Disclaimers

- I work for Alere and Alere produces testing devices for use at the POC…so I have more data on the testing areas my company covers.
- The handouts….
- I think POCT is pretty cool
- Has anyone attended my webinars on this subject?

Quality Control and Training

- Validation of the testing
- What level of training is needed and who needs to be trained
- Whose CLIA license?
  - Central laboratory's certificate
    - Synergistic arrangement – work closely with central lab's team to implement testing and meet regulations
      - Lab professionals know quality testing and testing regulations
      - POC personnel better serve patients
      - POCT results integrated with central lab results
  - Separate POC certificate for test site
    - POC must assure that all requirements are met
- Daily/weekly/monthly maintenance
- Proficiency testing
- Inventory management

Ultimate goal is to improve patient care and do the right thing for the patient

The Regulations

- Who accredits your lab?
  - CMS?
  - CAP?
  - Joint Commission?
  - COLA?
- What do they require?

State regulations can supercede all!!!

Four key CMS regulations for moderately complex tests

493.1253	• Test method verification accuracy, precision, reportable range and reference ranges
493.1254	• Maintenance and function checks
493.1255	• Calibration and calibration verification
493.1256	• QC procedures

CLIA

CMS 2004 brochure on how to complete the initial "performance verification." p.2

493.1256 – QC procedures

For each test system, the laboratory must test, at a minimum, two levels of external QC materials each day it performs a nonwaived test.

However, the regulations now allow the laboratory to reduce the frequency of testing external QC materials (equivalent QC procedure) for certain test systems.

CLIA

CMS: Equivalent Quality Control Procedures Brochure #4

So what is QC?

Where did it come from?

How does QC assure quality data?

Quality Control (QC)-*noun, verb*

Part of quality management focused on fulfilling quality requirements (ISO 9000)

The operational techniques and activities that are used to fulfill requirements for quality;

In healthcare testing, the set of procedures designed to monitor the test method and the results to ensure test system performance;

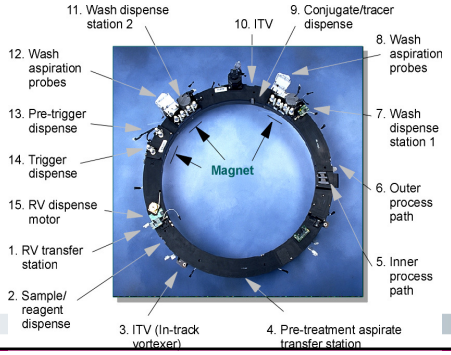
QC includes testing control materials, charting the results and analyzing them to identify sources of error, and evaluating and documenting any remedial action taken as a result of this analysis (AST4);

QC includes testing of normal and abnormal control materials, recording the results, identifying sources of error, and evaluating and documenting any corrective action taken.

Paraphrased from the CLSI definition

ARCHITECT® i2000 Immunoassay Analyzer

ARCHITECT® Immunoassay Process Path



The Achilles Heel of Daily QC

QC passes at 0800 QC fails at 0800

- What went wrong?
- When did it go wrong?
- What if more than one thing went wrong?

- **What do I do with all that data I collected in between?**

What about QC for these guys?

Alere Triage® Assay Procedure What the User Sees

Step 1

Add whole blood to device

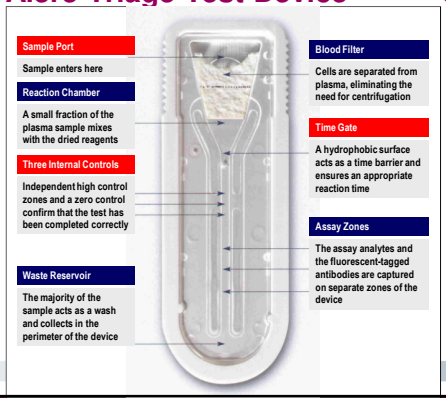
Step 2

Insert device into Meter

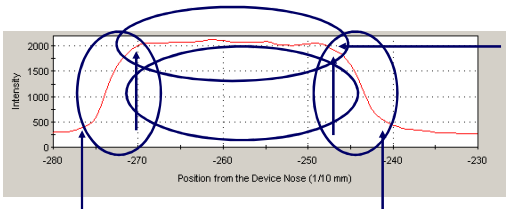
Step 3

Read Results

Alere Triage Test Device



Trace QC on a typical "spot"



Triage Device Controls

Up to two immunoreactive positive controls

One negative or non-specific binding control

- Helps in detection of interfering substances

These controls mimic the captures zones of analytes and verify:

- Sufficient sample added to the device
- The device performed the immunoassay correctly
- Lack of gross interferences
- Proper device manufacture
- Proper insertion of device into meter

Alere Triage QC Device

QC Device is run every day.

