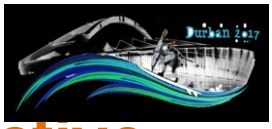


'How-To' Implement an Effective Proactive Risk Management Strategy

Sedef YENICE

Satellite Educational Workshop on Intelligent Clinical Laboratory Management: Impacts on Quality System Improvement
Hilton Durban - October 22, 2017

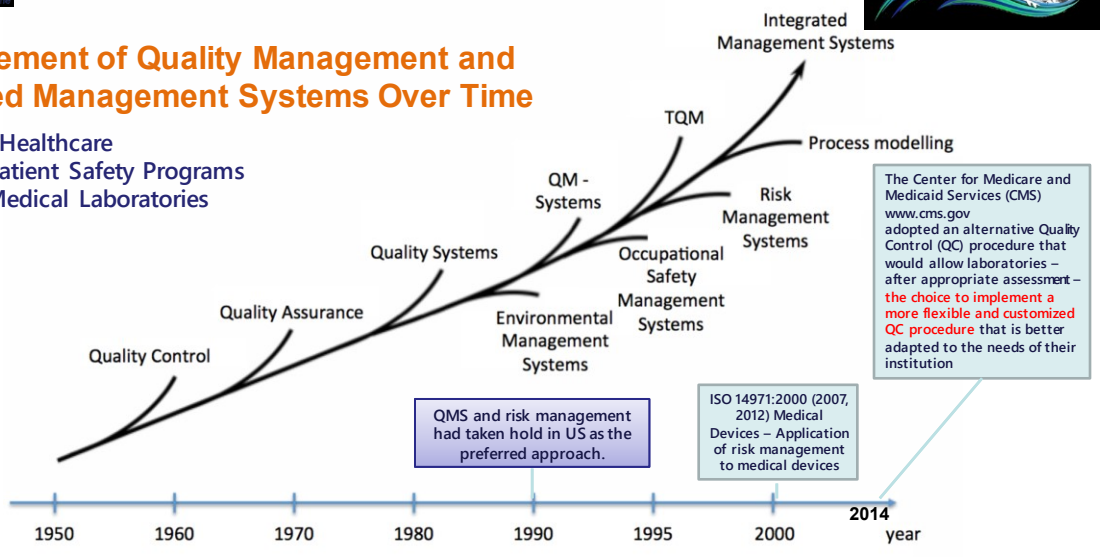
IFCC Committee on Clinical Laboratory Management
http://www.ifcc.org/ifcc-education-division/emd-committees/c-clm/

Presentation Outline

- 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

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



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	GUIDE
IVD	ISO 14971:2007 and 2012 International Organization for Standardization. Medical devices – Application of risk management to medical devices ISO 1 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

4

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 described in an international standard, ISO 14971.

Key Elements

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.

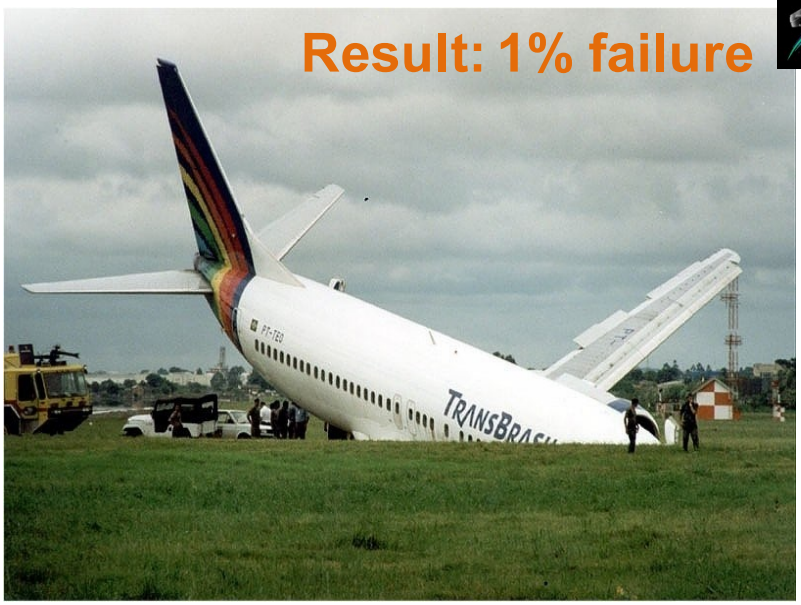
www.iso.org/ISO 14971:2012

What could possibly go wrong?

