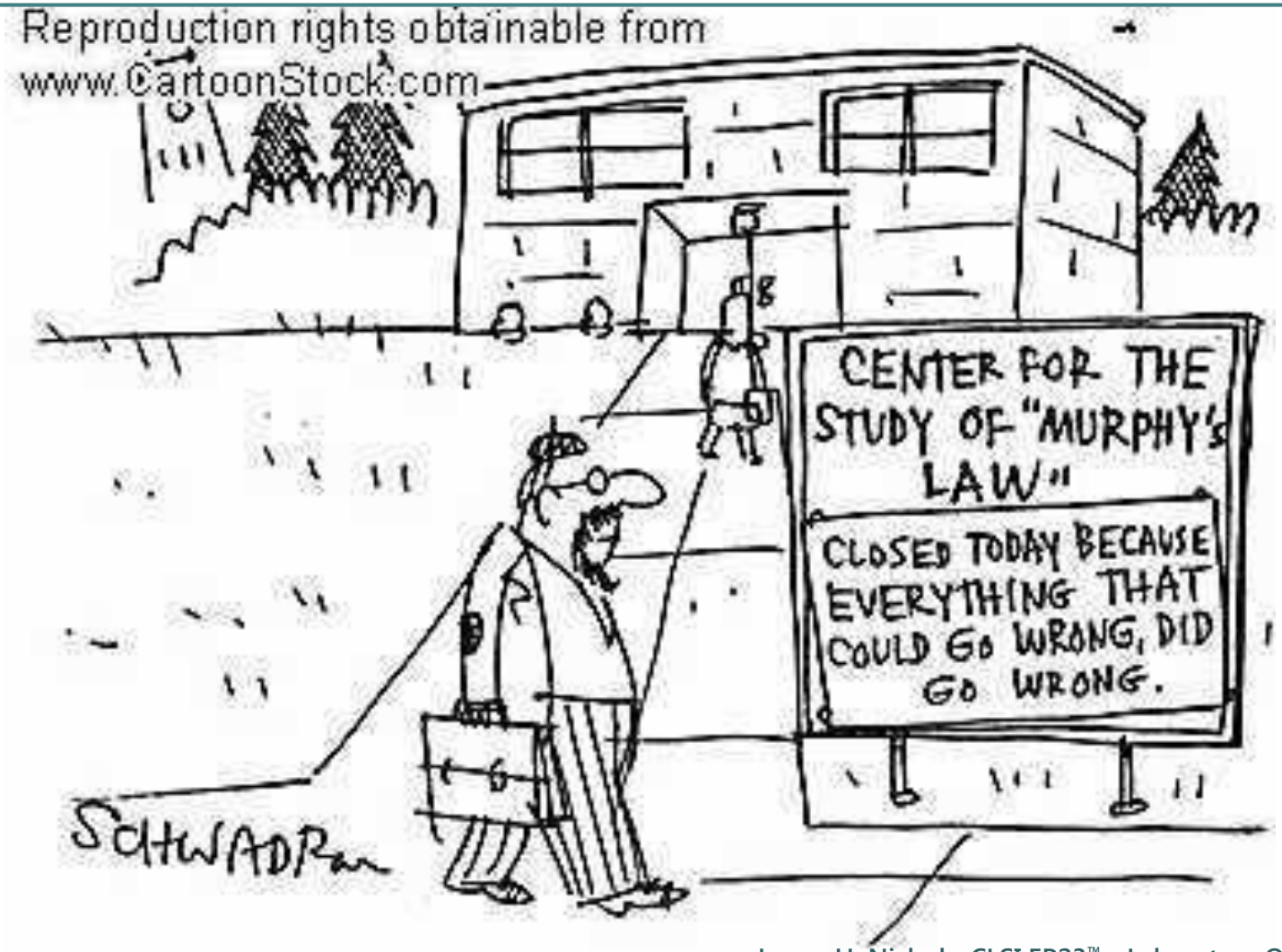
Klonoff DC. Diabetes Spectrum 27(3), 2014.

Error sources categorised by FDA:

Category	Sources of Error or Failure
Hardware	• Electronic failure • Physical trauma or vibration • Damage to the device from incorrect strip dimensional tolerances (third-party manufacturer) • Electrostatic discharge • Electromagnetic/radiofrequency interference • Battery reliability, lifetime, and replacement • Component(s) failure • Incorrectly manufactured
System	• Physical trauma or vibration • Incorrect calibration/adjustment (between lots of strips) • Calibration failure, interference, instability, or use beyond the recommended period of stability • Labeling not geared to intended user • Meter or operation complexity not geared to intended user • Inadequate training
Clinical	• Interference from endogenous substances • Severe conditions (e.g., dehydration, hypoxia, hyperglycemic hyperosmolar state, hypotension, ketoacidosis, or shock) • Interference from other sugars (e.g., maltose intravenous solutions)

Klonoff DC. Diabetes Spectrum 27(3), 2014.

Do we need a New Approach to Quality Control with Managing the Risks?



James H. Nichols, CLSI EP23™—Laboratory Quality Control Based on Risk Management, 2012

Milestones – Evolvement of Quality Control Over Time

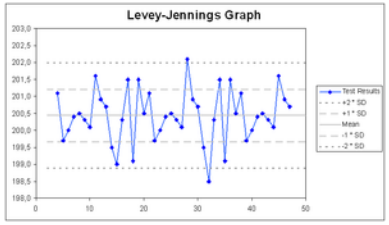
1920 1930

Walter Shewart first uses statistical process control and control charts

Dr. Walter A. Shewhart

1950

Levey & Jennings propose use of Shewart charts in the clinical laboratory – using duplicate QC measurements and 3 S limit



1960

Use of 2S limits proposed -RJ Henry

1980

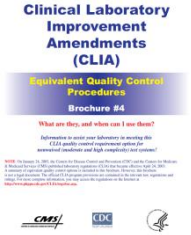
James Westgard proposed use of multi-rule QC

1990

CLIA'88 regulations are published: At least once each day patient specimens are assayed - each quantitative procedure include 2 control materials of different concentrations

2003

Equivalent QC.



2011

CLSI published EP23-A

2015

IQCP published

QC → EQC → EP23 → IQCP

Adapted from Person N. Siemens Healthcare Diagnostics Inc. 2013

Clinical Laboratory News

THE AUTHORITATIVE SOURCE FOR THE CLINICAL LABORATORIAN

AACC

NOVEMBER 2011
VOLUME 37, NUMBER 11
www.aacc.org

NEWS BRIEF

HEALTH R&D FUNDING STALLED

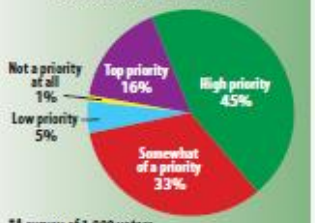
A report recently released by Research!America found that U.S. investments in health research and development (R&D) have remained relatively flat, especially considering the rising cost of conducting such research. This lag is negatively impacting economic growth for the country, as well as high-paying jobs.

The new report, "2010 U.S. Investment in Health Research," breaks down R&D spending by sector—federal and industry—and emphasizes that renewed U.S. investment in health R&D is needed to foster new treatments.

Overall, U.S. spending on health research rose 1.2% from $138.9 billion to $140.5 billion in 2010, while the cost of conducting research rose 2.8%. At the same time the U.S. spent $2.6 trillion on healthcare, health R&D dollars amounted to only 5.5% of total healthcare spending.

Last year, federal funding for health research reached $45.9 billion, a $550 million decrease from the previous year. The pharmaceutical industry increased R&D spending by $4.7 billion, representing a 14.6% increase; however, the biotechnology industry decreased investment by nearly $2.7 billion or 8% down from the previous year. Medical technology industry spending, which includes medical devices and diagnos-

SNAPSHOT
Health R&D Investment*



*A survey of 1,000 voters

Source: Your Congress–Your Health survey, March 2011, Charlton Research Company for Research!America.

A New Approach To Quality Control

How Can Risk Management Help Labs?

BY BILL MALONE

When the Centers for Medicare and Medicaid Services (CMS) finalized the Clinical Laboratory Improvement Amendments regulations in 2003, many in the lab community expressed dissatisfaction with what was perceived as ambiguous and unscientific guidance on how to conduct quality control (QC). While the regulations set basic requirements for testing external QC materials, most laboratories found they needed to go above and beyond these standards to avoid quality problems. In the 8 years since the agency published the final regulation, exactly how often labs need to perform external QC and other quality checks has been widely debated. Quality tools like Six Sigma, Lean, and others abound, but so far, a comprehensive approach to QC that suits regulators and a majority of the laboratory community has not emerged.

Now the Clinical and Laboratory Standards Institute (CLSI) has published a long-awaited guideline that aims to fill this gap, enabling labs to customize QC to match both changing technology and the uniqueness of each lab. However, in what form CMS and other accrediting organizations will adopt or endorse it remains to be seen.

See **Risk Management**, *continued on page 3*

Today's Quality Control Process

- Advantages
  - QC monitors the end product (result) of the entire test system.
  - QC has target values: if assay recovers the target, then everything is assumed stable (eg., instrument, reagent, operator, sample).
- Disadvantages
  - When a problem is detected, one must go back and reanalyze patients since the last "good" QC.
  - If results are released, then results may need to be corrected.
  - For Point of Care devices, does traditional QC work for every test?
- Need to get to fully automated analyzers that eliminate errors up front
  - Until that time, need a robust QC plan (QCP)

James H. Nichols, CLSI EP23™—Laboratory Quality Control Based on Risk Management, 2012

Types of Quality Control

- "On-Board" or Analyzer QC – built-in device controls or system checks
- Internal QC – laboratory-analyzed surrogate sample controls
- External QC – blind proficiency survey
- Other types of QC – control processes either engineered by a manufacturer or enacted by a laboratory to ensure result reliability

James H. Nichols, CLSI EP23™—Laboratory Quality Control Based on Risk Management, 2012

Quality Control Limitations

- No single QC procedure can cover all devices, because the devices may differ.
- QC practices developed over the years have provided laboratories with some degree of assurance that results are valid.
- Newer devices have built-in electronic controls, and "on-board" chemical and biological controls.
- QC information from the manufacturer increases the user's understanding of device's overall quality assurance requirements.