Mated to a meter

Cartridge identical to patient test cartridge

True optical system check, not electronically simulated

Six fluorescent zones of varying intensity

Fluorescent reads are compared to the performance at instrument manufacture

Checks Instrument Calibration, Laser/Cartridge Alignment, Laser Functionality

QC Lockouts

User ID - Only valid users can operate the system

Lot Expiration Date - Expired reagents cannot be run

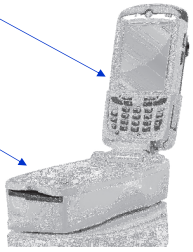
External Controls - Controls must be run on new reagent lots and according to the frequency set by the Lab supervisor

QC Device Not Run - The QC Device must run according to the frequency set by the Lab Supervisor

QC Device Failure - All QC Device tests must meet specifications

epoc System Components

- epoc Host Mobile Computer
- epoc Reader
- epoc Test Card



- epoc Data Manager (not shown)

epoc Test Process Steps

Collect reader, supplies (RT STORAGE!), syringe, etc and go to patient room

Scan operator ID and enter password

Insert test card into reader to start calibration (165 sec)

Data entry (scan patient ID, enter patient temp, vent data, etc.)

Collect blood sample (fresh whole blood from arterial, venous or capillary sources)

Introduce sample into card (within 5 min of calibration)

Transmit result to EDM and LIS via WiFi (1-2 seconds)

View result (after 30-second test time)

epoc QC Checks

Every time the Host and Reader connect, the Reader undergoes an automatic, 2 level, electronic QC test.

This will repeat every 8 hours if needed.

The Reader monitors the testing environment:

- The operating conditions are 15°-30° C, 400-825 mm Hg atmospheric pressure and <85% humidity.
- The Reader has internal thermometers and barometers and will shut down if these ranges are exceeded.
- The internal QC checks will fail if humidity is >85

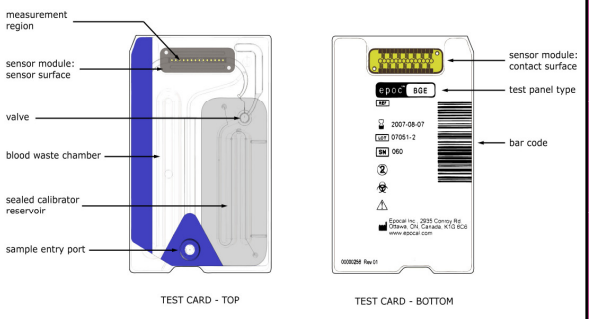
Other epoc QC Checks

An audible beep is produced when adequate sample is applied to the card.

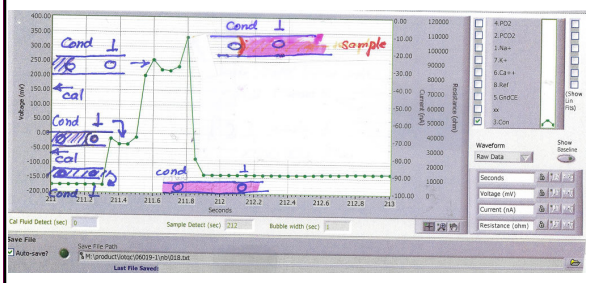
The system will flag the following conditions and not deliver a test result when:

- Using an expired card
- Rerunning an already used test card
- Putting in too little sample
- Introducing the sample too rapidly, too slowly or sample with an air bubble.
- Introducing the sample at the wrong time

Epocal's FlexCard™



Conductometric sensor as a fluidic control



epocal

27

493.1256 – QC procedures

For each test system, the laboratory must test, at a minimum, two levels of external QC materials each day it performs a nonwaived test.

However, the regulations now allow the laboratory to reduce the frequency of testing external QC materials (equivalent QC procedure) for certain test systems.

CLIA

CMS

CMS: Equivalent Quality Control Procedures Brochure #4

So I Have a Device That Claims EQC Features. What MUST I Do?

- Follow the manufacturer's package insert.
  - **Section 493.1256 – QC procedures is still under and educational directive. It is NOT being enforced.**
  - **NO CITATIONS**
  - **CMS inspectors continue to issue Educational Letters**

CLIA

CMS

So I Have a Device That Claims EQC Features. What Would CMS Like Me to Do?

Follow the manufacturer's package insert.

Evaluate the system's capability to monitor all analytical elements of the testing procedure

- Operator, analysis, environment, sample addition, sample/reagent interactions, test completion time.