Achieving a 99% level of quality mea 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



What are the Sources of Laboratory

?

Total Testing Process

Phases of the TTP	Definition	Examples of Activities in Phase	Estimat contrib to TTP
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%

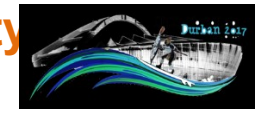
HIGHEST

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

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

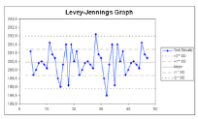
Milestones – Evolvement of Quality Control Over Time



1920 Walter Shewart first uses statistical process control and control charts

1930

1950 Levey & Jennings propose use of Shewart charts in the clinical laboratory – using duplicate QC measurements and 3 S limit

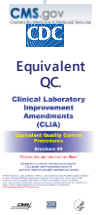


1960 Use of 2S limits proposed -RJ Henry

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

THE RIGHT QC

2015 IQCP published

QC → EQC → EP23 → IQCP

Adapted from Person N. Siemens Healthcare Diagnostics Inc. 2013

NEWS BRIEF

HEALTH R&D FUNDING STALLED

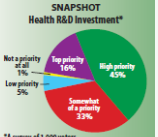
A report recently released by Research!America found that U.S. investments in health research and development (R&D) have remained relatively flat, especially considering the rising cost of conducting such research. This lag is negatively impacting economic growth for the country, as well as high-paying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

Clinical Laboratory News

THE AUTHORITATIVE SOURCE FOR THE CLINICAL LABORATORIAN

AACC

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

A New Approach To Quality Control

How Can Risk Management Help Labs?

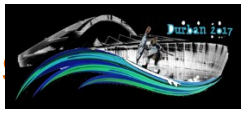
BY BILL MALONE

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 Proces



- 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

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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

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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 and introduced Laboratory Quality Control Based o 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.

What are those 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

One – size – fits - all QC vs Right QC

The concept was introduced in November 4, 2011.

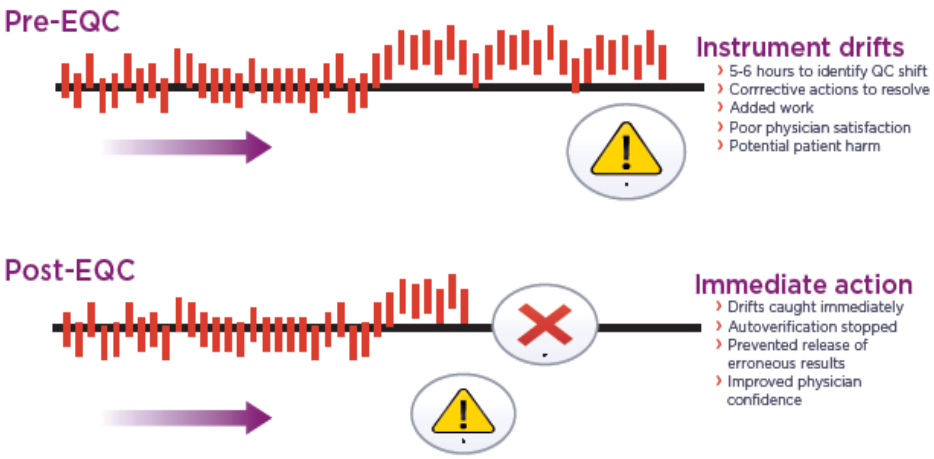
- **Every QC tool has its strengths and weaknesses (there is no perfect QC tool).**
- **QC frequency closely connected to managing risk of reporting inaccurate results**
- **Implement a combination of tools in order to properly control a test.**

- 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.

What should a QC strategy using QC samples include?