ISO. Clinical laboratory medicine – In vitro diagnostic medical devices – Validation of user quality control procedures by the manufacturer. ISO 15198. Geneva, Switzerland: International Organization for Standardization; 2004.

James H. Nichols, CLSI EP23™—Laboratory Quality Control Based on Risk Management, 2012

In October 2011, CLSI published EP 23 Laboratory Quality Control Based on Risk Assessment.

James H.Nichols Ph.D., DABCC, FACB, Chair of the CLSI EP23 Group

- EP23 explains the strengths and weaknesses of the different QC processes, and helps the laboratory determine the right combination of tools:

- Each laboratory's quality control plan is unique based on the device, the laboratory setting, and the risk to patients from inappropriate decisions based on incorrect or delayed test results.

- CLSI EP23 provides a template for laboratories to map their testing processes, identify weaknesses or hazards in the process map, define a control process that can detect failures and/or prevent reporting erroneous results, summarize the control processes in a quality control plan, implement and benchmark the effectiveness of their quality control plan, and modify a quality control plan as part of continual improvement.

The Quality Control Toolbox

- QC is not only about testing external QC samples, it is all the tools we can use to monitor test system performance.
- EP23 recognizes that a variety of QC tools exist and that no single QC tool is perfect.
- Analysis of QC samples is certainly a well established tool available to us.
- Key to effective use of QC samples is determining how often they need to be tested.

QC Tools

- Intralaboratory QC
- Interlaboratory QC
- Integrated (built-in) QC
- Measuring system function checks
- Electronic system checks
- Calibration checks
- Repeat testing of patient samples
- Monitoring aggregated patient results
- Implausible values
- Delta checks
- Correlation of multiple analytes in same sample

Improvement of QC Practices

Curtis Parvin

- Every QC tool has its strengths and weaknesses (there is no perfect QC tool).
- QC frequency closely connected to managing risk of reporting inaccurate results
- Implement a combination of tools in order to properly control a test.

- Parvin CA, Assessing the Impact of the Frequency of Quality Control Testing on the Quality of Reported Patient Results, *Clin Chem* 2008;54:
- Parvin CA, Robbins S, Evaluation of the Performance of Randomized versus Fixed Time Schedules for Quality Control Procedures, *Clin Chem* 2007;53:575-580
- Parvin CA, Gronowski AM. The effect of analytical run length on quality-control (QC) performance and the QC planning process. *Clin Chem* 1997;43:2149-54
- Parvin CA, et al. Designing a quality control strategy: In the modern laboratory three questions must be answered. ADVANCE for Administrators of the Laboratory 2011;(5):53-54.

One – size – fits - all QC vs Right QC

The concept was introduced in November 4, 2011.

The QC strategy using QC samples should include:

- The frequency of QC sample test events
- The type and number of QC samples tested per test event
- The statistical QC limits used to evaluate the results
- The frequency of periodic review for detecting shifts and trends
- The actions taken when results exceed acceptable limits

CLSI EP-23, Section 5.1.1

It's official: EQC is out and QC Plans are in!

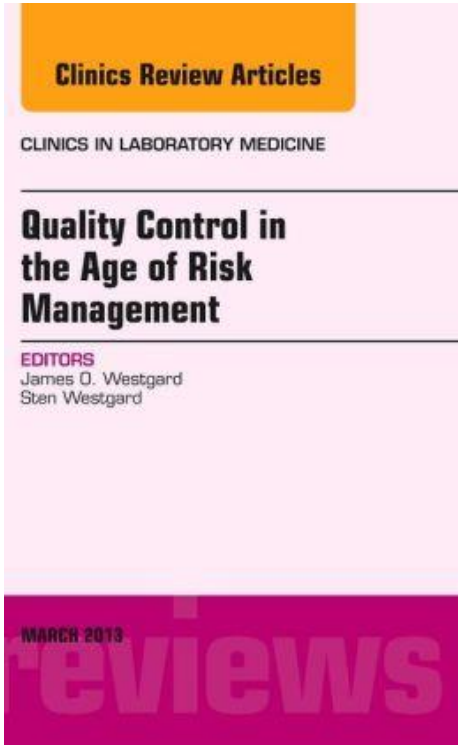
James O. Westgard, Sten A. Westgard
December 2011

CLIA 2003

"EQC" option

EQUIVALENT QC OPTIONS

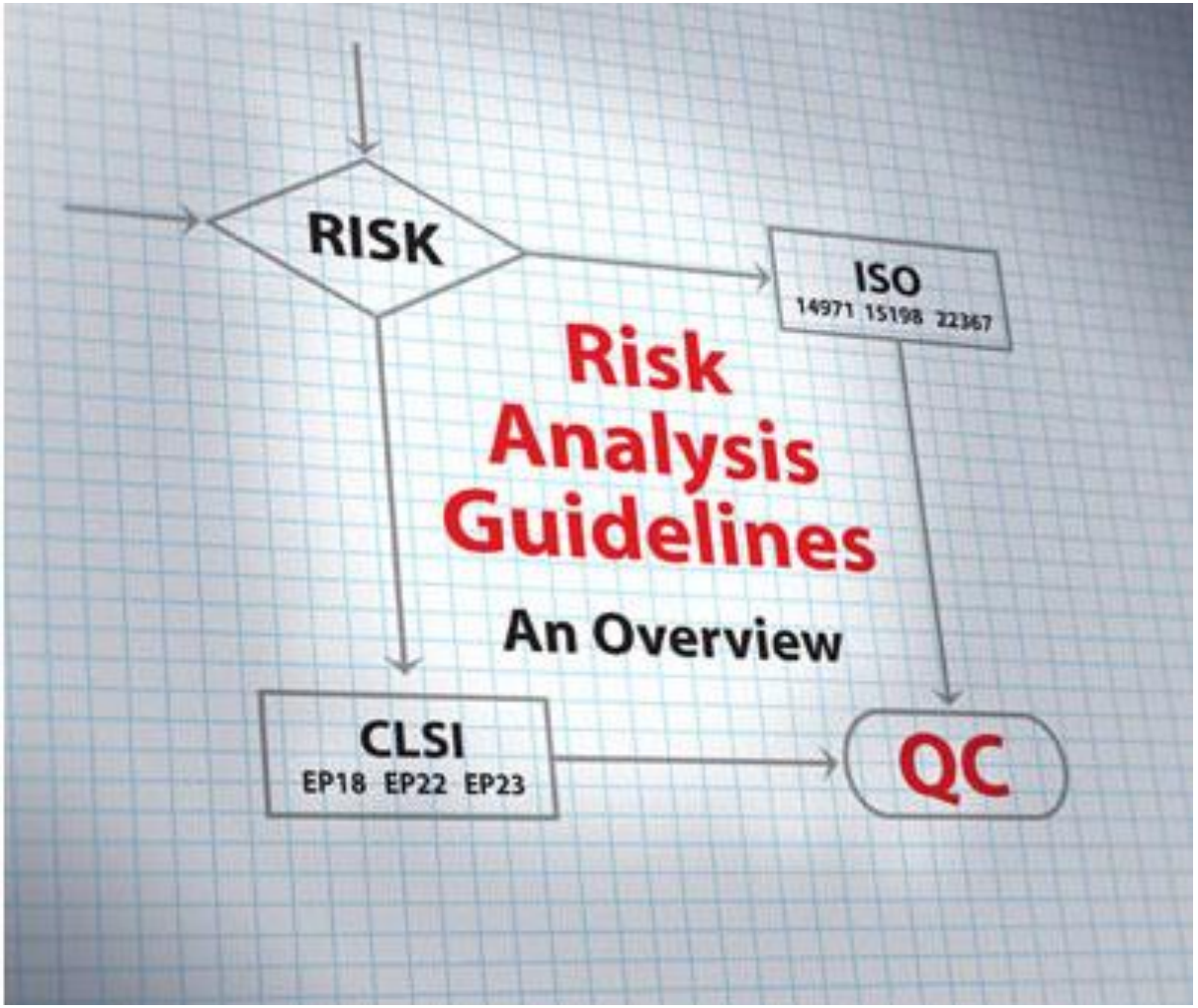
Equivalent QC Option	Test System Description	Evaluation Process: Internal Monitoring Systems*	Evaluation Process: Test Two Levels of External Controls	Equivalent QC Procedure Testing Frequency
Option 1 ALL	Test Systems with Internal Monitoring System that Checks ALL Analytic Components	Daily testing with acceptable results	Results acceptable for 10 consecutive testing days	Testing external controls at least once per calendar **month** and **daily** testing by the internal monitoring system*
Option 2 SOME	Test Systems with Internal Monitoring System that Checks SOME Analytic Components	Daily testing with acceptable results	Results acceptable for 30 consecutive testing days	Testing external controls at least once per calendar **week** and **daily** testing by the internal monitoring system*
Option 3 NONE	Test Systems WITHOUT Internal Monitoring System	N/A	Results acceptable for 60 consecutive testing days	Testing external controls at least once per calendar **week**



http://www.westgardqc.com/official-risk-qc.htm

Quality Control in the age of Risk Management, An Issue of Clinics in Laboratory Medicine
by
James O. Westgard (Editor)