Evaluate the system's Equivalent QC by one of three processes

CMS: Equivalent Quality Control Procedures Brochure #4

EQC Evaluation

	Evaluation Process		External QC checks
Option 1 System monitors all analytic components	Daily testing with internal monitoring systems	10 consecutive days of passing external QC	At least once per month
Option 2 System monitors some analytic components	Daily testing with internal monitoring systems	30 consecutive days of passing external QC	At least once per week
Option 3 System monitors no analytic components	NA	60 consecutive days of passing external QC	At least once per week

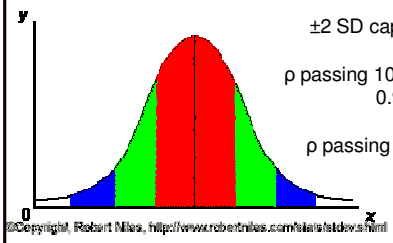
CMS: Equivalent Quality Control Procedures Brochure #4

EQC Evaluation

	Evaluation Process		External QC checks
Option 1 System monitors all analytic components	Daily testing with internal monitoring systems	10 consecutive days of passing external QC	At least once per month
Option 2 System monitors some analytic components	Daily testing with internal monitoring systems	30 consecutive days of passing external QC	At least once per week

There is NO evidence that 10 or 30 consecutive days of passing QC provides assurance that subsequent monthly testing is sufficient!

Normal Population Distributions



±2 SD captures 95% of data (0.95).
ρ passing 10 reps = 0.95^{10}=0.598.
0.95^{30}=0.215

ρ passing 10/11 reps = 0.897

± 1 SD captures 68% of data
±2 SD captures 95% of data
±3 SD captures 99.7% of data

EQC Evaluation

	Evaluation Process		External QC checks

How does 60 consecutive days of passing QC provide assurance that subsequent monthly testing is sufficient for a test that monitors NO analytic components?

Option 3 System monitors no analytic components	NA	60 consecutive days of passing external QC	At least once per week

CMS: Equivalent Quality Control Procedures Brochure #4

So I Have a Device That Claims EQC: What Do I Have to Do?

Follow the manufacturer's package insert.

Section 493.1256– QC procedures is NOT being enforced.

NO CITATIONS

CMS

Inspectors will continue to issue Educational Letters. Joint Commission too (?!?)

CAP

POC.07300 "Initial validation studies must include comparison of external and built-in controls for at least 20 samples."

COLA

Don't quite know…We (Alere) are working with COLA at high levels to translate clinically and scientifically supported QC into accreditation expectations.

What is the future for QC of POCT?

A Risk Management approach to Quality Control

No more one-size-fits-all formulas

Evaluate the QC features of the device

Analyze other elements of variability that must be controlled

Assess the severity of failures in each step of the testing process

Devise QC testing to monitor and catch said failures

This represents a shift from "Quality Compliance" to true Quality Control

CLSI to the Rescue!!!

CLINICAL AND LABORATORY STANDARDS INSTITUTE

EP23

User Defined QC Protocols for *In Vitro* Diagnostic Devices Based on Manufacturer's Risk Mitigation Information and the User's Environment

EP18

Risk Management Techniques to Identify and Control Laboratory Error Sources

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

How Does This Align With What CMS Would Like Me to Do?

Follow the manufacturer's package insert.

Evaluate the system's capability to monitor all analytical elements of the testing procedure

- Operator, analysis, environment, sample addition, sample/reagent interactions, test completion time.

(Vendors need to get better at producing this in writing)

Evaluate the system's Equivalent QC by one of three processes

CLIA

CMS

CMS: Equivalent Quality Control Procedures Brochure #4

3/9/12 CMS Official Memorandum

Alere

Key concepts from EP-23 will be an acceptable alternative QC policy. The New CLIA QC policy will be entitled Individualized Quality Control Plan (IQCP)

IQCPs are a formal representation and compilation of many things laboratories currently do for quality.

IQCPs permits the laboratory to customize its QC plan according to environment, reagents, testing personnel, specimens, and test system.

IQCP will be voluntary: Laboratories will have two choices for QC compliance: 1) Two levels of QC per day or, 2) IQCP. Package insert requirements must be met.

Education and transition dates TBD

EQC will be phased out at the end of the education and transition period

CMS: The "Right QC" Is IQCP

Alere

IQCP applies to CMS-certified, nonwaived laboratories

It is optional. Default is regulation - 493.1256(d)(3): 2 levels of liquid control/day

Includes existing and new analytes/test systems and specialties, except cytology/histopathology

Formalizes laboratories' risk management decisions

Considers known risks mitigated by manufacturer

Permits laboratories to develop an IQCP using their existing quality practices/information

Once effective, IQCP will supersede the current EQC policy.