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

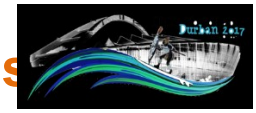
CLSI EP-23, Section 5.1.1



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

- **Marcus Aurelius**
Roma Emperor and Philosopher

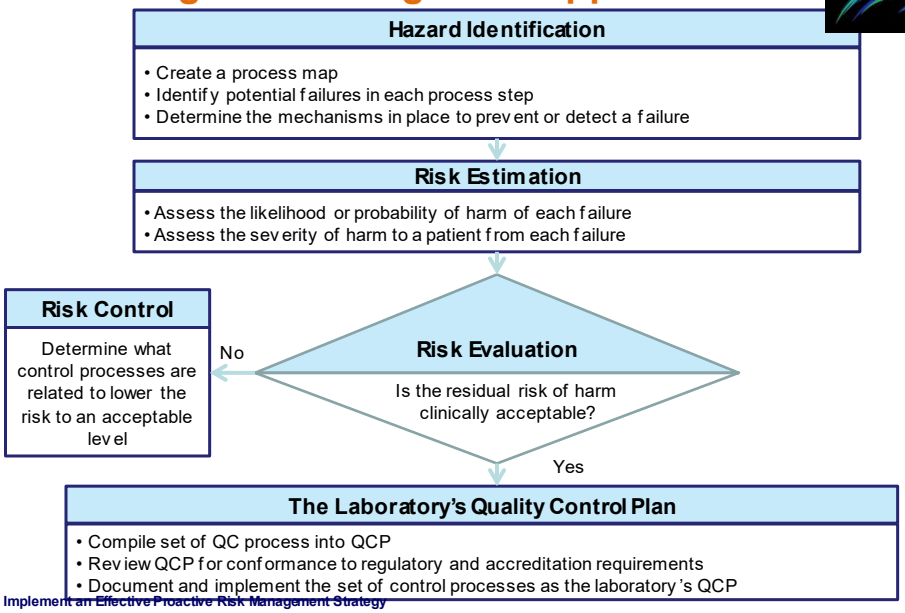
Why Quality Risk Management is important for laboratories?

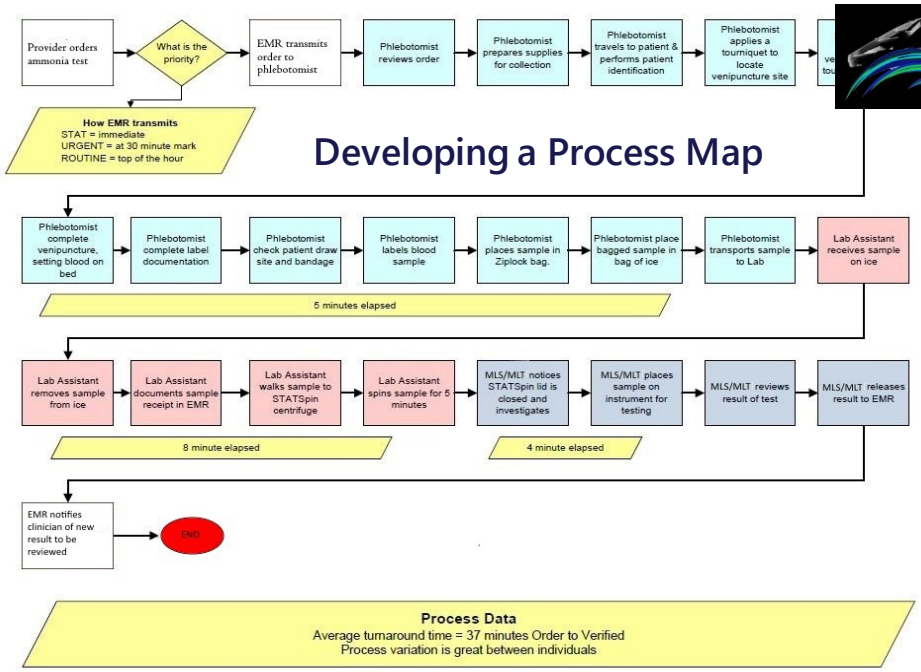


- Risk management may be best **proactive approach** to design an optimal overall QC Plan for the laboratory.
- We analyze many samples from which we derive information.
- The information impacts upon decision making and health of others.
- Poor information can lead to poor outcomes.
- Our samples have 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

How is a Quality Control Plan Developed Using Risk Management Approach?

