IQCP: Performing a Risk Assessment

Greg Cooper, CLS, MHA, CQA

Objectives

- Identify the mandatory components of an IQCP
- Discuss tools and resources to identify risks
- Evaluate hazards to determine their risk level
- Identify mitigating activities to reduce risk

Getting Started

IQCP began from the question of QC frequency

- Doing the right QC
  An honest thorough IQCP could reveal the need to increase QC frequency[1]

- Interest for most laboratories driven by:
  - Need to replace EQC by Jan 1, 2016
  - Manufacturer recommendation for QC frequency less than CLIA minimum[1]
  - Manufacturer makes no QC recommendation[1]

[1]http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIAbrochure12.pdf

Getting Started

Establish scope of the QCP

- Which tests in the lab will
  - Meet CLIA minimum
  - Exceed CLIA minimum
  - Have an IQCP
    - Required/not required
- Multiple instruments in different locations
  - QCP/IQCP is test/device/location specific2

[2]http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIAbrochure13.pdf

Guiding Principles

- Keep your IQCP on point and simple
  - Don’t over-complicate the work
- Do your homework
  - DO NOT be dependent on manufacturer templates
  - CMS will be looking for an assessment by the lab (Brochure 12)
- Give the IQCP an HONEST effort
- Use Excel or Word to create simple forms that summarize and highlight key findings and decisions
  - DO NOT recreate the product insert or instrument manual in a risk analysis format
    - Not a risk analysis – just a fruitless exercise in creative writing

The Key to a Good Risk Assessment

Build a really good IQCP Team

Your IQCP Team

- 5-7 people authorized by management to build a QCP
- Assign authority, responsibilities, accountability
- Core characteristics of members
  - People who can make decisions and finish a project
  - Inquisitive & creative thinkers
  - Knowledge of the process/ procedure
  - Open-minded
  - Stakeholder

Mandatory Components of the IQCP

3-5-3

3

3 Mandatory Phases of Testing

Pre-Analytic

Analytic

Post-Analytic

5

5 Mandatory Areas to Include

Specimen

People

Instrument

Reagent

Environment

3

3 Mandatory Sections of the IQCP

Risk Assessment

QC Plan

Monitoring Effectiveness

…side notes

1 IQCP for each location of testing

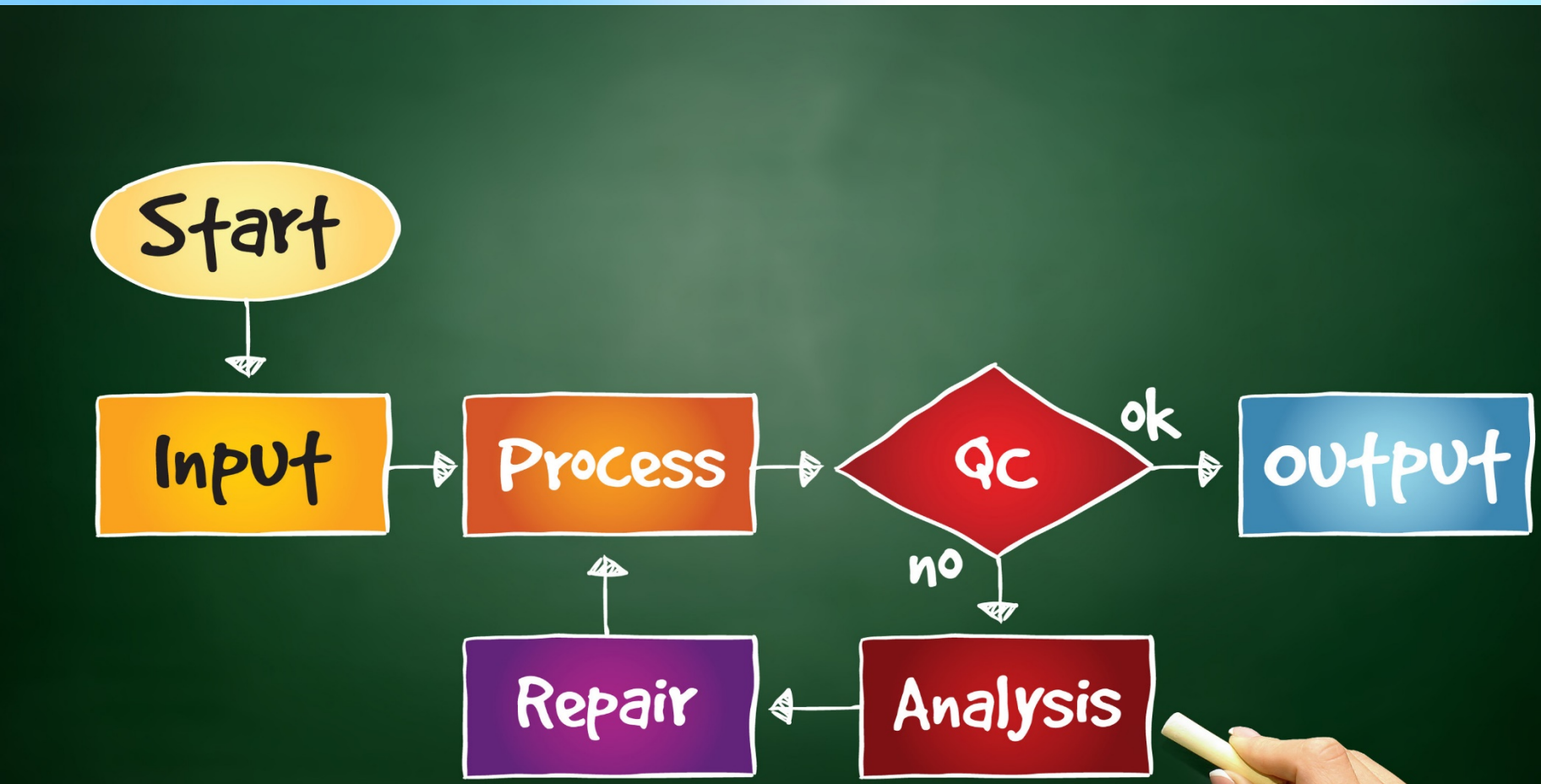
Cannot go below manufacturer’s recommendation

Can’t use manufacturer’s data or template IQCP alone – must contain your data and match your process