Year: 2013
Issue: Vol 33 | No. 1 | March 2013 | Pages 1-206

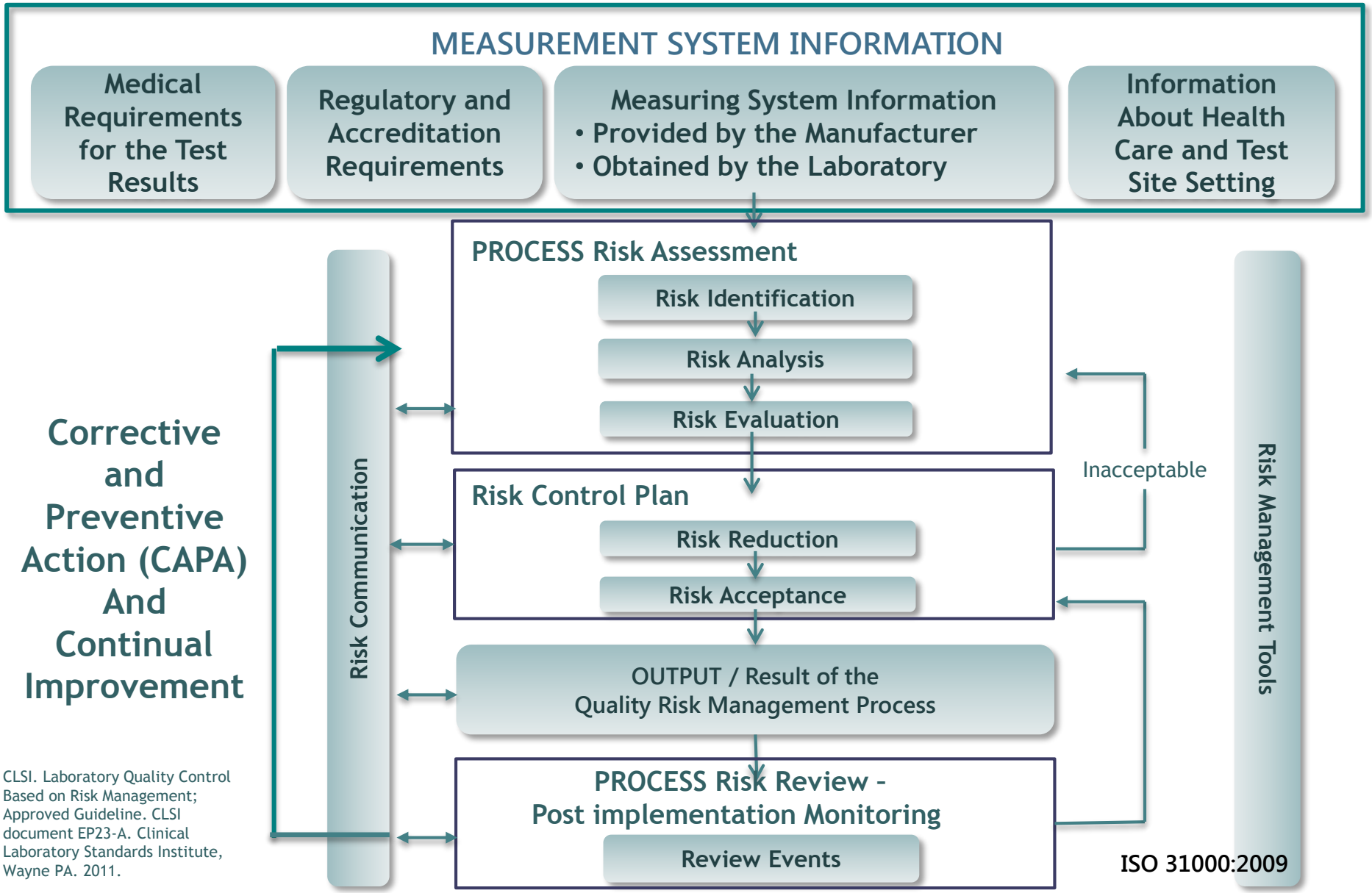


http://james.westgard.com/the_westgard_rules/2012/11/index.html

"The secret of all victory lies in the organization of the non-obvious."

- Marcus Aurelius
  Roma Emperor and Philosopher

Overview of a typical risk management Process to develop and continually improve a quality control plan



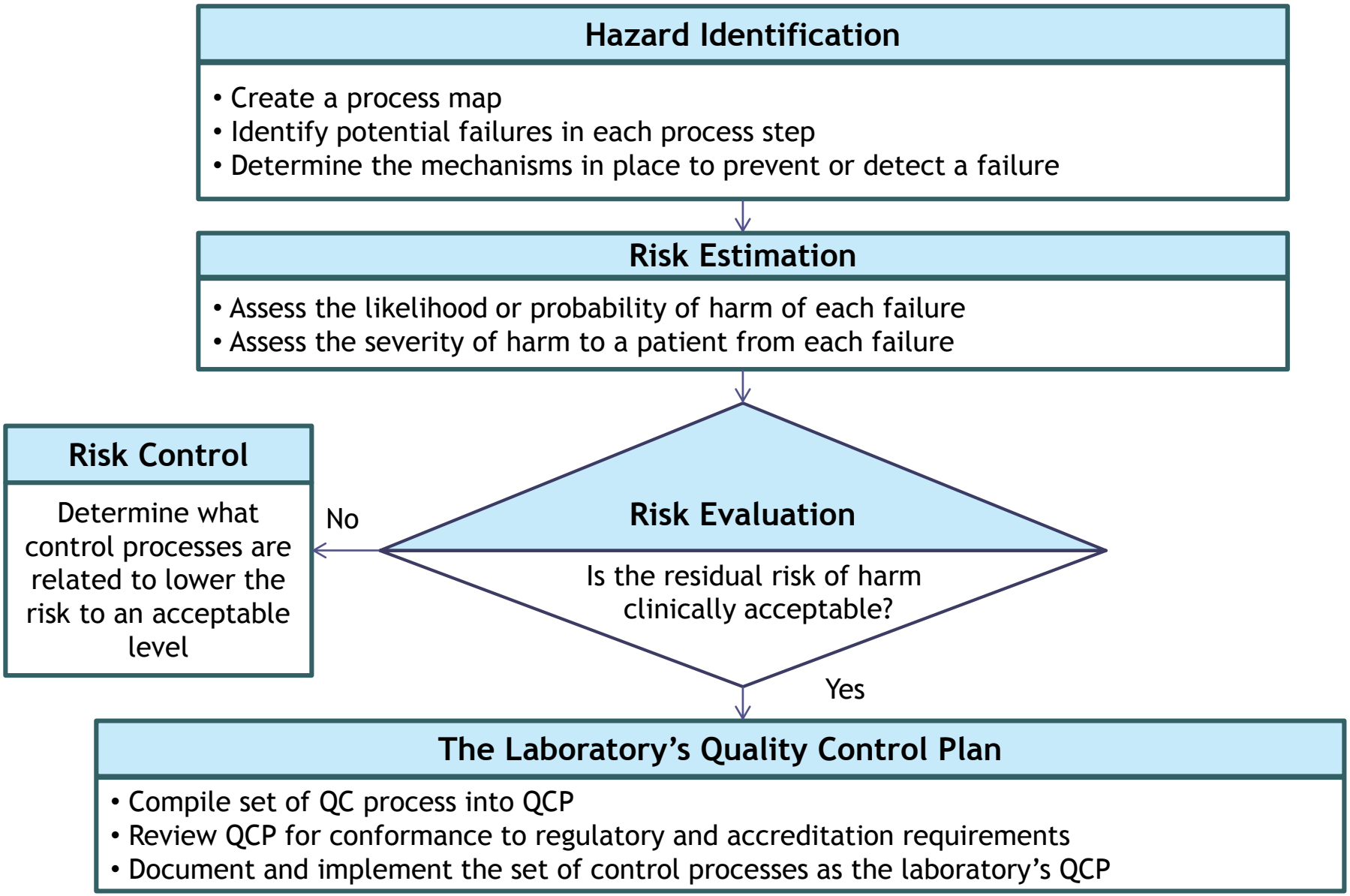
CLSI. Laboratory Quality Control Based on Risk Management; Approved Guideline. CLSI document EP23-A. Clinical Laboratory Standards Institute, Wayne PA. 2011.

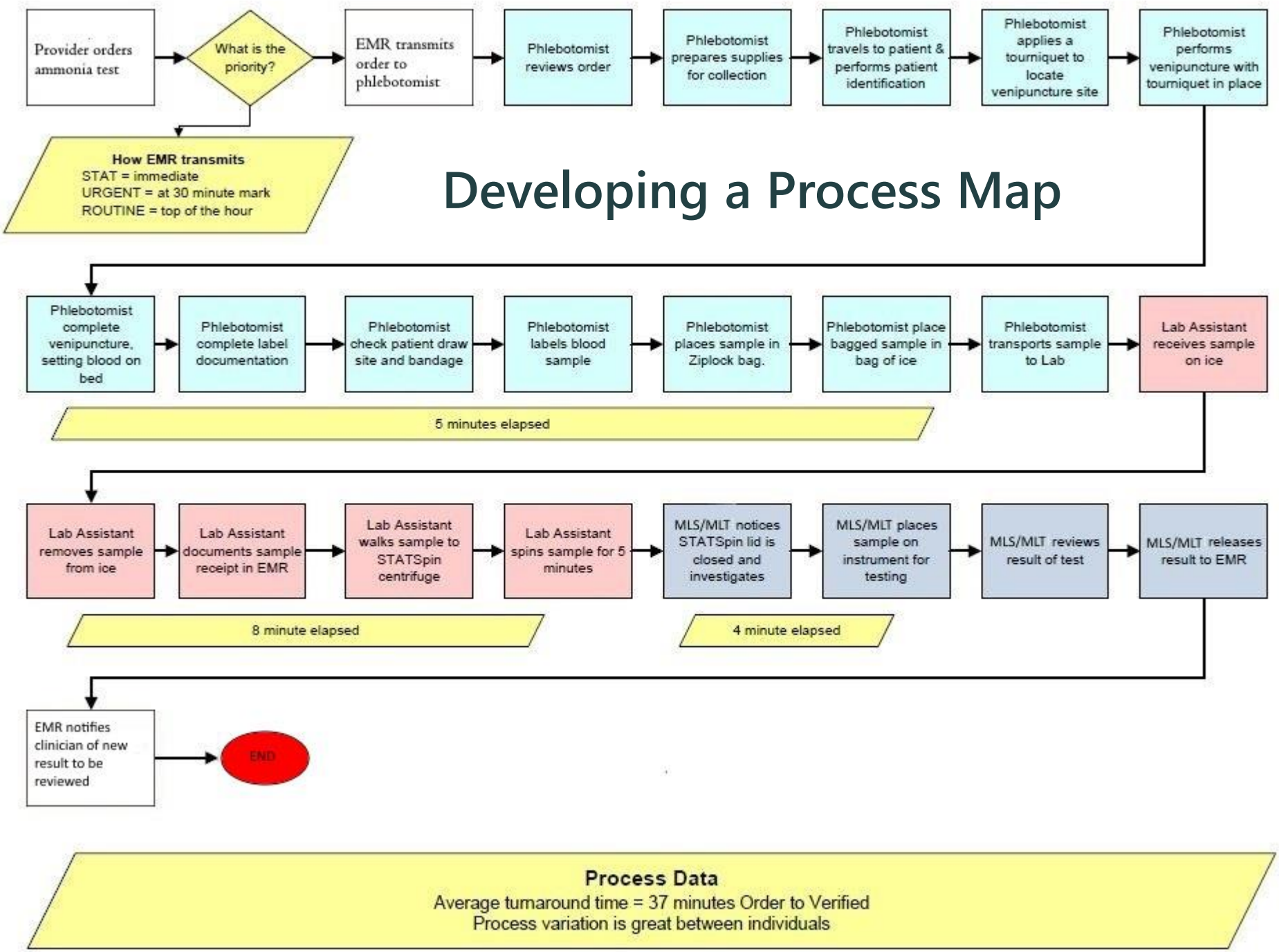
Why Quality Risk Management is important for laboratories?