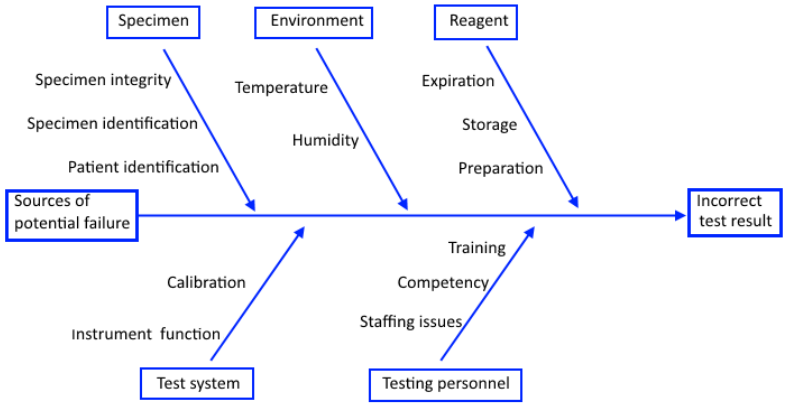




Where is the Risk in the Process?

Hazard Identification

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.

Risk Estimation

Risk Management Tools

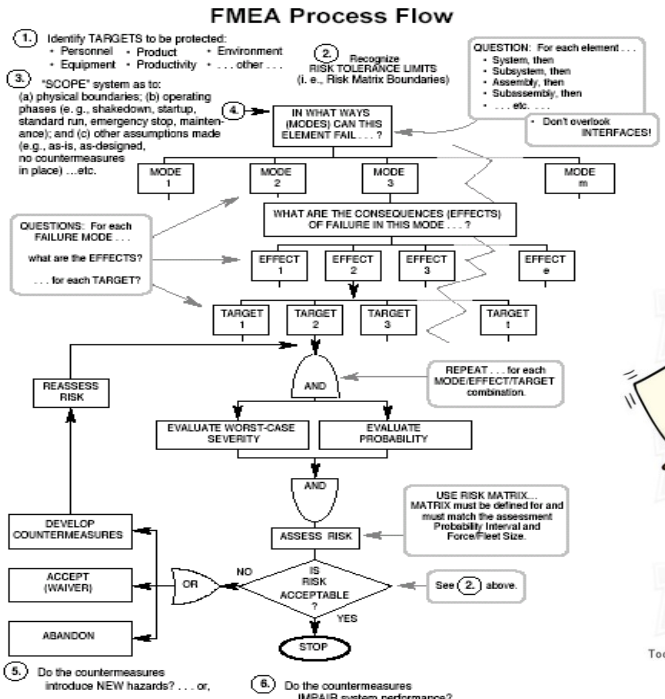
Examples of common risk management tools

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

Risk management tool	Description, attributes	Potential appli
Tools		
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 manu processes, su facilities and • 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



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

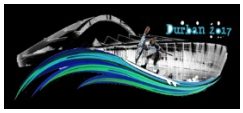
SCORE	SEVERITY OF HARM (SEV)	PROBABILITY OF OCCURRENCE (OCC)		DETECTABILTY PRIOR TO HARM (DET)
10	Catastrophic – Patient Death	Frequent	≥ 1/1,000	Almost impossible to detect
8	Critical – Permanent impairment or life-threatening injury	Probable	< 1/1,000 and ≥ 1/10,000	Low probability of detection
6	Serious – 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)

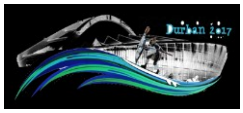


Common Terms	Score	Possible Description (ISO 14971)
Catastrophic	5	Results in patient death
Critical	4	Results in permanent injury of life-threatening injury
Serious	3	Results in injury or impairment requiring professional medical intervention
Minor	2	Results in temporary injury or impairment not requiring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

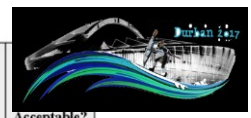
SEVERITY ≥ 6 (or ≥3)	Require an Essential Control Point
OCCURRENCE ≥ 6 (or ≥3)	Require an Essential Control Point which must be an effective method of detection
DETECTABILITY ≥ 6 (or ≥3)	Require an Essential Control which must be a process control that prevents failures
OCCURRENCE ≥ 6 and DETECTABILITY ≥ 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

An FMEA worksheet is created to record each process failure (hazard), failure 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



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	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

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.