Must have data to support frequency

Risk Analysis

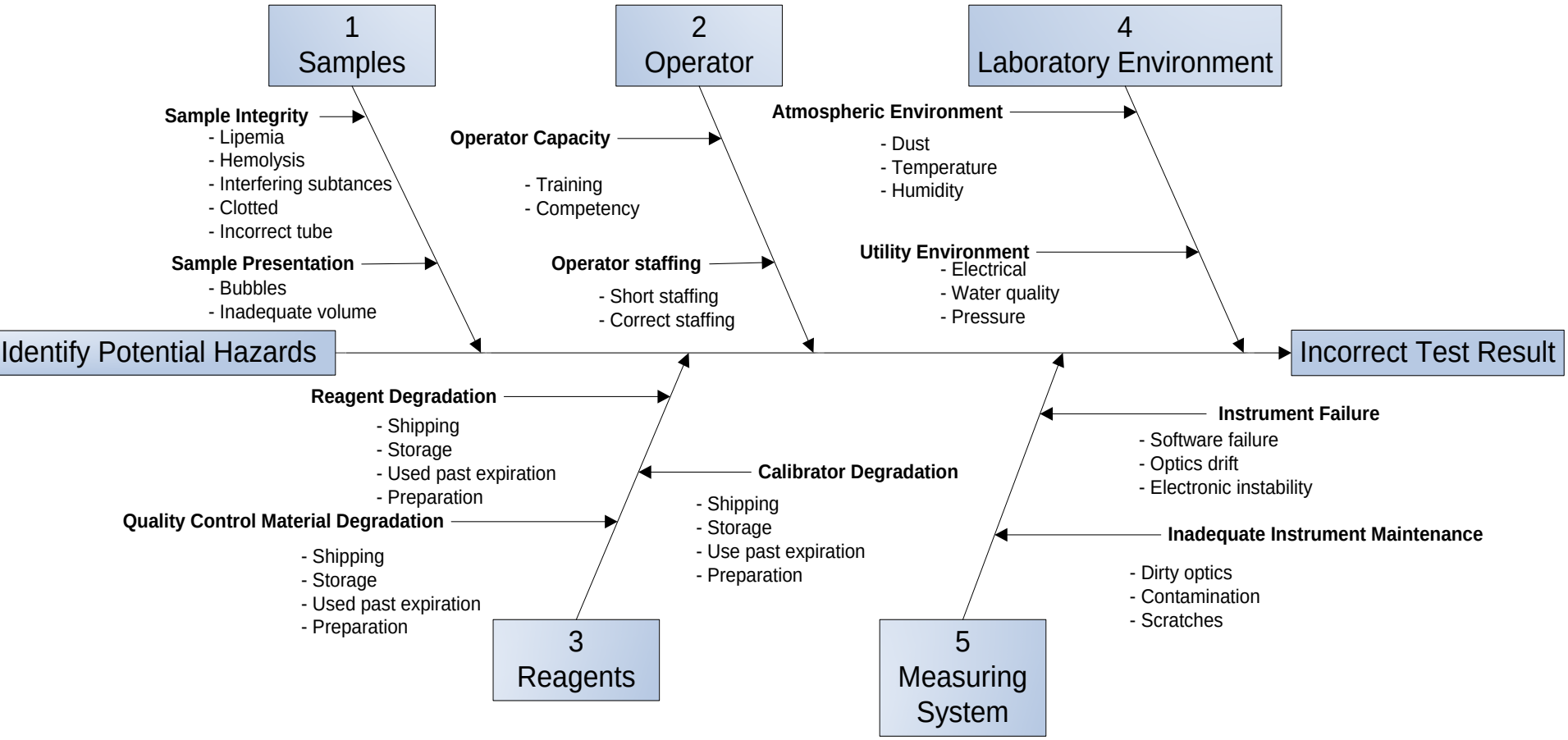
Process Map: Example



Some sources of risk

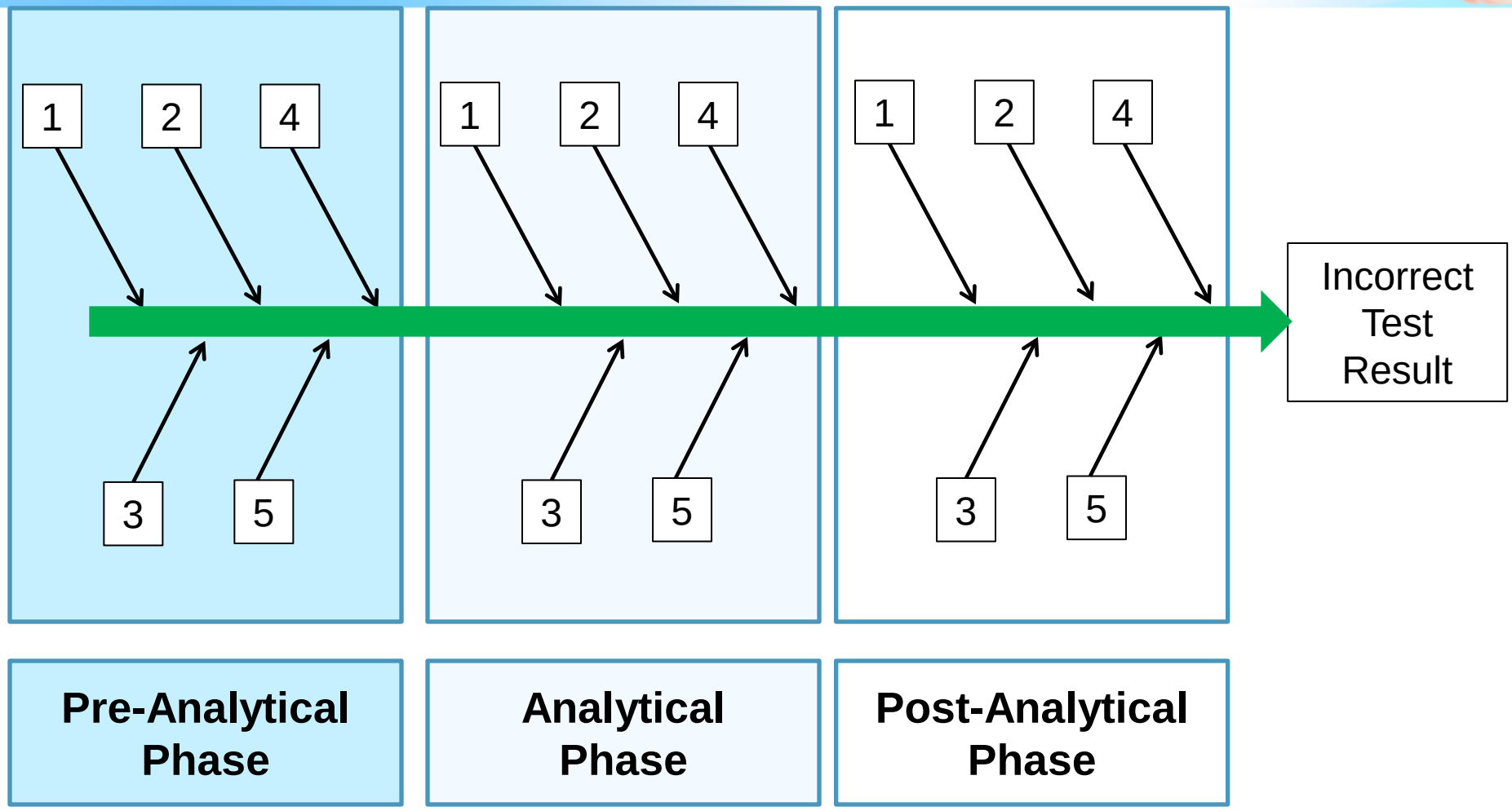
- Communication processes
- Knowledge and competency of test operators
- Management commitment
- Outside influences
- Resources
- Technical components
- Process/Procedure
- Financial – decisions based on cost not quality