- Risk management may be best proactive approach to design an optimal overall Quality Control Plan for the laboratory.
- We analyze many samples from which we derive information.
- The information impacts upon decision making and health of others.
- Poor information can lead to poor outcomes.
- Our samples have some variables that we can control, and others that are difficult to control, and others that we can not either foresee or control.
- Regardless of contributing events, the laboratory is usually viewed as the source of the problem.

Noble MA. Risk Management in the Medical Laboratory: Reducing Risk through Application of Standards

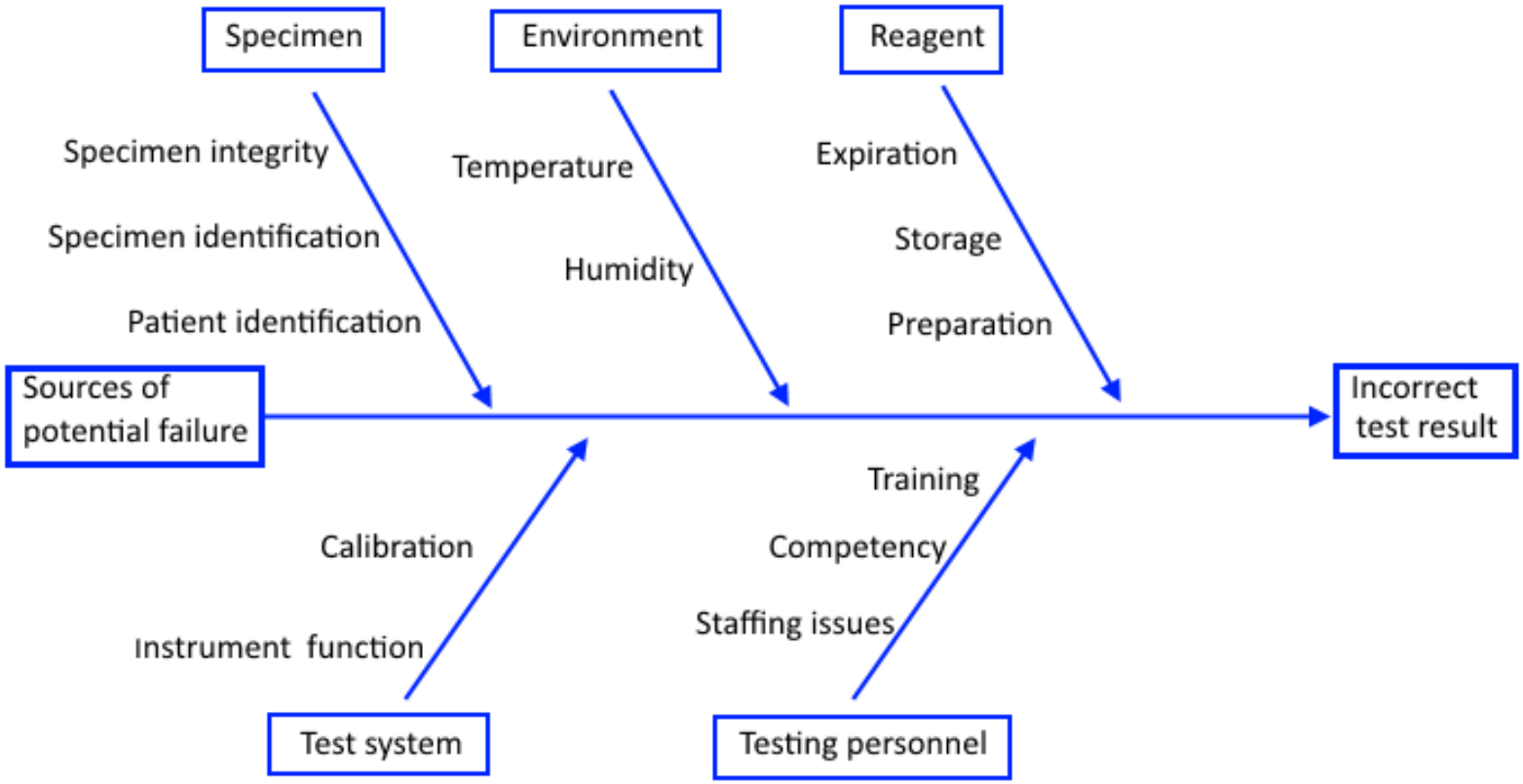
Using Risk Management to Develop a Quality Control Plan




Provider orders ammonia test
What is the priority?
EMR transmits order to phlebotomist
Phlebotomist reviews order
Phlebotomist prepares supplies for collection
Phlebotomist travels to patient & performs patient identification
Phlebotomist applies a tourniquet to locate venipuncture site
Phlebotomist performs venipuncture with tourniquet in place
How EMR transmits
STAT = immediate
URGENT = at 30 minute mark
ROUTINE = top of the hour
Developing a Process Map
Phlebotomist complete venipuncture, setting blood on bed
Phlebotomist complete label documentation
Phlebotomist check patient draw site and bandage
Phlebotomist labels blood sample
Phlebotomist places sample in Ziplock bag.
Phlebotomist place bagged sample in bag of ice
Phlebotomist transports sample to Lab
Lab Assistant receives sample on ice
5 minutes elapsed
Lab Assistant removes sample from ice
Lab Assistant documents sample receipt in EMR
Lab Assistant walks sample to STATSpin centrifuge
Lab Assistant spins sample for 5 minutes
MLS/MLT notices STATSpin lid is closed and investigates
MLS/MLT places sample on instrument for testing
MLS/MLT reviews result of test
MLS/MLT releases result to EMR
8 minute elapsed
4 minute elapsed
EMR notifies clinician of new result to be reviewed
END
Process Data
Average turnaround time = 37 minutes Order to Verified
Process variation is great between individuals

Where is the Risk in the Process?

Identify the Risks – Where is the risk in the process?



Malone B. A New Approach To Quality Control. *How Can Risk Management Help Labs?* Clinical Laboratory News, November 2011; (37)11:1-4.

Perform Risk Assessment

Examples of common risk management tools

Risk management tool	Description, attributes	Potential applications
Tools		
Diagram analysis • Flowcharts • Check sheets • Process mapping • Cause/effect diagrams	• Simple techniques that are commonly used to gather and organize data, structure risk management processes and facilitate decision-making	• Compilation of observations, trends or other empirical information to support a variety of less complex deviations, complaints, defaults or other circumstances
Risk ranking and filtering	• Method to compare and rank risks • Typically involves evaluation of multiple diverse quantitative and qualitative factors for each risk, and weighting factors and risk score	• Prioritizing operating areas or sites for audit or assessment • Useful for situations when the risks and underlying consequences are diverse and difficult to compare using a single tool
Fault-tree analysis	• Method used to identify all root causes of an assumed failure or problem • Used to evaluate system or subsystem failures one at a time, but can combine multiple causes of failure by identifying causal chains • Relies heavily on full process understanding to identify causal factors	• Investigate product complaints • Evaluate deviations
Hazard operability analysis (HAZOP)	• Tool assumes that risk events are caused by deviations from the design and operating intentions • Uses a systematic technique to help identify potential deviations from normal use or design intentions	• Access manufacturing processes, suppliers, facilities and equipment • Commonly used to evaluate process safety hazards
Hazard analysis and critical control point (HACCP)	• Identify and implement process controls that consistently and effectively prevent hazard conditions from occurring • Bottom-up approach that considers how to prevent hazards from occurring and/or propagating • Emphasizes strength of preventive controls rather than ability to detect	• Better for preventive applications than reactive • Valuable precursor or complement to process validation • Assessment of the efficacy of critical control points and the ability to consistently execute them for any process
Failure modes effects analysis (FMEA)	• Assumes comprehensive understanding of the process and that CPPs have been defined prior to initiating the assessment. Tool ensures that CPPs will be met. • Assesses potential failure modes for processes, and the probable effect on outcomes and/or product performance • Once failure modes are known, risk reduction actions can be applied to eliminate, reduce or control potential failures	• Evaluate equipment and facilities; analyse a manufacturing process to identify high risk steps and/or critical parameters

WHO guidelines on quality risk management

FMEA Process Flow

1. Identify TARGETS to be protected:
   - Personnel
   - Product
   - Environment
   - Equipment
   - Productivity
   - . . . other . . .

2. Recognize RISK TOLERANCE LIMITS (i. e., Risk Matrix Boundaries)

3. "SCOPE" system as to: (a) physical boundaries; (b) operating phases (e. g., shakedown, startup, standard run, emergency stop, maintenance); and (c) other assumptions made (e.g., as-is, as-designed, no countermeasures in place) …etc.