CMS presentation at CLSI EP23 workshop, May 2012

What Won't Change?

Alere

Existing CLIA QC and quality system concepts.

No regulations will change!

CMS's outcome oriented survey approach.

Laboratories must follow manufacturers' instructions.

Laboratory director has overall responsibility for QCP.

CMS presentation at CLSI EP23 workshop, May 2012

When and What Till Then?

Alere

There will be an education and transition period for laboratories before IQCP is fully effective.

In the interim, CMS-certified laboratories should:

- Continue to follow existing QC protocols.
- Learn about EP23 concepts and IQCP.
- Plan and complete their transitions accordingly
- Phase out EQC (if applicable).
- Decide to implement default QC or IQCP.

CMS presentation at CLSI EP23 workshop, May 2012

CAP? JC? COLA?

CMS will solicit accrediting organizations (AOs) to determine their interest in IQCP.

Accredited laboratories should continue to meet their accrediting organizations' QC standards until they receive notice from their AOs.

CMS presentation at CLSI EP23 workshop, May 2012

Where to Obtain Information

- **CMS/CLIA Website:** http://www.cms.hhs.gov/clia/
- **CMS CLIA Central Office:** 410.786.3531
- **IQCP Link:** IQCP@cms.hhs.gov
- EP23 Workbook

CMS presentation at CLSI EP23 workshop, May 2012

But Instead of This……

	Evaluation Process		External QC checks
Option 1 System monitors all analytic components	Daily testing with internal monitoring systems	10 consecutive days of passing external QC	At least once per month
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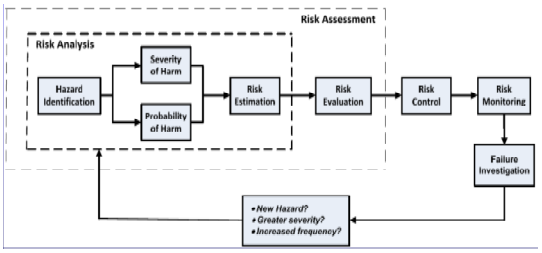
CMS: Equivalent Quality Control Procedures Brochure #4

Do This!!!



Life-Cycle Risk Management Process

EP23 + IQCPs = Don't Do This

	Evaluation Process		External QC checks
Option 1 System monitors all analytic components	Daily testing with internal monitoring systems	10 consecutive days of passing external QC	At least once per month
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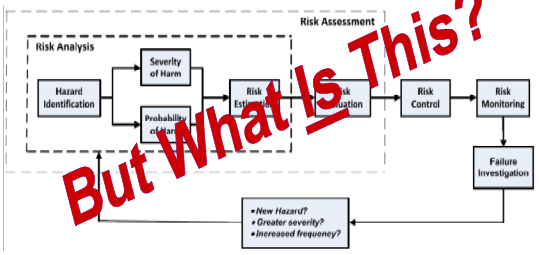
Do This!!!



But What Is This?

Life-Cycle Risk Management Process

Alere

Gruesomely Complex

Ineffective Hand-waving

Alere

Statistical Data

Existing QC procedures

SOPs

Run rules

Package Inserts

QC charts

Training!!!

Risk Management approach to QC

FIRST UNDERSTAND THE DIFFERENCE BETWEEN HAZARD AND RISK

Risk Management approach to QC

Second ask the right questions

What is needed to assure quality safety?

How frequently (time and replicates) should this be tested?

What are the key conditions or potential failures that could pose risk of harm to the patient?

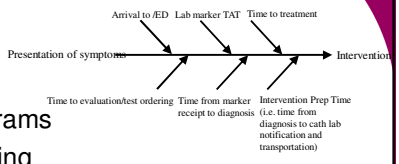
Are safety features sufficient to protect from harm?

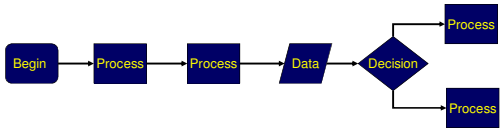
What is controlled/not controlled?

Are validation/verification studies sufficiently robust?