Fishbone Diagram



CLSI: Laboratory Quality Based on Risk Management. EP23-A. 2011

A Fishbone Approach



1 – Samples 2 – People 3 – Reagent 4 – Environment 5 - Instrument

Test System

Pre-Analytical
Calibration
Calibration Verification
Maintenance daily, w / m / semi-annual
Electrical Monitoring, Surge Protection Dedicated Circuit
Water Supply (if required) Water quality Water integrity (air)
Humidity (mfr requirement)
Temp. (mfr requirement)
PT Performance
Calibration of ancillary equip

Analytical
Consumables (quality)
Reagent dispense
Sample dispense
Reaction Chamber Temperature
Measurement Filter wheel Light source integrity Clot detection Interfering substances
Quality Determination QC approach used QC materials used QC frequency QC Rules Patient risk (# patients between QCs)

Post-Analytical
Results: review / approve
Result Transmission
Retrospective Review
Trend Analysis
Sigma Metrics
Frequency of recalibration
Freq. of Device Failures
Verification of Test Results

Information Gathering / Analysis
Test System for POCT

Pre-Analytical
Calibration
Calibration Verification
Maintenance daily, w / m / semi-annual
Electrical Monitoring, Surge Prot Dedicated Circuit, Battery
Water Supply (if required) Water quality Water integrity (air)
Humidity (mfr requirement)
Temp. (mfr requirement)
PT Performance
Calibration of ancillary equip

Analytical
Consumables (quality)
Reagent dispense
Sample dispense
Reaction Chamber Temperature, Black Box
Measurement Filter wheel Light source integrity Clot detection Interfering substances
Quality Determination QC approach used QC materials used QC frequency QC Rules Patient risk (# patients between QCs)

Post-Analytical
Results: review / approve
Result Transmission
Test Report
Retrospective Review
Trend Analysis
Sigma Metrics
Frequency of recalibration
Freq. of Device Failures
Verification of Test Results

Analysis
Brainstorming a POCT Test

Analytical
Reaction Chamber Black Box
Measurement Interfering Substances
Quality Determination QC approach used QC materials used QC frequency Patient risk (# patients between QCs)

PROCESS MAPPING OR FISHBONE DIAGRAM

Possible Hazard Points
What Can Go Wrong?

Analysis
Brainstorming a POCT Test

Analytical
Reaction Chamber Black Box
Measurement Interfering Substances
Quality Determination QC approach used QC materials used QC frequency Patient risk (# patients between QCs)

PROCESS MAPPING OR FISHBONE DIAGRAM

Possible Hazard Points
• Does the the device manual or the product insert describe in detail the analytical sequence? • Does the product insert, the device manual or the manufacturer describe in sufficient detail how the function checks work and are themselves • Has the manufacturer provided a product reliability score or the mean time between failure?

Analysis
Brainstorming a POCT Test

Analytical
Reaction Chamber Black Box
Measurement Interfering Substances
Quality Determination QC approach used QC materials used QC frequency Patient risk (# patients between QCs)

PROCESS MAPPING OR FISHBONE DIAGRAM

Possible Hazard Points
• Does the product insert….
• How is the patient cleared for interfering substances?

Analysis
Brainstorming a POCT Test

Analytical
Reaction Chamber Black Box
Measurement Interfering Substances
Quality Determination QC approach used QC materials used QC frequency Patient risk (# patients between QCs)

PROCESS MAPPING OR FISHBONE DIAGRAM

Possible Hazard Points
• Does the product insert….
• How is the patient cleared for …
• What QC modality is used? Function checks only? Electronic QC only? Traditional QC?
• First party, second party or third party controls used? • Embedded control used? • Liquid or solid phase QC? Shortcomings?
• How frequently is QC run? • Can errors/mistakes/failures/hazards be detected immediately?
• How are QC limits established? • What QC rules are used?
• How many patient test results are reported between QC testing events?

Grading and Ranking Risk

Can use FMEA approach

- Grade (score 1-5 or 1-10) for occurrence, severity, detection
- Multiply scores to get Risk Priority Number (RPN)
- Rank for importance by RPN and Acceptance criteria
  - How much risk is acceptable? Set by team

Alternative grading system

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

Adapted from ISO 14971

An EXAMPLE
HIV Rapid Plasma Test

Potential hazards identified by IQCP team

1. EDTA plasma only
2. Sample stable up to 7 days
3. Technique is critical
4. Result read at 20-40 minutes post inoculation
5. Built in controls do not verify reactive/non-reactive
6. Kit controls are specifically formulated for the test
7. First party external controls are tested once per week

HIV Rapid Plasma Test

Consequences (Severity) associated with a bad HIV result

- A false positive could lead to broken relationships or families
- A false negative could lead to new infections for unwary partners

EDTA plasma only

1. **Associated risks** identified by IQCP team
   - Bad result or no result with other anticoagulants
2. **Severity assessment** by IQCP team
   - Probability of occurrence is estimated to be remote
   - Consequences of a bad result if reported and acted on can be critical
3. **Evaluation and mitigation** by IQCP team
   - Risk acceptable
   - Mitigation: None required

Evaluation

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

Adapted from ISO 14971

First party external controls are tested once per week

1. **Associated risks** identified by IQCP team
   - Error or faults in the test system are not detected when they occur
   - Once per week testing of control materials does not allow adequate ongoing monitoring of accuracy and precision as required by CLIA
2. **Severity assessment** by IQCP team
   - Probability of errors or faults is estimated to be occasional
   - Failure to detect error or fault can have critical consequences
3. **Evaluation and mitigation** by IQCP team
   - Risk not acceptable
   - Mitigation: Use third party controls; test more frequently than once per week

Alternative grading system

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

Adapted from ISO 14971

To summarize:

- Form a team
- Set the scope of the QCP
  - Which tests will have an IQCP
- Gather relevant information
- Perform the analysis
  - Identify hazards and prioritize the importance
- Evaluate the risk, decide on and implement mitigations

To summarize

- Keep it simple
- Stay on point
- Do not rely solely on manufacturer templates
- When doing the analysis and making decisions ALWAYS be guided by what is best for your patients.