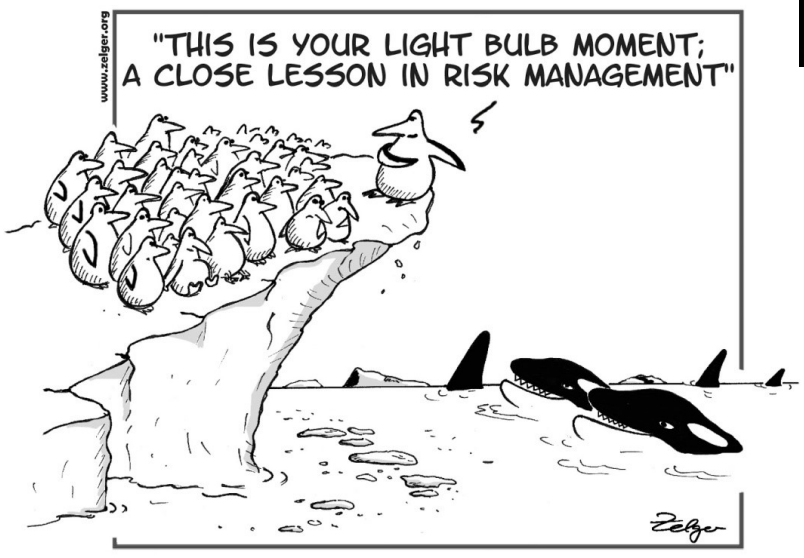
CLINICAL CHEMISTRY 2010; Vol. 56, No. 6, Supplement: A30.

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

Audience Response

Does your laboratory currently have a proactive quality risk assessment plan?

1. Yes
2. No



Advanced training in the Antarctic territories

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

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Clinical Laboratory Improvement Amendments (CLIA)

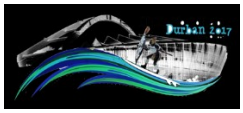
- How to Apply for a CLIA Certificate, Including International Laboratories
- State Agency & Regional Office CLIA Contacts
- Accreditation Organizations/Exempt States
- Categorization of Tests
- Certificate of Waiver Laboratory Project
- Certification Boards for Laboratory Directors of High Complexity 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.

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

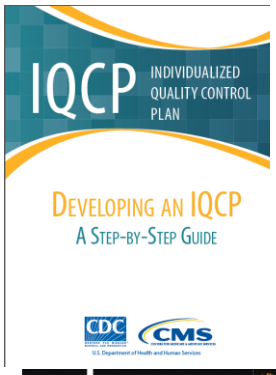
- Syphilis serology
- General Immunology
- Routine Chemistry
- Urinalysis
- Endocrinology
- Toxicology
- Hematology
- Immunochemistry
- Clinical cytogenetics

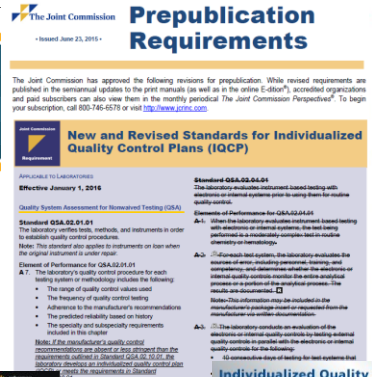
Radiobioassay
Histocompatibility
Microbiology
- Bacteriology
- Mycobacteriology
- Mycology
- Parasitology
- Virology

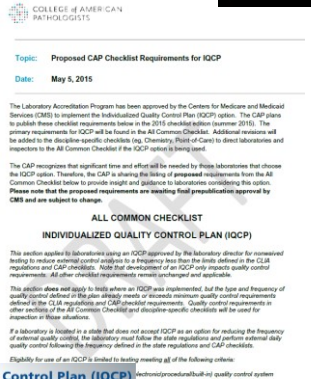
Not Eligible for IQCP

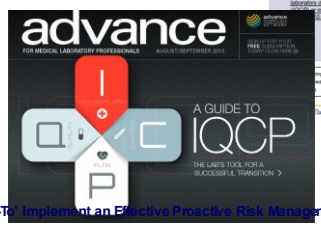
- Pathology
- Histopathology
- Oral Pathology
- Cytology