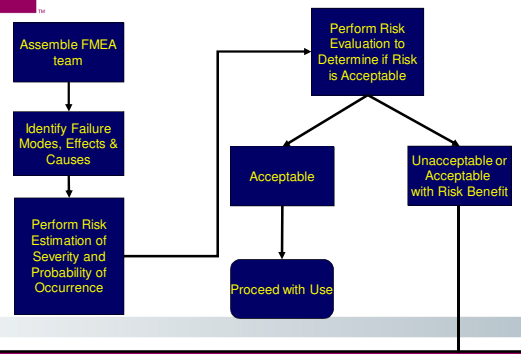
Risk Assessment Tools

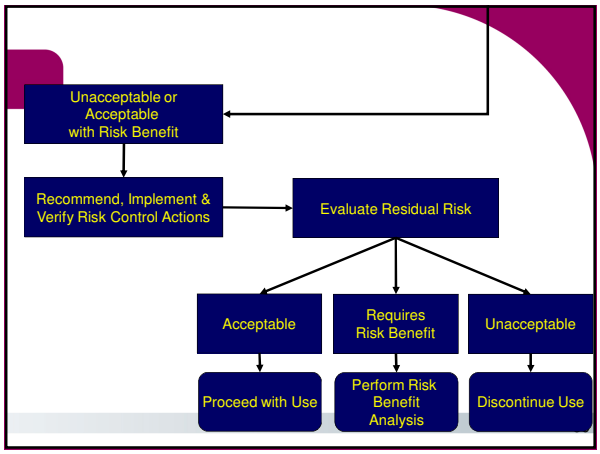
- Brainstorming
- 5 Whys
- Fishbone diagrams
- Process mapping





"Use" FMEA flowchart





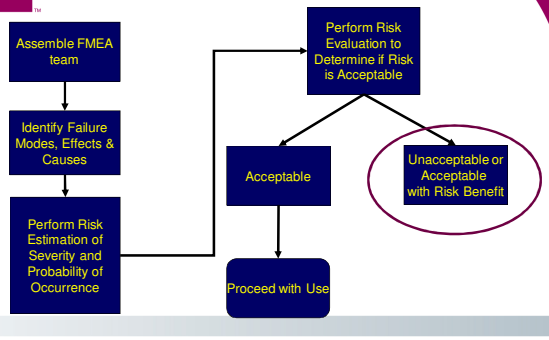
FMEA Basics

Function	Failure Modes	Effects of Failure	Severity	Cause of Failure	Probability			

Let's Learn with an Example

Function	Failure Modes	Effects of Failure	Severity	Cause of Failure	Probability	Design Control		
Parachute	Chute doesn't open	Injury, Abrasions		Failure to unfurl				
	Chute tears	Fall and die		Age				
				Birds, planes				
Rope	Rope breaks			Age				

FMEA flowchart



Risk Benefit

Risk Management approach to QC

Ask the right questions

- What is needed to assure quality of test results? Does the manufacturer recommendation for QC minimize laboratory risk to an acceptable level?
- What are the key conditions or potential failures that could occur in the laboratory that pose risk of harm to the patient?
- What is controlled/not controlled?
- Are validation/verification studies sufficiently robust
- Are EQC features sufficient to protect patient from harm?
- How frequently (time and replicates) should QC be tested?

G. Cooper, BioRad. 2007 AACC QC Webinar

Variables to Consider

Environmental conditions: Temperature, humidity	Intended medical use of test result: HIV vs triglyceride	Clinical setting: Main lab, POC, Outpatient, ER, ICU, Ambulance, Non-traditional setting
Time lapse: Are result acted on immediately or not?	Testing frequency, testing personnel and turnover	Condition of ancillary equipment: Centrifuges, refrigerators, heat baths
Power requirements/ fluctuations	Radio and electromagnetic waves	Age of the device

G. Cooper, BioRad. 2007 AACC QC Webinar

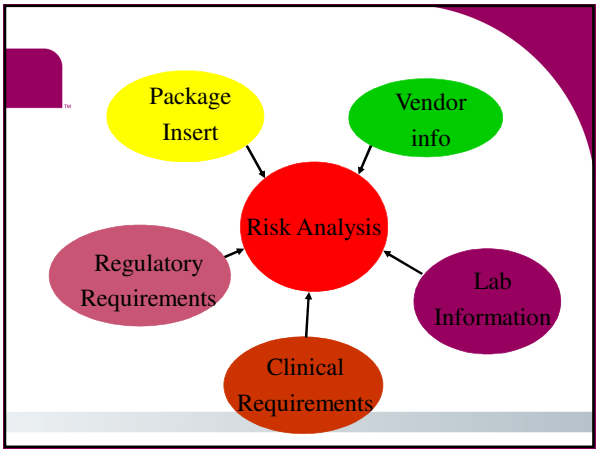
Develop an FMEA

Think in terms of the five elements of a process.