Reference materials

- CMS IQCP Link: http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Individualized_Quality_Control_Plan_IQCP.html
- CLIA Brochure 12: http://www.cms.lgov/Regulations-and-Guidances/Legislation/CLIA/Downloads/CLIAbrochure12.pdf
- CLIA Brochure 13: http://www.cms.lgov/Regulations-and-Guidances/Legislation/CLIA/Downloads/CLIAbrochure13.pdf
- EP23-A Laboratory Quality Control Based on Risk Management, Clinical and Laboratory Standards Institute, Wayne PA

THANK YOU

IQCP: Risk Assessment

Valerie Ng, PhD MD
Alameda Health System/Highland Hospital
Oakland CA
vang@alamedahealthsystem.org

Risk Assessment

- How To Do? CLSI EP23-A™

CLSI EP23-A ™

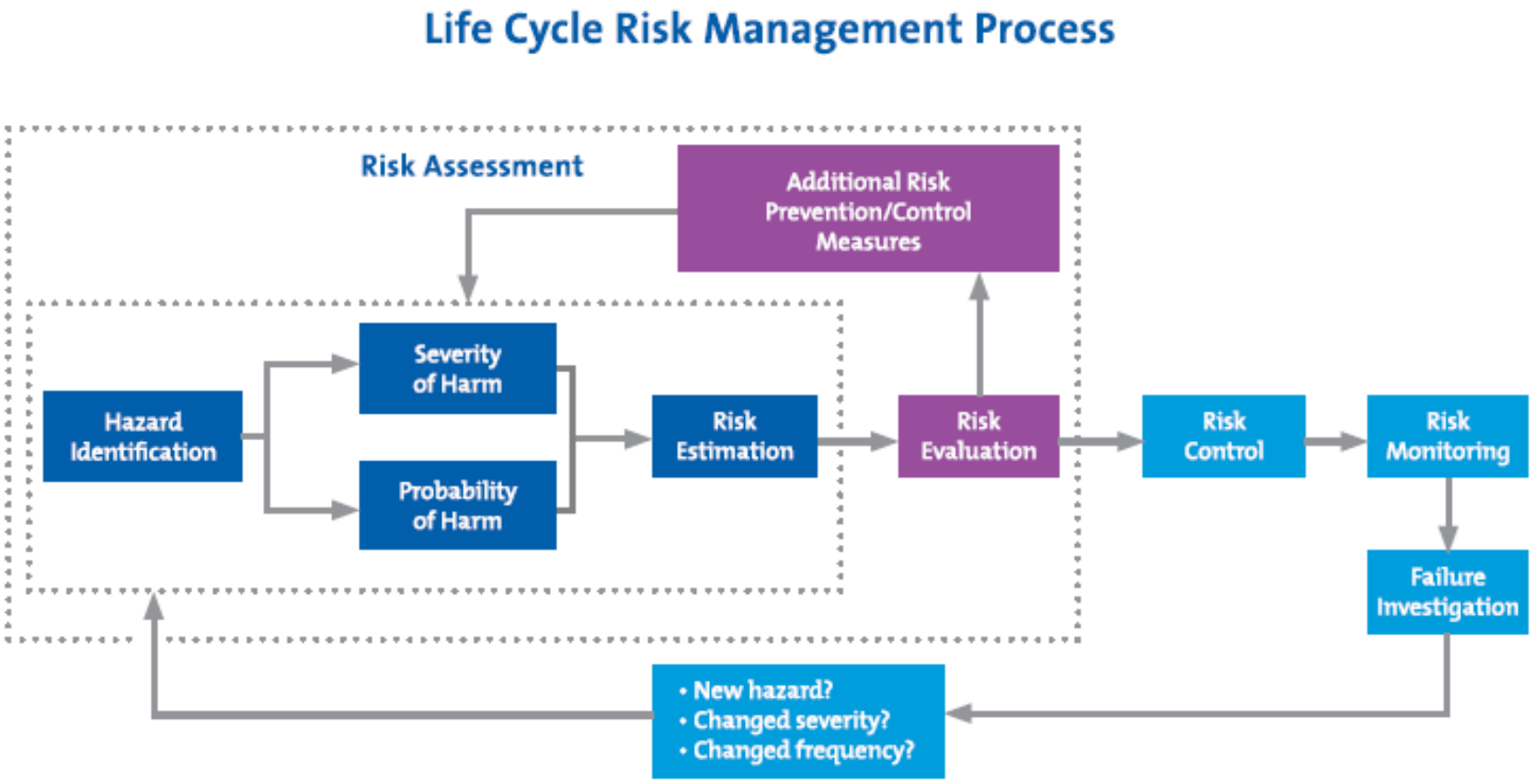
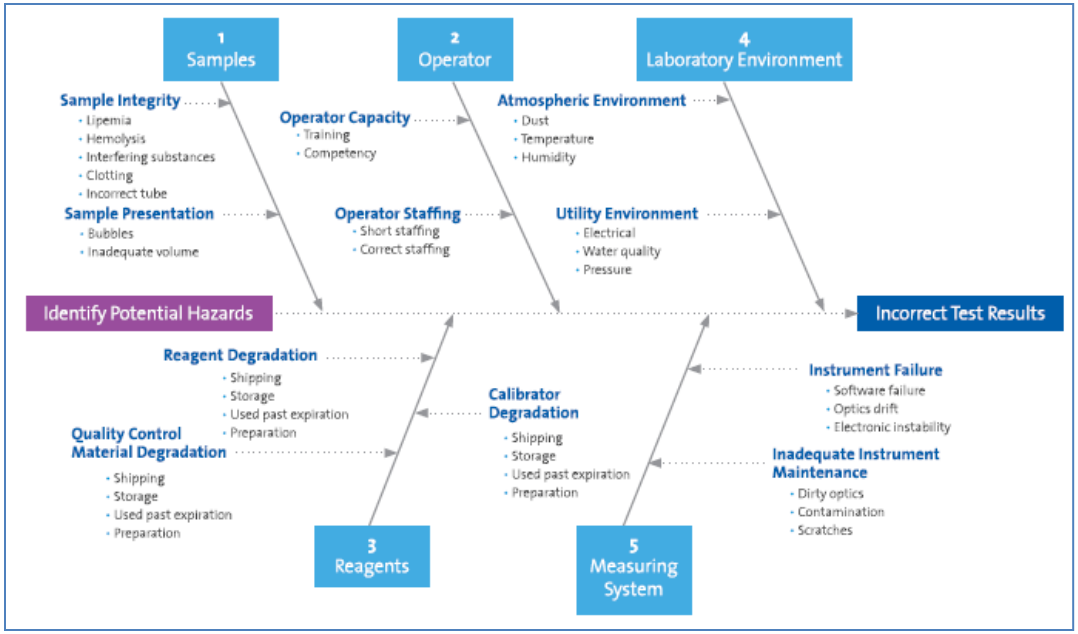