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









CAP TODAY

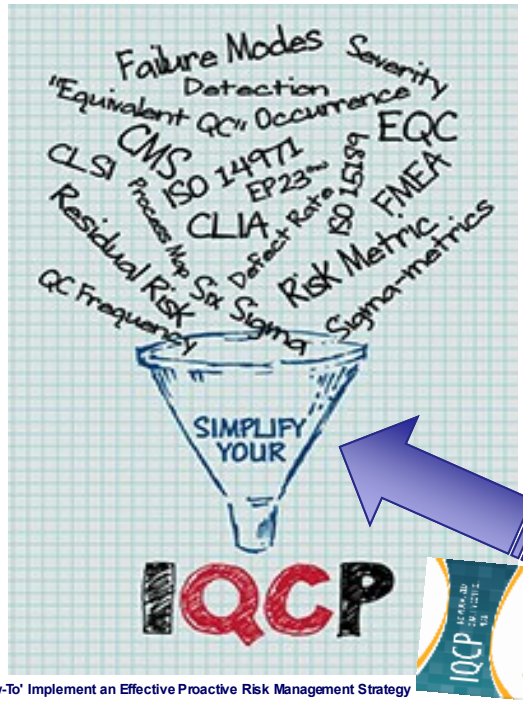
The one publication most important to your job!

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.



James O. Westgard, PhD.

IQCPANIC?

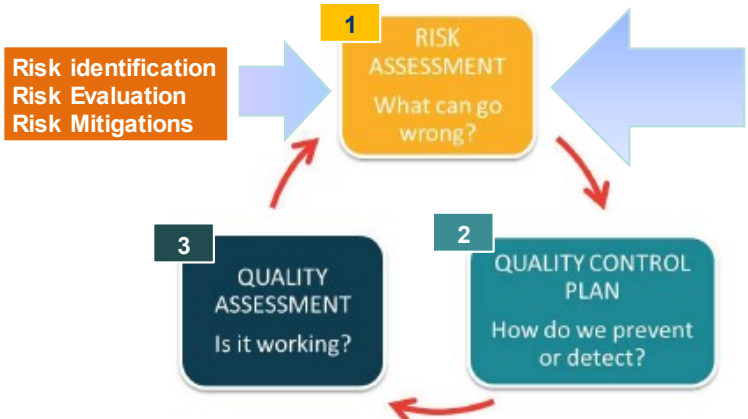
http://www.westgard.com

Developing an IQCP

IQCP = RA + QCP + QA

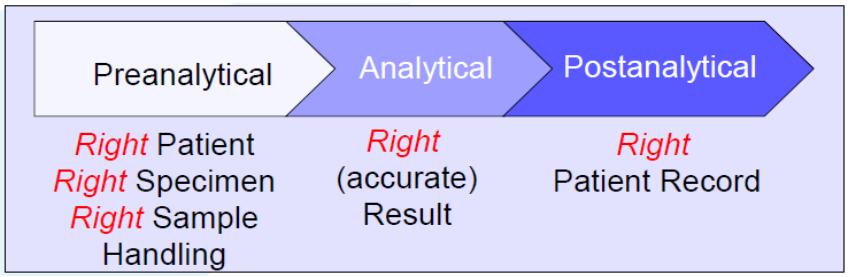
Thus, the laboratory will need to consider the corresponding risks in each of these phases and applicable regulatory requirements and include three parts.