4. IN WHAT WAYS (MODES) CAN THIS ELEMENT FAIL . . . ?

QUESTION: For each element . . .
- System, then
- Subsystem, then
- Assembly, then
- Subassembly, then
- . . . etc. . . .

- Don't overlook INTERFACES!

MODE 1 | MODE 2 | MODE 3 | MODE m

WHAT ARE THE CONSEQUENCES (EFFECTS) OF FAILURE IN THIS MODE . . . ?

QUESTIONS: For each FAILURE MODE . . .
- what are the EFFECTS?
- . . . for each TARGET?

EFFECT 1 | EFFECT 2 | EFFECT 3 | EFFECT e

TARGET 1 | TARGET 2 | TARGET 3 | TARGET t

AND

REPEAT . . . for each MODE/EFFECT/TARGET combination.

EVALUATE WORST-CASE SEVERITY | EVALUATE PROBABILITY

AND

USE RISK MATRIX… MATRIX must be defined for and must match the assessment Probability Interval and Force/Fleet Size.

ASSESS RISK

IS RISK ACCEPTABLE ?

NO

See 2. above.

YES

OR

REASSESS RISK

DEVELOP COUNTERMEASURES

ACCEPT (WAIVER)

ABANDON

STOP

5. Do the countermeasures introduce NEW hazards? . . . or,

6. Do the countermeasures IMPAIR system performance?

. . . if so, develop NEW COUNTERMEASURES !

Perform Risk Assessment

An FMEA worksheet is created to record each process failure (hazard), failure cause, effect (harm), severity, existing process controls (to prevent the failure), probability of occurrence (of the failure), detectability (prior to harm), and comments explaining rationale.

#	Component	Potential failure mode	Effect	Failure cause	SEV	Existing controls	OCC	DET	Comments/ Rationale
1	Reagent	Stability not meeting claim (negative drift)	Incorrect results/ misdiagnosis	Reagent deterioration due to improper storage	8	SOP (validated storage conditions), trained personnel; weekly QC	6	2	Manufacturer's instructions
2	Reagent	Large bias shift at lot change	Incorrect results/ misdiagnosis	Reagent lot-lot differences	8	QC acceptance testing, supplier qualification	6	2	
3	Instrument	Increased imprecision at high analyte concentrations	Incorrect results/ misdiagnosis	Lamp aging	6	Preventive maintenance program / SOP (lamp replacement schedule)	2	8	Manufacturer's instructions
4	Instrument	Sporadic "outlier" readings	Incorrect results/ misdiagnosis	Unstable power source in lab	8	Voltage regulator, installation qualification	4	10	Observed with similar instruments
5	Calibrator	Large bias shift after calibration	Incorrect results/ misdiagnosis	Incorrect calibrator value assigned by manufacturer	8	Certificate of traceability, post-calibration QC, proficiency testing	6	2	
6	Calibrator	Large bias shift after calibration	Incorrect results/ misdiagnosis	Calibrator reconstitution error	8	Qualified personnel, SOP, training, post-calibration QC, proficiency testing	4	2	
7	Sample	Sporadic "outlier" results	Incorrect results/ misdiagnosis	Drug interference (known interferent)	8	Specimen requisition form; hospital pharmacy drug alert system	4	10	Observed in method verification study
8	Sample	Unsuitable sample (hemolyzed)	No result/delayed treatment	Improper specimen preparation	4	SOP (sample preparation); training/ personnel qualification	6	4	Requires re-draw

Powers DM. LABMEDICINE 36(10): 2005

Perform Risk Assessment

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 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*	*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

RISK EVALUATION - Risk acceptability chart

Probability	Severity of Harm				
	Catastrophic	Critical	Serious	Minor	Negligible
Frequent	Unacceptible Risk	Unacceptible Risk	Unacceptible Risk	Unacceptible Risk	Unacceptible Risk
Probable	Unacceptible Risk	Unacceptible Risk	Unacceptible Risk	Unacceptible Risk	Acceptible Risk
Occasional	Unacceptible Risk	Unacceptible Risk	Acceptible Risk	Acceptible Risk	Acceptible Risk
Remote	Unacceptible Risk	Unacceptible Risk	Acceptible Risk	Acceptible Risk	Acceptible Risk
Inconceivable	Acceptible Risk	Acceptible Risk	Acceptible Risk	Acceptible Risk	Acceptible Risk

ISO 14971

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

RISK EVALUATION - Risk Matrix, 3 scales can be set up.

SCORE	SEVERITY OF HARM (SEV)	PROBABILITY OF OCCURRENCE (OCC)		DETECTABILTY PRIOR TO HARM (DET)
10	Catastrophic – Patient Death	Frequent	≥ 1/1,000	Almost impossible to detect
8	Critical – Permanent impairment or life-threatening injury	Probable	< 1/1,000 and ≥ 1/10,000	Low probability of detection
6	Serious – injury or impairment requiring medical intervention	Occasional	< 1/10,000 and ≥ 1/100,000	Medium probability of detection
4	Minor – temporary injury or impairment not requiring medical intervention	Remote	< 1/100,000 and ≥ 1/1,000,000	High probability of detection
2	Negligible – inconvenience or temporary discomfort	Improbable/ theoretical	< 1/1,000,000	Almost certain to be detected

The risks need to be evaluated against criteria approved by the lab director.
Values 6 and above must be addressed.
Detectability scale has an inverse relationship to the probability of detection.

RISK EVALUATION
Frequency (also called "Probability") 1 – 5 scale

Common Terms	Score	Example (ISO 14971)	PROBABILITY OF OCCURRENCE
Frequent	5	≥ 1/1,000	More than 1x/week
Probable	4	< 1/1,000 and ≥1/10,000	Once every few months
Occasional	3	< 1/10,000 and ≥1/100,000	Once a year
Remote	2	< 1/100,000 and ≥1/1,000,000	Once every few years
Improbable	1	< 1/1,000,000 and ≥10,000,000	Unlikely to ever happen

RISK EVALUATION
Severity (Scale 1 – 5)

Common Terms	Score	Possible Description (ISO 14971)
Catastrophic	5	Results in patient death
Critical	4	Results in permanent injury of life-threatening injury
Serious	3	Results in injury or impairment requiring professional medical intervention
Minor	2	Results in temporary injury or impairment not requiring professional medical intervention
Negligible	1	Inconvenience or temporary discomfort

RISK EVALUATION
Detectability (Scale 1 – 5)

Common Terms	Score	Example
Low	5	Control is ineffective
	4	Control less likely to detect the failure
	3	Control may or may not detect the failure
	2	Control almost always detects the failure
High	1	Control can detect the failure

Criticality

- **Multiply Frequency x Severity x Detectability**

  Example: Probable (4) x Catastrophic (5) x High likelihood to detect failure (1) = 20

Criticality	Result
Low	<10
Mid	10 – 20
High	>20

Higher criticality numbers must have quality control actions in place.

RISK EVALUATION

SEVERITY ≥ 6 (or ≥3)	Require an Essential Control Point
OCCURRENCE ≥ 6 (or ≥3)	Require an Essential Control Point which must be an effective method of detection
DETECTABILITY ≥ 6 (or ≥3)	Require an Essential Control which must be a process control that prevents failures
OCCURRENCE ≥ 6 and DETECTABILITY ≥ 6	The process activity lacks adequate controls and corrective action must be initiated, either to reduce the failure rate or to increase the ability to detect a failure or both.

Powers DM. LABMEDICINE 36(10): 2005

A-90

Studies On The Improvement Of Critical Laboratory Value Notification Using A Failure Mode And Effect Analysis

S. Yenice, C. Maden, T. Esin. *Gayrettepe Florence Nightingale Hospital, Istanbul, Turkey,*

Objective: To identify potential failure modes, causes and effects concerning patient safety, implement and assess the sustained improvement acts using a failure mode and effect analysis (FMEA) technique in reporting of critical laboratory values (CLV) of clinical chemistry tests for emergency cases and inpatients. FMEA is a procedure that analyzes potential failure modes within a given system. Each failure mode is classified by severity to determine the effect of failures on the system. Most patient safety reporting systems concentrate on analyzing adverse events after an injury has taken place. Healthcare FMEA, in contrast to a root-cause analysis, offers users analytical tools that can enable a team to proactively identify vulnerabilities in a care system and deal with them effectively. In essence, FMEA was used as a systematic, engineering-based approach in this study to identify such system vulnerabilities in CLV notification process and to correct them before they occur.

Methods: A five-step process was used.

Step 1: Patient Safety Committee decided to study on the potential failure modes, causes, effects and improvement acts about the CLV notification process.

Step 2: A multidisciplinary team was assembled including experts and individuals from the departments of Clinical Biochemistry, Internal Medicine, Emergency Care, Adult and Newborn Intensive Care Units, Nursing Service and Quality Management.

Step 3: Team members developed processes and subprocesses, then verified a flow-process diagram.

Step 4: Focusing on the subprocesses, team members listed all potential failure modes to determine their severity, occurence and probability. The hazard scoring matrix was used to define the risk priority numbers (RPN) and probability of an event's reoccurence and its severity. The Decision Tree was used to determine if corrective actions should be taken.

Step 5: The team determined what the best course of action was to take. Outcome measures were identified to analyze results and rapid Plan-Do-Study-Act methodology was used to test redesigned processes. Statistical analysis were performed to compare the pre- and post-RPNs.

Results and Conclusion: Six processes and 31 subprocesses were identified. 66 potential failure modes, 97 potential failure causes and effects were determined. Improvement actions were performed. Pareto diagrams were used to compare the pre- and post-RPNs. FMEA is a potent and invaluable tool to trap the potential failures. Yet, process is complex, time-consuming, and requires an intensive labor input. Therefore, a good team effort and detailed planning should be reserved. Overall assessment of processes revealed a high level of improvement (66%) that most became the standard operating procedure.

Yenice S, Maden C, Esin T.

Studies on The Improvement Of Critical Laboratory Value Notification Using A Failure Mode And Effect Analysis.

CLINICAL CHEMISTRY 2010; Vol. 56, No. 6, Supplement: A30.