Figure 2. Risk Management Process

CLSI EP23-A ™

- Organizing the risk assessment
  - Fishbone analysis
  - Set up your document



Targeted Failure Mode (Hazard)	Measuring System Feature or Recommended Action	Known Limitations of Feature or Recommended Action	Control Process Effective?	The QCP Actions Required to Address Known Limitations	Residual Risk Acceptable? (Yes/No)

CLSI EP23-A ™

Probability of Harm

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

Severity of Harm

- **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** = patient death

Table 3. Risk Acceptability Matrix

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

Application

- Point of Care Testing (POCT) under review
  - Development of IQCP – need to perform risk assessment
  - Blood Gas Testing
    - Performed entirely by Respiratory Care Practitioners
    - Laboratory oversight
    - QC practice – currently CLIA ’88 compliant
      - one external liquid control sample every 8 hours of testing
      - calibrator or control in each run unless the instrument "autocals" at least every 30 minutes

POCT Blood Gas Testing Review

- Hazard Identification - direct observation of testing process

1. Inadequate mixing of specimen or QC material
2. QC result
    1. Walking away from the instrument without reviewing QC result
    2. If QC result reviewed, not reviewed with current applicable QC acceptable range

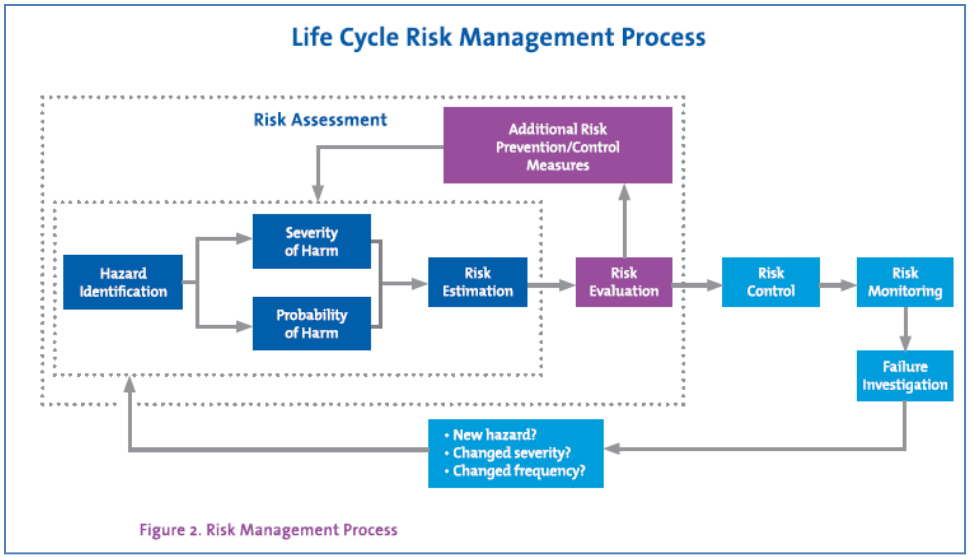
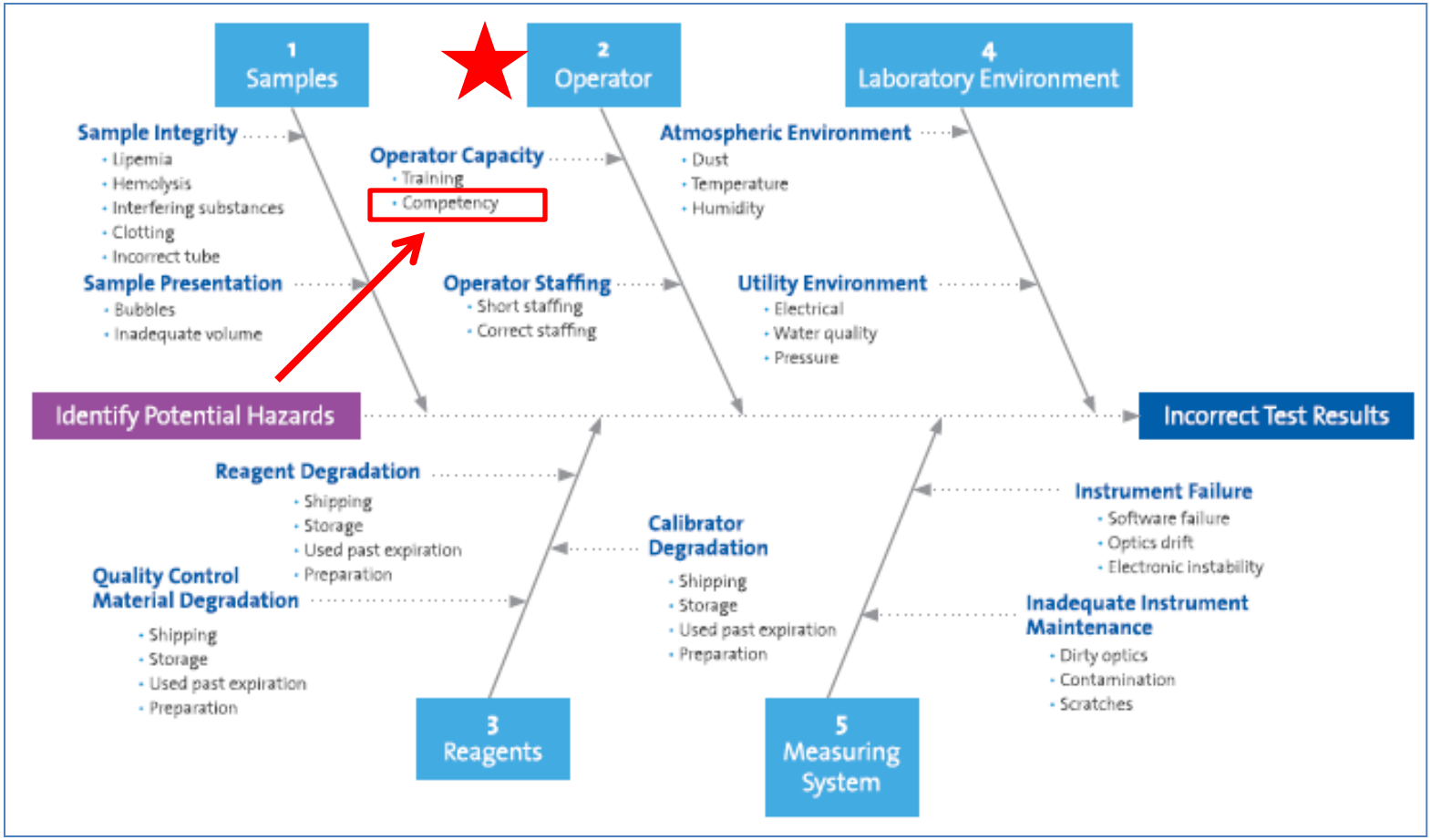