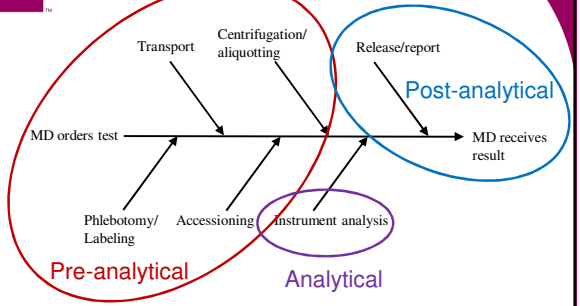
People: Training, Experience, Attitude	Materials (Reagents and consumables): Integrity, Storage, Reconstitution, Preparation (mixing), Use	Equipment (Hardware and Software): Use, Maintenance, Reliability	Methods: Calibration, Capability, Sensitivity, Specificity, Accuracy, Precision	Environment: Temperature, Humidity, Air flow, Power supply, Water quality

BTW: This is committee work!

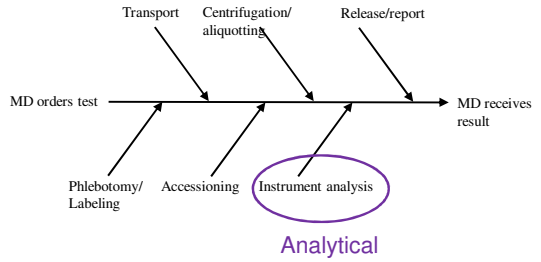
G. Cooper, BioRad. 2007 AACC QC Webinar



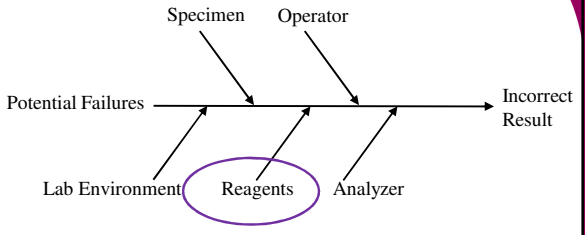
Testing Process Fishbone Diagram



Testing Process Fishbone Diagram



Instrument Error Fishbone Diagram



FMEA Basics

Function	Failure Modes	Effects of Failure	Severity	Cause of Failure	Probability			

FMEA Step #1

- Function
  - Proper function of reagents
- Failure modes
  - Incorrect storage
  - Expired reagents
  - Mechanical failure
  - Reagent drift

Function	Failure Modes	Effects of Failure	Severity	Cause of Failure	Probability			
Reagent function	Incorrect storage							
	Expired reagents							
	Mech. failure							
	Reagent drift							

FMEA Step #2

- Function
  - Proper function of reagents
- Failure modes
  - Incorrect storage
  - Expired reagents
  - Mechanical failure
  - Reagent drift
- Assess the effects and severity of each failure
  - Falsely elevated results Elevations > x% = ???
  - Falsely depressed results Depressions < y% = ????
  - No results = delayed results
- Determine the cause of each failure (expect overlap) and the probability of that occurrence

Function	Failure Modes	Effects of Failure	Severity	Cause of Failure	Probability			
Reagent function	Incorrect storage	FP, FN						
	Expired reagents	FP, FN						
	Mech. failure	No results						
	Reagent drift	FP, FN						

Ranking Severity of Failure and Probability of Harm

Severity

- **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

Probability

- **Frequent** — Once per week
- **Probable** — Once per month
- **Occasional** — Once per year
- **Remote** — Once every few years
- **Improbable** — Once in the life of the test system

ISO 14971

Risk Acceptability Matrix

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

ISO 14971

Process Severity Evaluation Criteria

Effect	Severity of effect	Ranking
Hazardous, without warning	May endanger patient. Involves non-compliance with gov't. regulation without warning.	10
Hazardous, with warning	Same as above only with warning	9
Very High	Major injury to patient requiring emergency intervention	8
High	Minor injury to patient; patient dissatisfied	7
Moderate	Results acceptable; not cosmetically satisfactory	6
Low	100% of results may have to be retested; some patient dissatisfaction	5
Very Low	Timing/efficiency defects noticed by most users	4
Minor	Same as above, but, defect noticed by average user	3
Very Minor	Same as above, but, defect noticed only by the discriminating user	2
None	No effect	1

Adapted from Quality Support Group, Inc

Process Occurrence Evaluation Criteria

Probability of Failure	Possible Failure Rates	C_{pk}	Rankings
Very high, failure is almost inevitable	≥ 1 in 2	< 0.33	10
	1 in 3	≥ 0.33	9
High, repeated failures	1 in 8	≥ 0.51	8
	1 in 20	≥ 0.67	7
Moderate, occasional failures	1 in 80	≥ 0.83	6
	1 in 400	≥ 1.00	5
	1 in 2000	≥ 1.17	4
Low, relatively few failures	1 in 15,000	≥ 1.33	3
	1 in 150,000	≥ 1.50	2
Remote, unlikely	≤ 1 in 1,500,000	≥ 1.67	1