Identified:
6 major processes
31 subprocesses
66 failure modes
97 potential failure causes

Conclusion: The Quality Control Plan

- Construct the QCP.
- A QCP is necessary for result quality, and each QCP is unique.
- Include each of the identified QCP actions in the QCP.
- A QCP is the industry standard. It depends upon the extent to which the device's features achieve their intended purpose in union with the laboratory's expectation for ensuring quality results.
- Monitor QCP for Effectiveness - Once implemented, the QCP is monitored for effectiveness and modified as needed to maintain risk at a clinically acceptable level.

Clinical and Laboratory Standards Institute (CLSI). Risk Management Techniques to identify and and control laboratory error sources: Approved guideline - second edition. CLSI Document EP18 – A2 (ISBN 1-56238-712-X). Clinical and Laboratory Standards Institute . 940 West Valley Road, Suite 1400, Wayne, Pennyslvania 19087-1898 USA, 2009.

EP-23 Example: Checklist

Appendix E. Quick Guide Checklist for Establishing a Quality Control Plan Based on Risk Management

Recent advances in technology have significantly enhanced the accuracy and reliability of certain measuring systems. In recognition of these advances, regulatory and accreditation bodies may provide opportunities for laboratories to establish QCP based on risk assessments. Appropriate site-specific QCP can be established through a systematic analysis and evaluation of factors that can adversely affect the quality of test results, and by using an assortment of QC tools to mitigate patient risk. The particular combination of measuring system, laboratory, or test site environment and clinical application should be considered when establishing a QCP. Some of the factors considered by the laboratory are listed in this checklist that may provide a useful overview of a laboratory's complete QCP. Additional guidance can be found in CLSI document EP18.[1]

Measuring System: Activated Clotting Time (POCT)

A. Information Gathering. *(Section 6, Appendix A, and EP22, Sections 1 and 2)*	Yes
1. **Regulatory and accreditation requirements permit site-specific QCPs.**	☑
2. The quality of laboratory examinations depends on a partnership between IVD manufacturers and the laboratory.	
a. The manufacturer provides adequate instructions for using their methodology with their packaged measuring system.	☑
b. **Manufacturer's risk mitigation information** includes information regarding the scope and effectiveness of recommended QC procedures in terms of potential measuring system failures and the hazards associated with such failures.	☐ no
c. The manufacturer's risk mitigation information includes recommendations on how to best detect and mitigate residual risks, and describes how the mitigation affects the quality of patient test results.	☐ no

Valerie Ng. IQCP Plan

EP-23 Example: Checklist

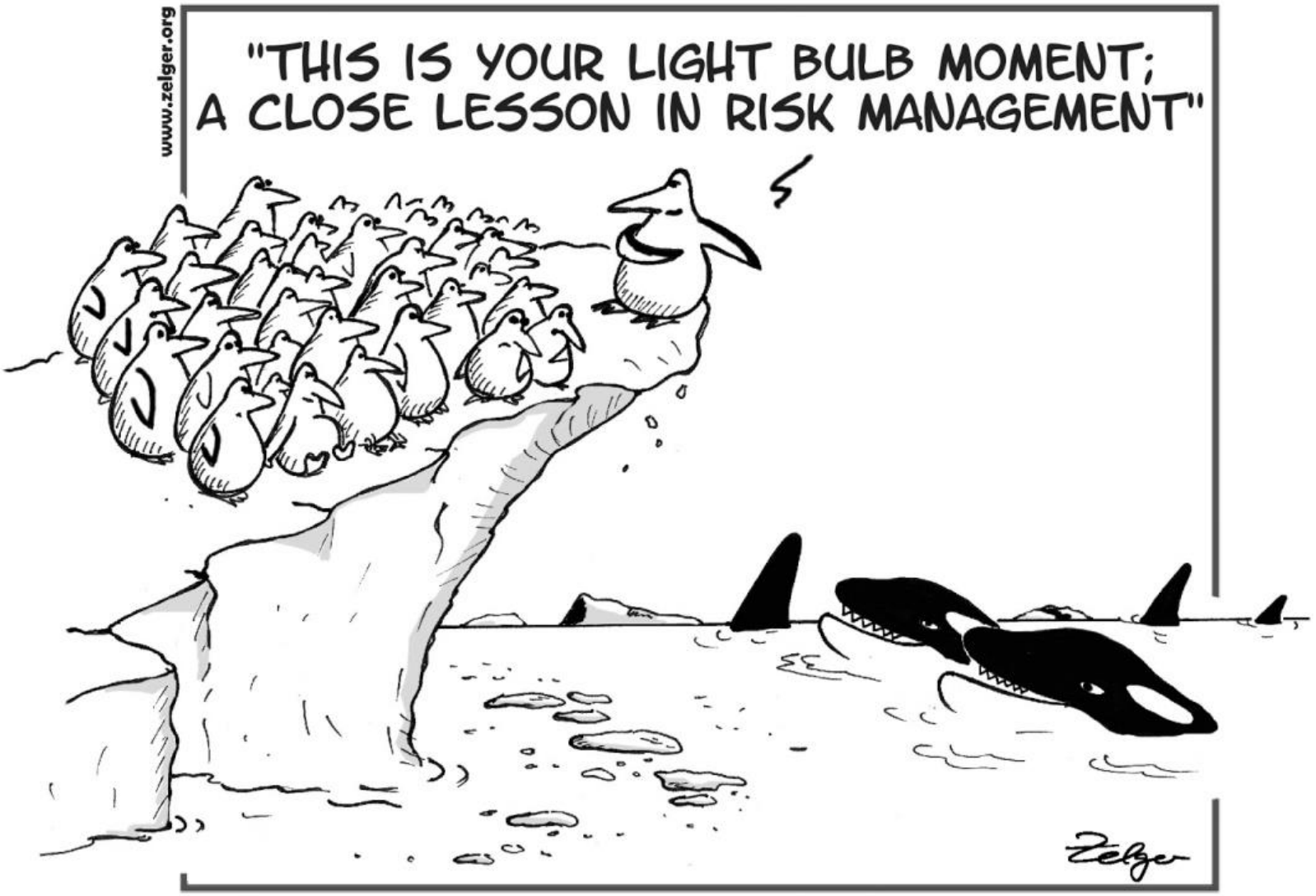
1. Hazard identification. *(Section 7)* a. The laboratory uses the manufacturer, laboratory, and regulatory information to identify potential weaknesses in the examination process that present risk to patients. b. The laboratory critically assesses the information to determine if it is appropriate for the conditions that exist in the laboratory or test setting. ***Hazard Identification is documented in the following laboratory records:*** Fishbone analysis.	☑ ☑
2. Laboratory identified sources of errors that could lead to patient harm. The laboratory reviews the process flow chart, and identifies hazards and measuring system control processes to determine if the risk is clinically acceptable. ***Risk assessment is documented in the following laboratory records:*** ACT hazard analysis.	☑
3. The laboratory's QCP. The laboratory documents all risk mitigation procedures as the QCP. The QCP: a. Meets regulatory/accreditation requirements. b. Meets manufacturer's recommendations. c. Incorporates appropriate QC processes identified to mitigate risk of harm to a patient. ***Risk mitigation is documented in the following laboratory records:*** P&P QC and ACT validation cover sheet.	☑ ☑ ☑

Valerie Ng. IQCP Plan

EP-23 Example: Checklist

C. **Postimplementation Monitoring.** *(Section 8)*	
1. Evaluation of the effectiveness of the laboratory QCP. The laboratory develops a plan for reviewing and evaluating key QC indicators on a periodic basis as well as mechanisms to investigate and evaluate all customer complaints received. A protocol is established to ensure appropriate communication and implementation of any manufacturer updates or recalls. *QCP review is documented in the following laboratory records:* Monitor proficiency testing results & patient outcomes	☑
2. Troubleshooting/determining. Cause of unacceptable performance. When unacceptable levels of performance are identified, the cause is determined and the risk of harm to patients is assessed. *Unacceptable levels of performance are documented in the following laboratory records:* Unacceptable PT documented with PT summary report. Adverse patient outcome documented as internal investigation.	☑
3. Corrective action – CQI. The laboratory's implemented QCP is modified as needed to prevent a recurrence of identified problems. *Modifications to the QCP are documented in the following laboratory records:*	☐ n/a (yet)

Valerie Ng. IQCP Plan



Advanced training in the Antarctic territories

The "Individualized Quality Control Plan" (IQCP) is the Clinical Laboratory Improvement Amendments (CLIA) Quality Control (QC) policy became effective as an alternative QC option for all laboratory tests on January 1, 2016.

Clinical Laboratory Improvement Amendments (CLIA)

- How to Apply for a CLIA Certificate, Including International Laboratories
- State Agency & Regional Office CLIA Contacts
- Accreditation Organizations/Exempt States
- Categorization of Tests
- Certificate of Waiver Laboratory Project
- Certification Boards for Laboratory Directors of High Complexity Testing
- CLIA Brochures
- CLIA Regulations and Federal Register Documents
- CLIA Related Hearing Decisions and Compliance Topics
- CLIA Statistical Tables/Graphs
- CME Courses for Laboratory

Individualized Quality Control Plan (IQCP)

The "Individualized Quality Control Plan" (IQCP) is the Clinical Laboratory Improvement Amendments (CLIA) Quality Control (QC) policy currently under development as an alternate QC option allowed by 42CFR493.1250. The guidance and concepts for IQCP are a formal representation and compilation of many things laboratories already do to ensure quality test results. IQCP permits the laboratory to customize its QC plan according to test method and use, environment, and personnel competency while providing for equivalent quality testing.