Figure 2. Risk Management Process

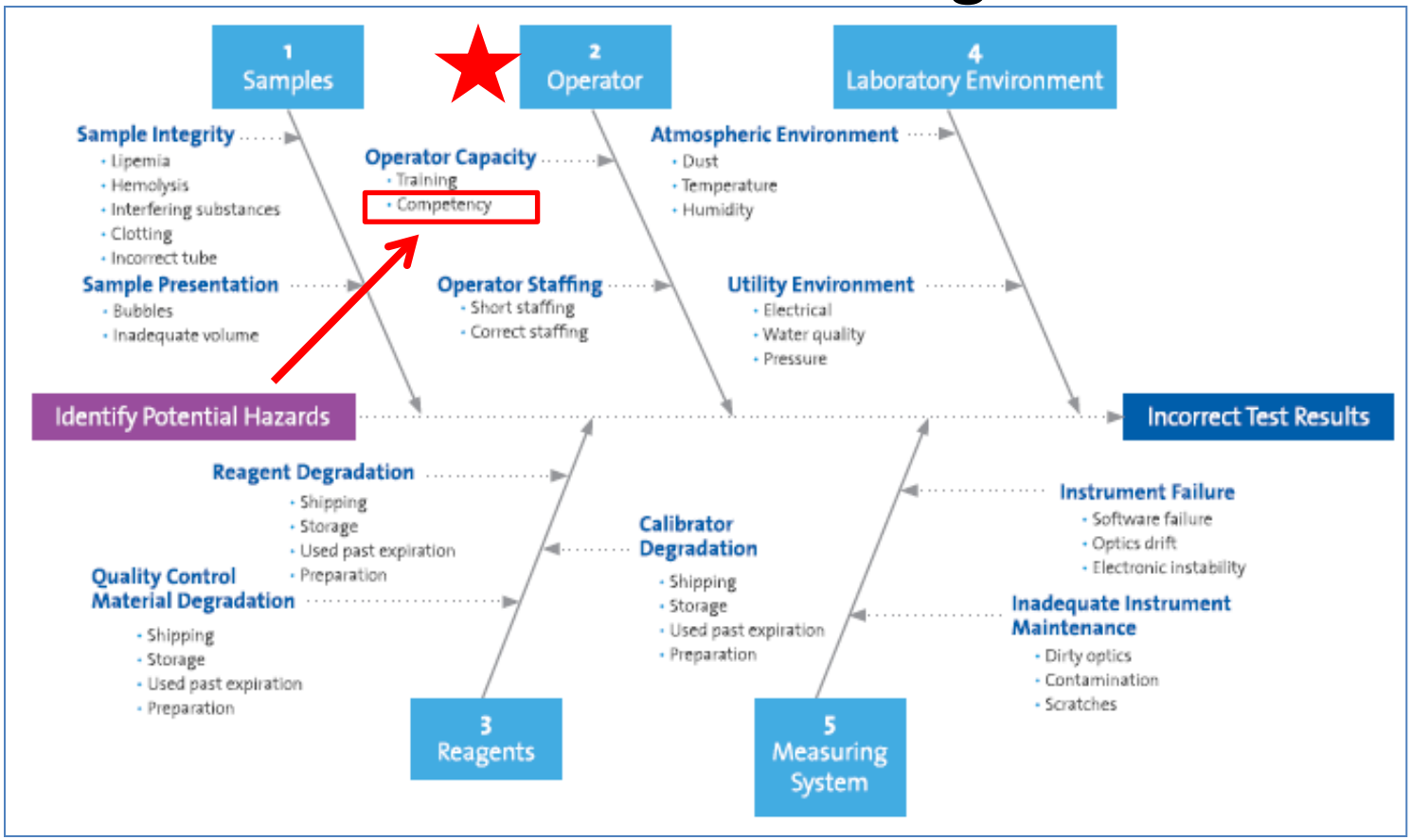
Hazard risk assessment

- Inadequate mixing of specimen or QC material



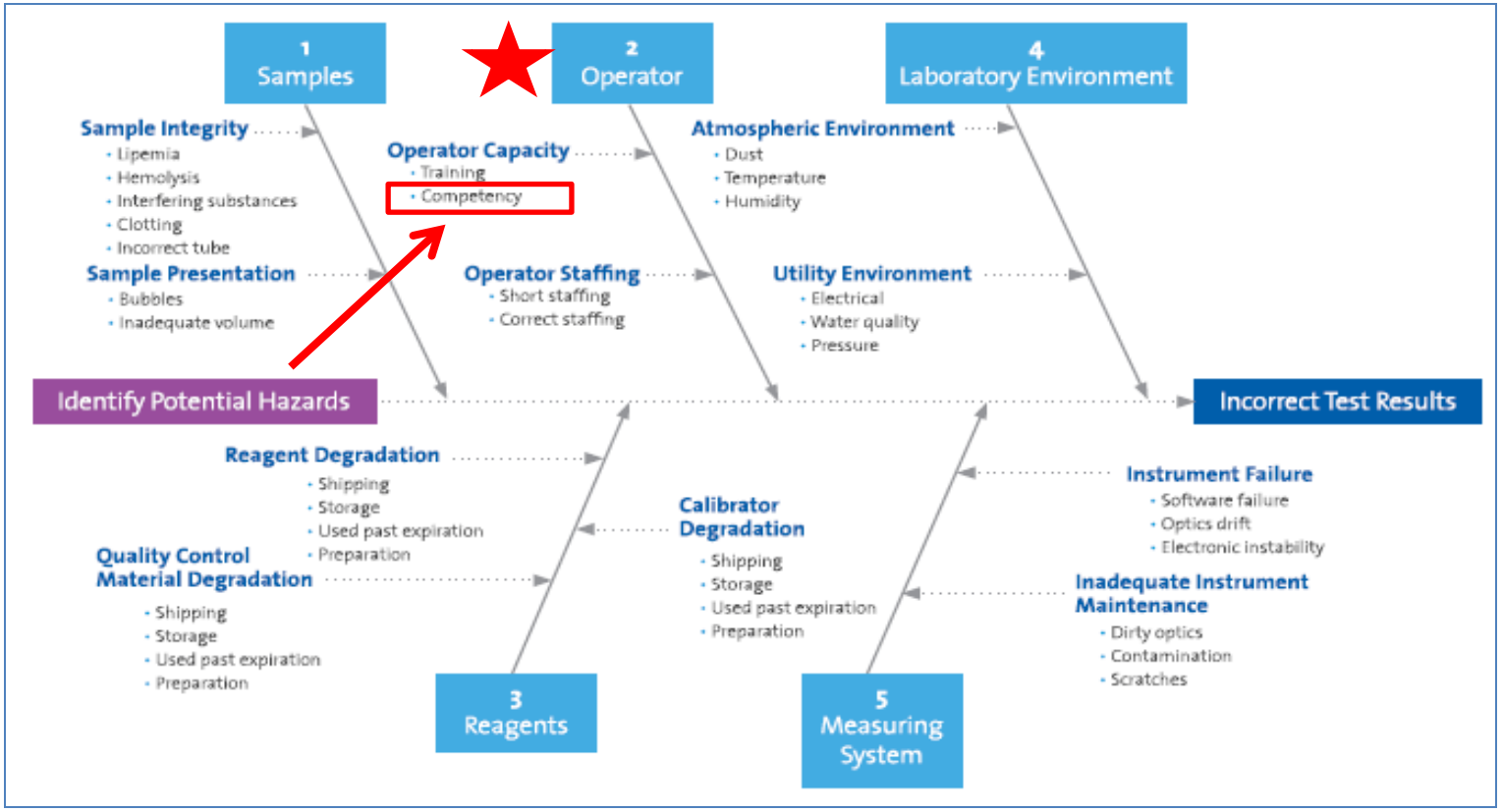
Hazard risk assessment

- QC result - Walking away from the instrument without reviewing QC result



Hazard risk assessment

- If QC result reviewed, not reviewed with current applicable QC acceptable range



Risk Assessment

- **Frequent** = once per week
- **Probable** = once per month
- **Occasional** = once per year
- **Remote** = once every few years
- **Improbable** = 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** = patient death

Table 3. Risk Acceptability Matrix

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

IQCP

Targeted Failure Mode (Hazard)	Measuring System Feature or Recommended Action	Known Limitations of Feature or Recommended Action	Control Process Effective?	The QCP Actions Required to Address Known Limitations	Residual Risk Acceptable? (Yes/No)
Inadequate mixing of patient specimen or QC material	Instrument auto-calibrates every 30 minutes	None detected in last decade	Not completely	Personnel training & regular competency assessment	Yes
No immediate review of QC results	Instrument auto-calibrates every 30 minutes	None detected in last decade	Not completely	Personnel training & regular competency assessment	Yes
Not reviewing QC results against current acceptable range	Instrument auto-calibrates every 30 minutes	None detected in last decade	Not completely	Personnel training & regular competency assessment	Yes

IQCP Implemented

Competency Assessment Time Point (Select one): ☐ **Initial** ☐ **6 months** ☐ **Annual**

Name/Licensure: _____ **Operator ID #** _____

The trainer observes the trainee and attests to his/her competency by signing at the end of the document

The trainer observes the trainee and attests to his/her competency by signing at the end of the document

Rapid Point
- **One level of**
- **Alternate qu**
period.

A. Handling Rapid QC Complete controls:
- Controls must be stored at room temperature of 18 – 25°C away from direct sunlight.
- Controls can also be stored at 2° – 25° C with no adverse effects.
- Equilibrate controls at room temperature for at least 8 hours before use.

B. Testing Controls