IQCP considers the entire testing process: pre-analytic, analytic, and post-analytic



IQCP Development Process

- Gather Information – IQCP is based on facts
- Medical, regulatory, testing device and situation
- Risk Assessment – know processes; identify potential risks



Must assess – samples, operators, test environment, testing systems, reagents

Review policies; remove/handle all significant risks

1

IQCP ACT: Data Gathering

Rapid TAT

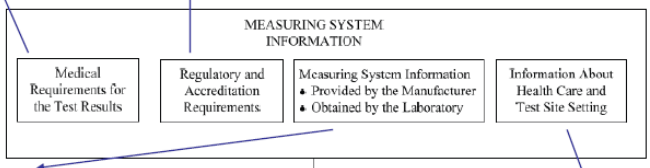
Reasonable accuracy & precision

ACT is typically imprecise

O2 saturation imprecision tolerable

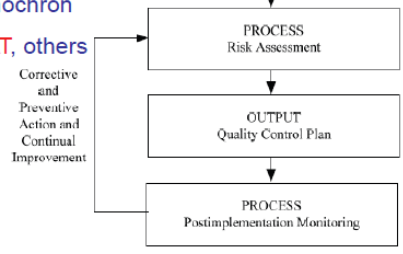
ACT (coag) - 2 levels QC each day of testing

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



ACT: iSTAT, Hemochron

Blood Gas: iSTAT, others

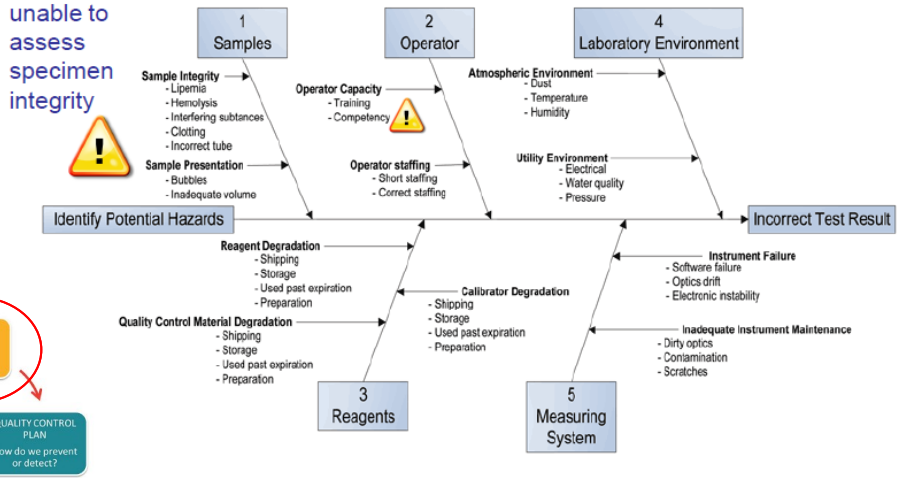


Cardiac Cath lab with testing performed by RN (non-CLS)

1

IQCP ACT: Risk Assessment

Whole blood – unable to assess specimen integrity



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IQCP ACT: Risk Assessment

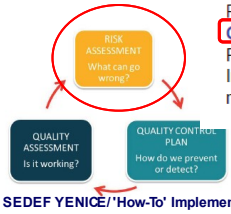
Severity of harm

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



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

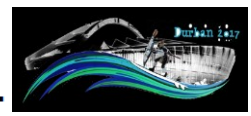
Recent advances in technology have significantly enhanced the accuracy and reliability of certain measuring systems. In recognition of these advances, regulatory and accreditation bodies may provide opportunities for laboratories to establish QCP based on risk assessments. Appropriate site-specific QCP 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