Refer to the downloads and the related links section below for the following information:

- Slide presentation, audio recording and written transcript from the CMS IQCP National Call on May 19 2014, file: 2014-05-09-CLIA ;
- CLIA Individualized Quality Control Plan (IQCP) benefits;
- Initial Plans and Policy Implementation for Clinical and Laboratory Standards Institute (CLSI) Evaluation Protocol-23 (EP), 'Laboratory Quality Control Based on Risk Management', as Clinical Laboratory Improvement Amendment (CLIA) Quality Control (QC) Policy, file: CMS1253857;
- Implementing the Individualized Quality Control Plan (IQCP) for Clinical Laboratory Improvement Amendments (CLIA), file: CMS1256877;
- Individualized Quality Control Plan (IQCP): A New Quality Control (QC) Option, file: Survey and Cert Letter 13-54;
- IQCP letter for CLIA certificate of compliance laboratories sent January 30, 2015;
- IQCP letter for provider-performed microscopy procedure laboratories sent January 30, 2015;
- CLIA brochure #11 - CLIA Individualized Quality Control Plan Introduction;
- CLIA brochure #12 - CLIA IQCP, Considerations When Deciding to Develop an IQCP;
- CLIA brochure #13 - CLIA IQCP, What is an IQCP?;
- FAQs for IQCP;

What is IQCP?

IQCP is the new QC option for non-waived test devices in US. CMS states that an IQCP is specific for a testing device and testing situation. The intent is to eliminate failures and detect nonconformities before reporting incorrect results.

What is the basis for IQCP?

CMS structured IQCP on the risk management concepts presented in the CLSI EP23-A guideline. To note that CLSI is not a regulatory body and the purchase of this guideline is not necessary to develop an IQCP.

When is IQCP useful?

Manufacturer's instructions for QC are absent or less stringent than CLIA.

Individualized Quality Control Plan (IQCP): A New Quality Control (QC) Option Available at: http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-54.pdf

Eligible for IQCP

- Syphilis serology
- General Immunology
- Routine Chemistry
- Urinalysis
- Endocrinology
- Toxicology
- Hematology
- Immunochemistry
- Clinical cytogenetics
- Radiobioassay
- Histocompatibility
- Microbiology
  - Bacteriology
  - Mycobacteriology
  - Mycology
  - Parasitology
  - Virology

Not Eligible for IQCP

- Pathology
- Histopathology
- Oral Pathology
- Cytology

Developing an Individualized Quality Control Plan (IQCP)

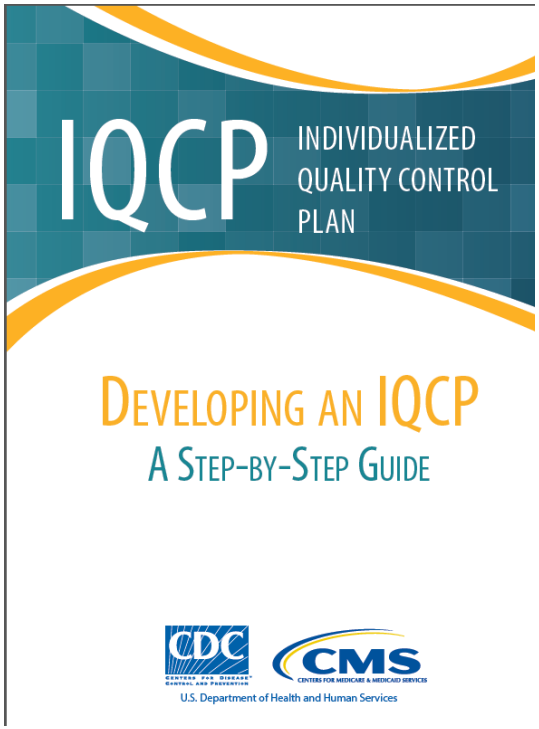
According to CMS.gov, "IQCP considers the entire testing process: pre-analytic, analytic, and post-analytic; thus, the laboratory will need to consider the corresponding risks in each of these phases and applicable regulatory requirements." and must include three components:

James O. Westgard, PhD.

IQCPANIC?

http://www.westgard.com

Joint Commission and CAP developed their own requirements for IQCP. COLA has adopted as it stands.



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. D 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. R~~

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

~~A 3. D 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~~

ring category A; **C** indicates scoring category C; D indicates that documen
hediate Threat to Health or Safety; ⚠ indicates situational decision rules a

The Joint Commission

COLLEGE of AMERICAN PATHOLOGISTS

Topic: Proposed CAP Checklist Requirements for IQCP

Date: May 5, 2015

The Laboratory Accreditation Program has been approved by the Centers for Medicare and Medicaid Services (CMS) to implement the Individualized Quality Control Plan (IQCP) option. The CAP plans to publish these checklist requirements below in the 2015 checklist edition (summer 2015). The primary requirements for IQCP will be found in the All Common Checklist. Additional revisions will be added to the discipline-specific checklists (eg, Chemistry, Point-of-Care) to direct laboratories and inspectors to the All Common Checklist if the IQCP option is being used.

The CAP recognizes that significant time and effort will be needed by those laboratories that choose the IQCP option. Therefore, the CAP is sharing the listing of **proposed** requirements from the All Common Checklist below to provide insight and guidance to laboratories considering this option. **Please note that the proposed requirements are awaiting final prepublication approval by CMS and are subject to change.**

ALL COMMON CHECKLIST

INDIVIDUALIZED QUALITY CONTROL PLAN (IQCP)

This section applies to laboratories using an IQCP approved by the laboratory director for nonwaived testing to reduce external control analysis to a frequency less than the limits defined in the CLIA regulations and CAP checklists. Note that development of an IQCP only impacts quality control requirements. All other checklist requirements remain unchanged and applicable.

*This section **does not** apply to tests where an IQCP was implemented, but the type and frequency of quality control defined in the plan already meets or exceeds minimum quality control requirements defined in the CLIA regulations and CAP checklist requirements. Quality control requirements in other sections of the All Common Checklist and discipline-specific checklists will be used for inspection in those situations.*

If a laboratory is located in a state that does not accept IQCP as an option for reducing the frequency of external quality control, the laboratory must follow the state regulations and perform external daily quality control following the frequency defined in the state regulations and CAP checklists.

Eligibility for use of an IQCP is limited to testing meeting all of the following criteria:

electronic/procedural/built-in) quality control system
reagents used for microbial identification and
t an IQCP as defined in the checklist
Anatomic Pathology and Cytopathology
gy or Cytopathology test can be assigned to a different
g. FISH testing may be classified as either a
st).

IQCP

Page | 1

WEBINAR

An IQCP Development Roadmap: One Medical Center's Journey Toward Implementation

Duration: **60 Minutes**

Date: **NOV.5.2015 2:00 PM - 03:00 PM**

Price: $225.00

Member Price: $179.00

IQCP ACT: Data Gathering

Rapid TAT

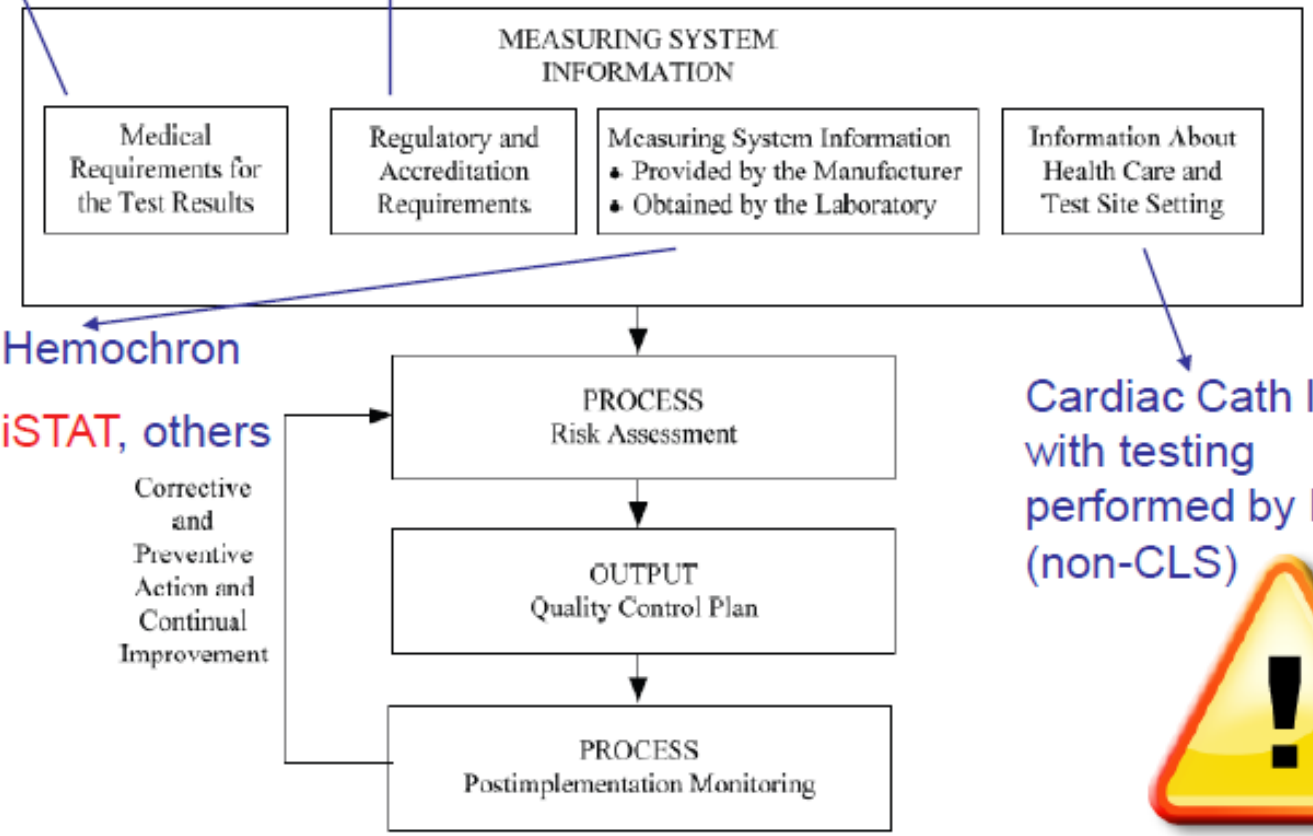
Reasonable accuracy & precision

ACT is typically imprecise

O2 saturation imprecision tolerable

ACT (coag) - 2 levels QC each day of testing

Blood Gas – 3 levels QC every 24 hours, with 1 level each 8 hours



ACT: iSTAT, Hemochron

Blood Gas: iSTAT, others

Cardiac Cath lab with testing performed by RN (non-CLS)