1. If prompted, enter your password.
2. Touch QC ampoule button and then touch "Analyze" to analyze a Required QC sample.
3. When prompted, introduce the level of the control shown on the screen:
   a. Scan the barcode on the on the QC sample.
   b. Open
   c. Attach
   d. Insert
   screen
   e. Touch the "Continue" button. (Right Arrow) The system aspirates the sample.
4. When prompted, remove the Quick adapter from the sample port and then touch the "Continue" button. (Right Arrow)
5. If prompted, enter your operator ID and then touch the Continue button. (Right Arrow)
6. View the results. The system will alert you if you are NOT within range. **Repeat analysis if any parameter is out of range. Investigate all QC failures.**

6. View the results. The system will alert you if you are NOT within range. **Repeat analysis if any parameter is out of range. Investigate all QC failures.**

I have been trained and am competent to perform the test using the Rapid Point 405.

Trainee Signature: _____ **Date:** _____

Trainer Signature: _____ **Date:** _____

IQCP Implemented

7411 East 31st Street, Oakland CA 94602

PROCEDURE **PAGE 26 OF 27**

pH, BLOOD GASES AND COOXIMETRY – RAPIDPOINT™ 405 ANALYZER

APPENDIX 3: Competency Assessment Form

Goal: Demonstrate competency in the use of the Rapid System

Competency has been directly observed	Evaluator Initials
Identifies components of t	
Demonstrates knowledge	
Verifies the patient information on the requisition slip matches that on the sample label.	
Handles the sample properly. Observe universal precautions.	
Mixes the sample thoroughly by rolling between the palms and inverting several times	
Properly introduces the sample into the Rapid Point sample port.	
Demonstrates proper entry of patient demographi Point.	
Demonstrates proper documentation of patient t	
Demonstrates access to stored patient results	
Explains troubleshooting procedures and documentation	
Identifies alternative testing procedure	
Describes the care of the system	

Competency has been directly observed **Evaluator Initials**

Mixes the sample thoroughly by rolling between the palms and inverting several times

_____

Name/Licensure (print legibly)

has demonstrated competency in the use of the Rapid Point 405.