Adapted from Quality Support Group, Inc

Process Detection Evaluation Criteria

Qualitative probability	Quantitative probability of not detecting	Ranking
Remote likelihood that erroneous results would be undetected		
• detection reliability at least 99.99%	1/10,000	1
• detection reliability at least 99.80%	1/5,000	2
Low likelihood that erroneous results would be undetected		
• detection reliability at least 99.5%	1/2,000	3
• detection reliability at least 99%	1/1,000	4
Moderate likelihood of detection		
• detection reliability at least 98%	1/500	5
• detection reliability at least 95%	1/200	6
• detection reliability at least 90%	1/100	7
High likelihood that that erroneous results would be undetected		
• detection reliability at least 85%	1/50	8
• detection reliability at least 80%	1/20	9
Extreme likelihood that erroneous results would be undetected	1/10 +	10

Adapted from Quality Support Group, Inc

Function	Failure Modes	Effects of Failure	Severity	Cause of Failure	Probability	Design and/or Process controls	Detection	RPN
Reagent function	Incorrect storage	FP, FN		Storage temp fail		Temp monitors		
				Left on bench		Training, Sweeps		
	Expired reagents	FP, FN		Exp. date passed		Training, Barcode		

Function	Failure Modes	Effects of Failure	Severity	Cause of Failure	Probability	Design and/or Process controls	Detection	RPN
Reagent function	Mech. failure	No results		Shipping damage		Inspect by loading dock, Run QC		
				Storage damage		Store on top shelf, Training		
	Reagent drift	Expired reagent		Use of exp. rgt		Barcodes		
		Expired calibrat'n		Use of exp. cal		Onboard dating		

A Triage Example

Each Triage device has a barcode that contains critical information, including expiration date.

Devices are stored at 2-8 degrees C and must be brought to RT for use.

Once at room temperature, the devices are stable for 14 days

Function	Failure Modes	Effects of Failure	Severity	Cause of Failure	Probability	Design and/or Process controls	Detection	RPN
Reagent function	Incorrect storage	FP, FN		Storage temp fail		Temp monitors		
				Left on bench		Training, Sweeps		
	Expired reagents	FP, FN		Exp. date passed		Training, Barcode		

Function	Failure Modes	Effects of Failure	Severity	Cause of Failure	Probability	Design and/or Process controls	Detection	RPN
Reagent function	Incorrect storage	FP, FN		Storage temp fail		Temp monitors		
				Device at RT >14 days		Write RT exp on devices, Sweeps		
	Expired reagents	FP, FN		Exp. date passed		Barcode		

Now….What Needs Fixing?

- Identify those conditions that lead to unacceptable levels of error severity and frequency.
- Determine operating processes or tests (quality control) to detect those conditions

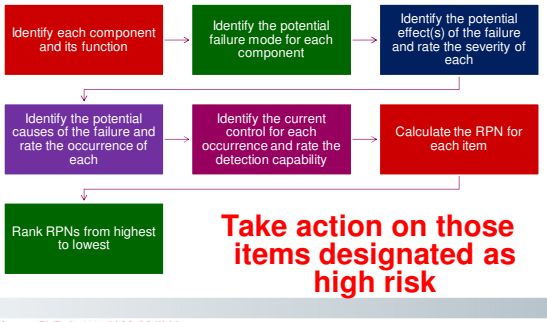
1st • Eliminate causes of failure so that it does not OCCUR

2nd • Reduce probability of OCCURRENCE

3rd • Reduce SEVERITY of the failure

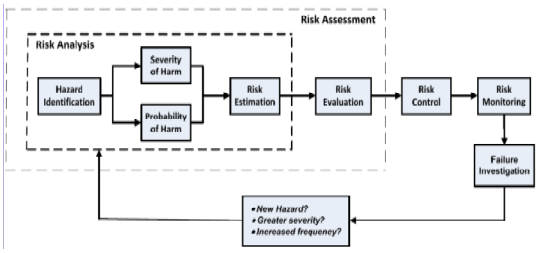
4th • Improve DETECTION of the failure

As a Result You Will



Take action on those items designated as high risk

Do This!!!



Life-Cycle Risk Management Process

Other Resources

- ISO (www.iso.org)
  - ISO 9000:2005 Quality Management systems-Fundamentals and vocabulary
  - ISO 14971:2007 Medical Devices-Application of risk management to medical devices
- But how are you supposed to understand all the instrument features that could mitigate risk?