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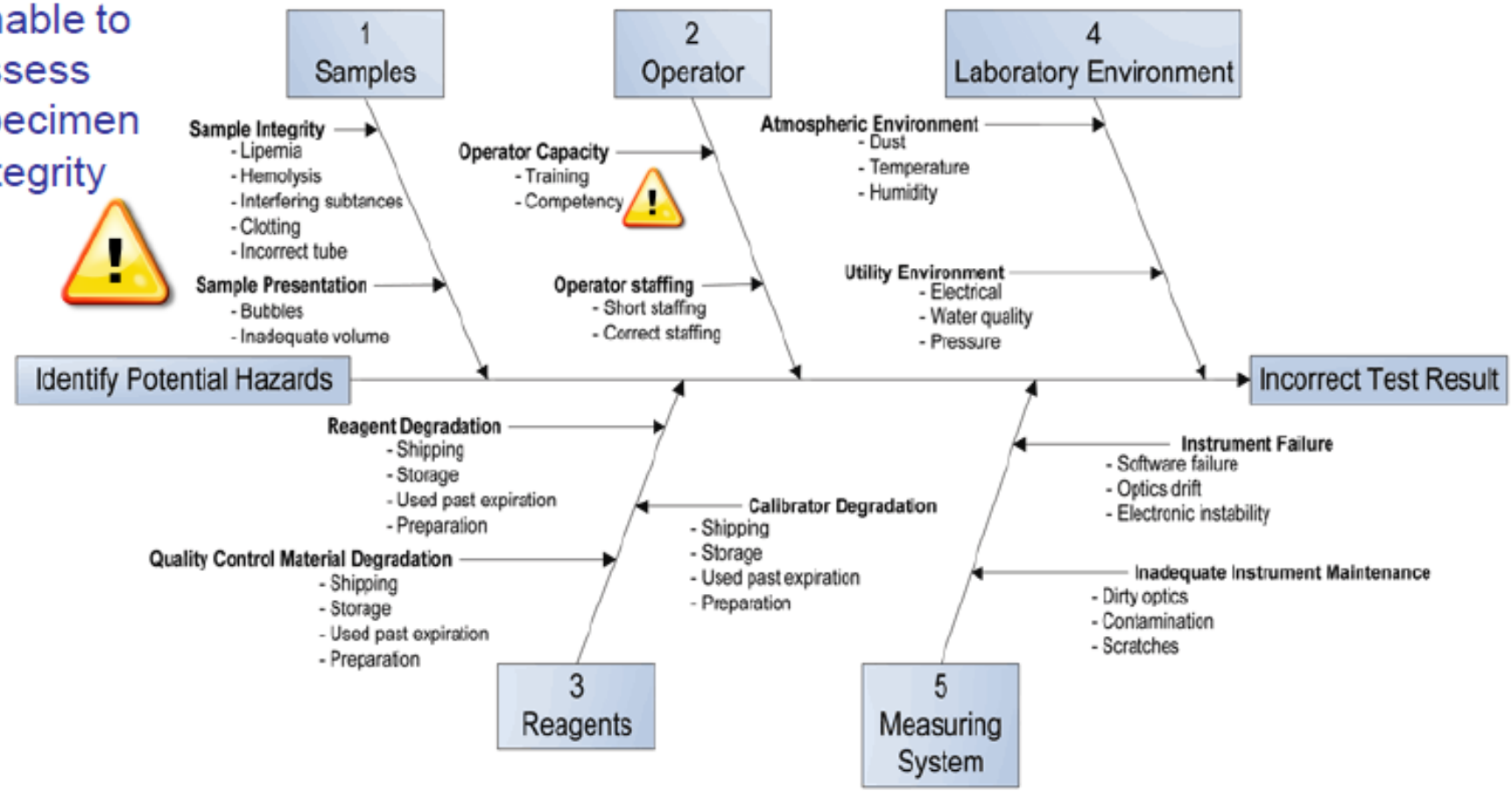
IQCP ACT: Risk Assessment

Whole blood – unable to assess specimen integrity



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IQCP ACT: Risk Assessment

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

ISO 14971

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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captodayonline.com http://www.captodayonline.com/iqcp-without-agony-point-care/

IQCP without agony at the point of care

Anne Paxton

April 2016—For many point-of-care testing coordinators, the prospect of developing Individualized Quality Control Plans is far from enticing. But there has never been much chance that laboratories could opt out of the Centers for Medicare and Medicaid Services' new quality control framework for much of their nonwaived testing.

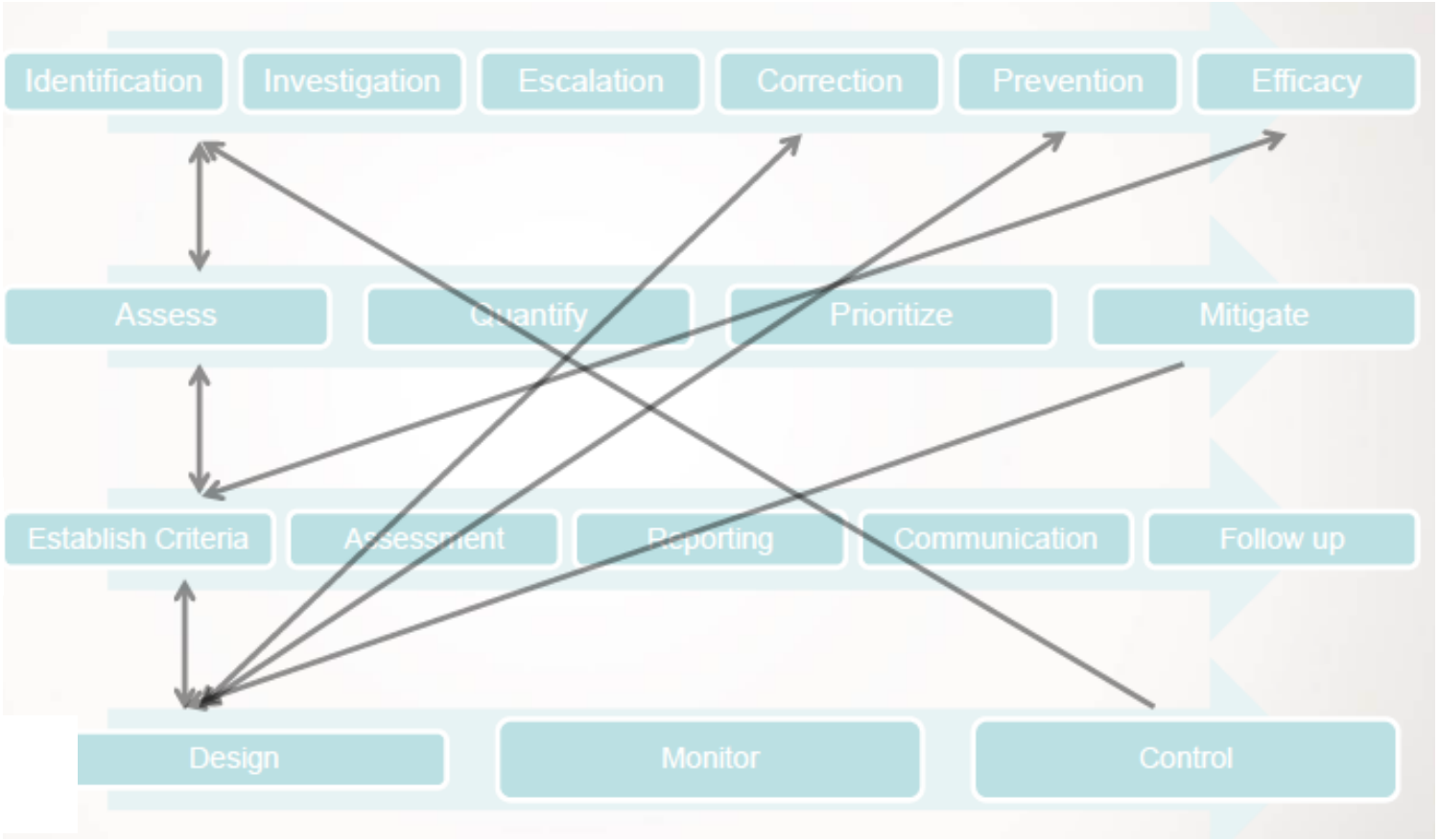
Interconnecting Quality Processes: Closed Loop Quality Management

CAPA PROCESS

RISK MANAGEMENT

AUDIT MANAGEMENT

GOOD LAB PRACTICES



Perspectives for the future: Pros and Cons

- What does Quality Control Plan based on Risk Management mean for laboratories in specific terms? Process maps, fishbone diagrams, in depth - risk analysis, and statistical QC protocols and the cost management?

  It is a big challenge for the labs particularly in the case of developing countries. But identifying risks and controls for all phases of laboratory testing is still a progress and acceptable. IQCP may be way ahead, since the specific guidance, training, workload and extra costs are required.

- The vast majority of errors involving the clinical laboratory occur in the pre- and post-analytical phases of testing, including many steps and processes which are "pre-pre" and "post-post" problems that take place outside the confines of the lab .
  Beyond these steps, the largest challenge for clinical labs are the remaining problems in analytical testing.
  But the need to take on the that with an effective QCP is clear.

Perspectives for the future: Pros and Cons

- Labs have a choice now. They can do a risk assessment evaluation to better determine how their tests are performing and how much QC they should run.

- New regulations of an IQCP may outweigh the cost savings of the small labs with fewer instruments, so they still run daily minimum QC. Labs with many instruments, may find the potential cost savings opportunity is greater than the cost of implementing an IQCP.

- The Quality Risk Management plan defines the control mechanisms for detecting and preventing errors combined with the elements of Closed Loop Quality Management which provides the methodology for periodic quality assessment to ensure QCP effectiveness

THANK YOU

GROUP
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HOSPITALS

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