Evaluator:_____

Date:_____

IQCP Implemented

PROCEDURE **PAGE 27 OF 27**

pH, BLOOD GASES AND COOXIMETRY – RAPIDPOINT™ 405 ANALYZER
APPENDIX 3: Competency Assessment Form

Rapid Point Competency Quiz

Name:_____ **Operator ID:** _____

True or False

1. Requisitions and samples are matched as the time measurements are made. _____
2. Full calibrations are performed every 8 hours. _____
3. The fill volume of a syringe is dependent on the syringe size. _____
4. Liquid controls are tested on each analyzer every 8 hours. _____
5. A calibration may be interrupted to assay a stat sample. _____
6. Proficiency testing samples are included with the day's workload _____
7. If you have a problem with a proficiency sample, you can compare results. _____
8. Defective cartridges are replaced by the manufacturer. _____

Complete the statement

1. Full calibration is performed every ____ hours. It includes calibrating _____ components.
2. A 1-point calibration is performed every _____ minutes.
3. If the AQC results contain an outlier, the 405 instrument will _____ on the screen.
4. The 405 instrument will indicate a failed pO2 QC by _____on the screen.
5. A "D39" code indicates _____ sample and prompts _____ change.
6. Critical values are documented in the _____. Documentation requires the initials, location And the _____ notification was delivered.
7. Technical assistance is available _____ by con
8. If the 405 is powered down 6 hours, which step testing (circle all applicable items)
   a. Clean the port
   b. Initialized / power up.
   c. Replace the board reagents
   d. Prime the wash
   e. Add reagents
   f. Calibrate
   g. Assay QC materials
   h. QC performance must be acceptable, Investigate failed QC.
   i. Review temperature
   j. Address instrument flags.

f. Calibrate
g. Assay QC materials
h. QC performance must be acceptable, Investigate failed QC.

Score _____ **Passed (≥ 80%)** _____ **Remedial** _____

Comment: _____

Test evaluator (name/licensure - print legibly): _____

Now you can do it

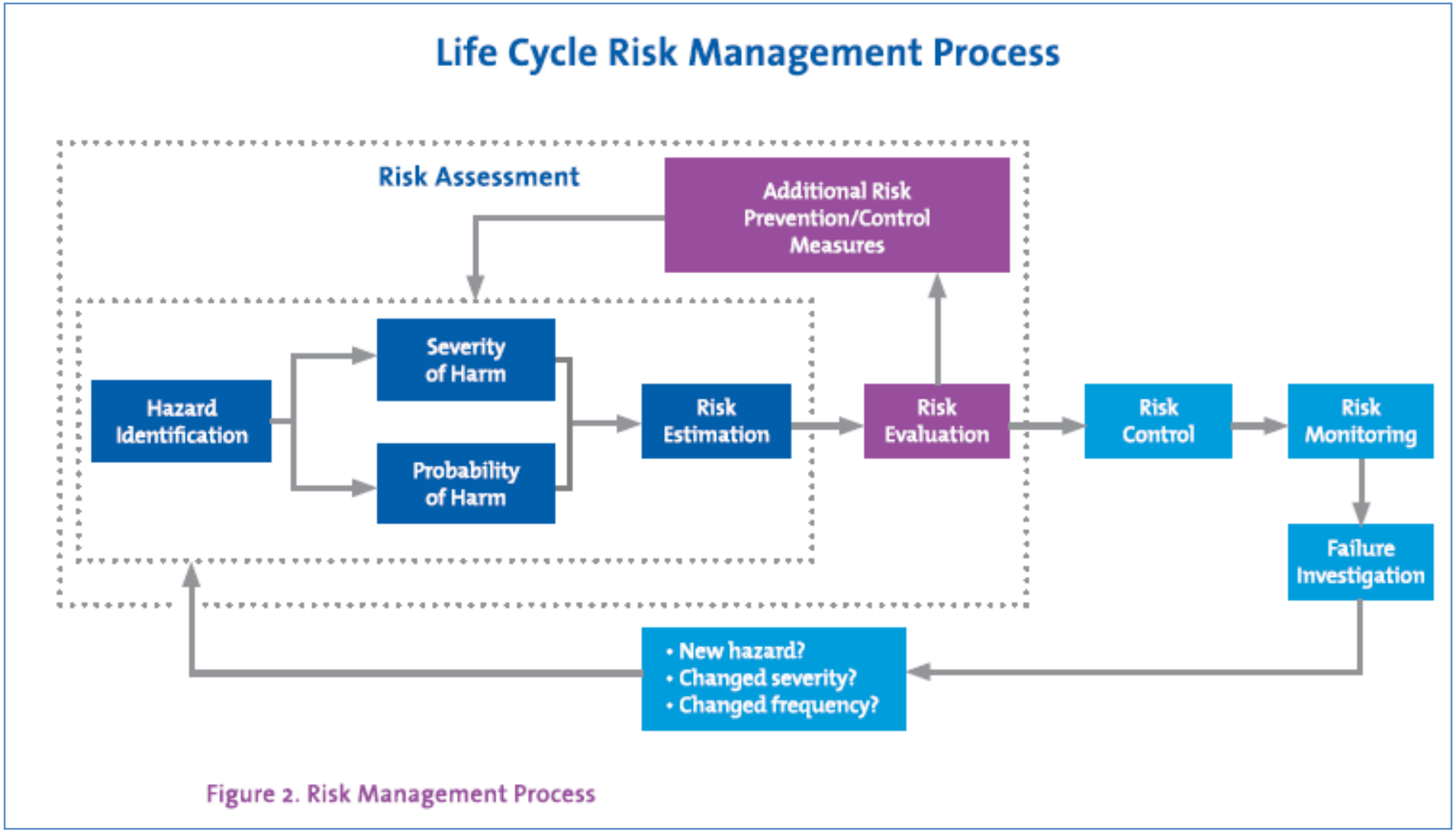


Figure 2. Risk Management Process