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.	☑ ☑ ☑ ☑



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)	☐

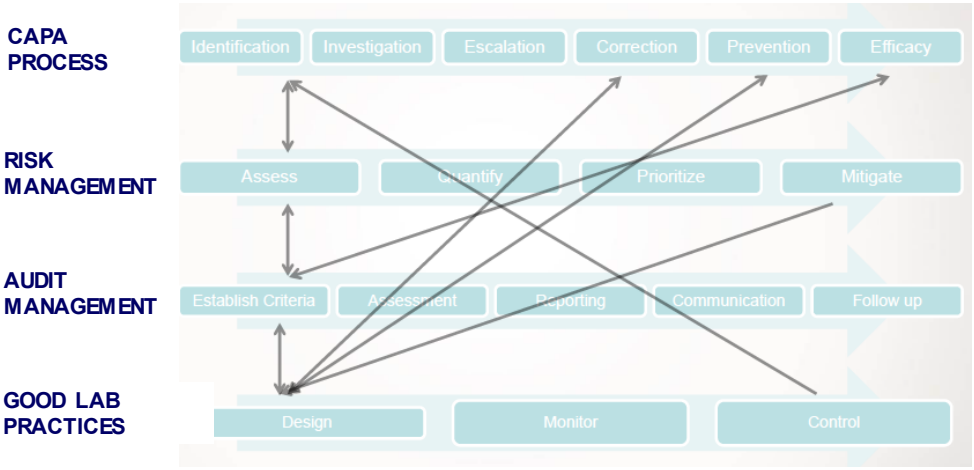
3

Quality Assessment

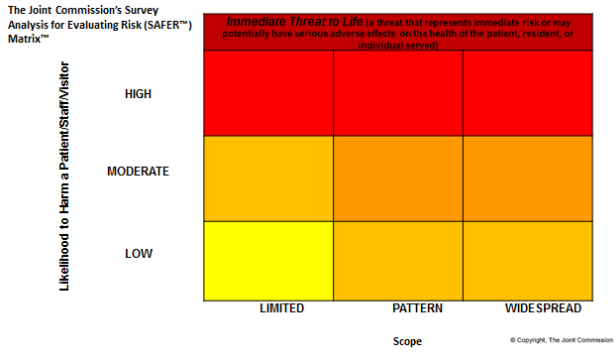
Describes the review process for ongoing monitoring of the effectiveness of the IQCP

- QC review/data
- Proficiency testing results
- Patient results review
- Specimen rejection logs
- Turn-around time reports
- Records of preventive measures, corrective actions and follow-up
- Personnel competency records
- Complaints
- Inspection observations
- Investigation of any process failure and follow up activity (modifications as necessary)

Interconnecting Quality Processes Closed Loop Quality Management



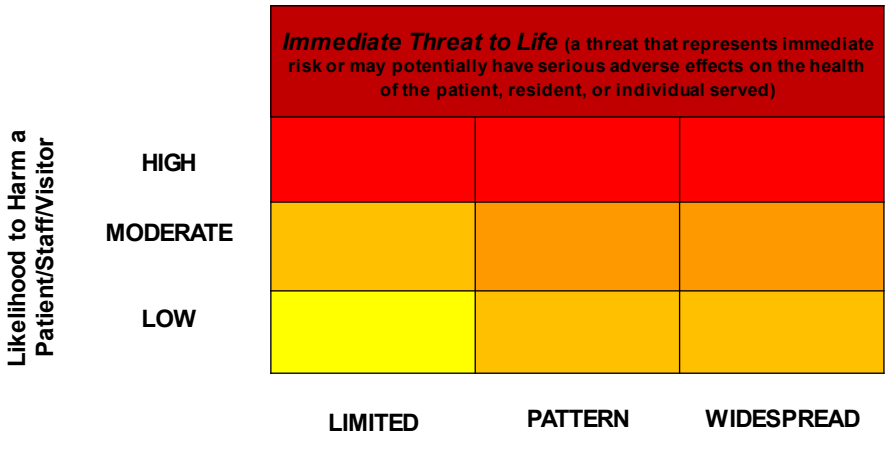
New strategy on the block!



https://www.jointcommission.org/topics/safer_matrix_resources.aspx

The Joint Commission's Survey Analysis for Evaluating Risk (SAFER™) Matrix™

- JC's new (as of 2017) scoring methodology
- Better identifies and communicates risk levels associated with cited deficiencies
- Help organizations prioritize and focus on corrective actions



https://www.jointcommission.org/topics/safer_matrix_resources.aspx

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.

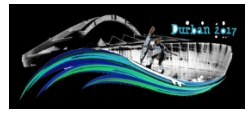
- The vast majority of errors involving the clinical laboratory occur in the pre- and post-analytical phases of testing, including many steps and processes which are "pre-pre" and "post-post" problems that take place outside the confines of the lab .
  Beyond these steps, the largest challenge for clinical 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.

SEDEF YENICE/ 'How-To' Implement an Effective Proactive Risk Management Strategy



THANK YOU

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sedefyenice@gmail.com