You're Gonna Need Help

Device manufacturers need to provide LOTS more information about their QC features

- Detailed descriptions of device risk mitigation features
- Identify the targeted failure mode for each mitigation
- Descriptions of how the risk mitigation feature or recommended action performs its intended function
- Known limitations of the risk mitigation feature or recommended action
- Studies performed to verify the feature or recommended action achieves the intended purpose

EP22-Presentation of Manufacturer's Risk Mitigation Information for Users of *in vitro* Diagnostic Devices

- Guidance to Vendors
- ~~Document design features that detect and/or control test system variability and/or failures.~~
- ~~Describe failure modes, risk reduction features and data to support the effectiveness of those features.~~

☹

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EP22 Items Vendors Would Have Addressed

Reagent deterioration • During shipment • Over time	Expired reagents	QC sample degredation	Calibrator degredation	Sample data entry error
Operator certifications	Low/High sample volume	Clots/particulates/bubbles	Sample carryover	Wear & tear on replaceable parts
	Environmental limitations	Sample limitations	QC maintenance	

Suggested EP22 Entries

- Targeted failure mode
- Test system feature or recommended action
- Description how the feature or recommended action is intended to function
- Known limitations of feature or recommended action
- Actions required to address known limitations
- Studies performed to demonstrate the ability of the feature/recommendation to achieve intended purpose
- Summary of study

Alere Triage QC Device

QC Device is run every day.

Mated to a meter

Cartridge identical to patient test cartridge

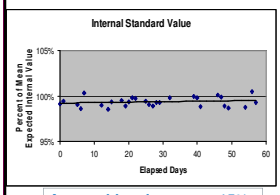
True optical system check, not electronically simulated

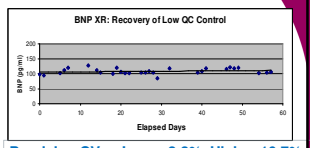
Six fluorescent zones of varying intensity

Fluorescent reads are compared to the performance at instrument manufacture

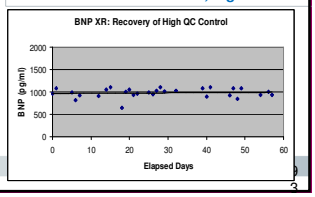
Checks Instrument Calibration, Laser/Cartridge Alignment, Laser Functionality

How do the QC Device and Liquid QC Compare? A 57-Day Study



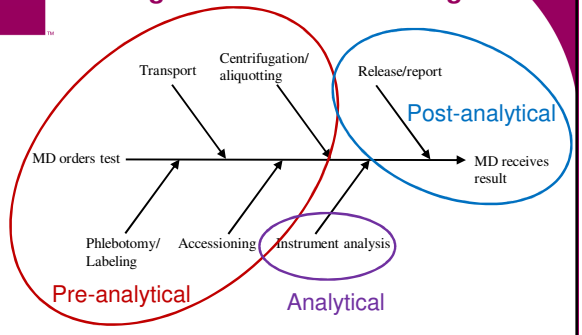


Precision CVs: Low = 8.8%, High = 10.7%



Acceptable tolerance: ±15%

Testing Process Fishbone Diagram

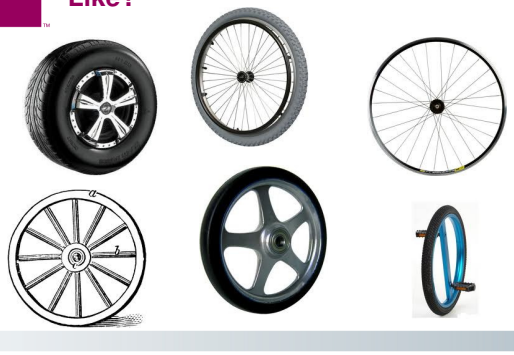


EP23 Workbook Key Process Steps

1. Operator training and competency
2. Reagent/calibrator/parts procurement and storage
3. Patient sample acceptability evaluation
4. System startup
5. System calibration
6. Loading and testing of patient samples
7. Proper device function
8. Test result review

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

But What Will IQCPs Really Look Like?



This is the future for QC of POCT

A Risk Management approach to Quality Control

- No more one-size-fits-all formulas
- Evaluate the QC features of the device
- Analyze other elements of variability that must be controlled
- Assess the severity of failures in each step of the testing process
- Devise QC testing to monitor and catch said failures

This represents a shift from "Quality Compliance" to true Quality Control

Questions?

Thank You!

Today is the youngest you'll be for the rest of your life. Act like it.