



COLLEGE of AMERICAN
PATHOLOGISTS

IQCP

**Ensuring Your Laboratory's
Compliance With Individualized
Quality Control Plans**

November/December 2016

Objectives

- Describe the different components of an IQCP
- Review new CAP checklist requirements for IQCP
- Use examples of IQCP to facilitate IQCP development
- Identify additional resources for developing an IQCP
- Prepare laboratory records for inspection of an IQCP



Why Are We Spending So Much Time on This Topic?



Q1/Q2 2016 Inspection Deficiency Trends

1. No IQCP in place and EQC still in use
2. IQCP not signed by director prior to implementation
3. CAP IQCP forms not completed or used as a substitute for the QCP or risk assessment
4. Risk assessment missing required elements/not customized for laboratory/site variations
5. Quality control plan not well defined (missing frequency or type of QC, etc)
6. External controls not performed every 31 days, at minimum
7. No IQCP for microbiology when following CLSI protocols instead of CLIA default QC (media, susceptibility, bacterial ID)

In the Beginning...

- **1992: CLIA 1988—final regulations published**
 - **2 levels of QC per day (default QC); one-size fits all**
- **2004: Equivalent Quality Control (EQC) option published in CMS Interpretive Guideline**
 - **1st attempt at alternative QC; 2 levels of QC per day or EQC**
 - **Disadvantages: limited scope, prescriptive, analytical focus only**
- **2015 (Dec): EQC discontinued**
- **2016: Individualized Quality Control Plan (IQCP); based on risk assessment**

New QC Option: Individualized Quality Control Plan

- Will not necessarily reduce the QC testing practices
- Will allow you to develop a customized QC plan for your laboratory specific to specimens, your test system, reagents, environment, and testing personnel
- Regulations contain some restrictions for eligibility of use



CAP included IQCP in July 2015 version of accreditation checklists

- **Integrated into CAP checklist requirements**
- **CAP option for IQCP is more restrictive than US government requirements in some areas**
- **Laboratories may develop their own IQCP design model**

All Common Checklist

New IQCP section with 5 new IQCP requirements

Other Checklists

Chemistry, Microbiology, POCT, etc.
Revisions to existing QC requirements throughout checklists to allow for use of traditional QC or IQCP

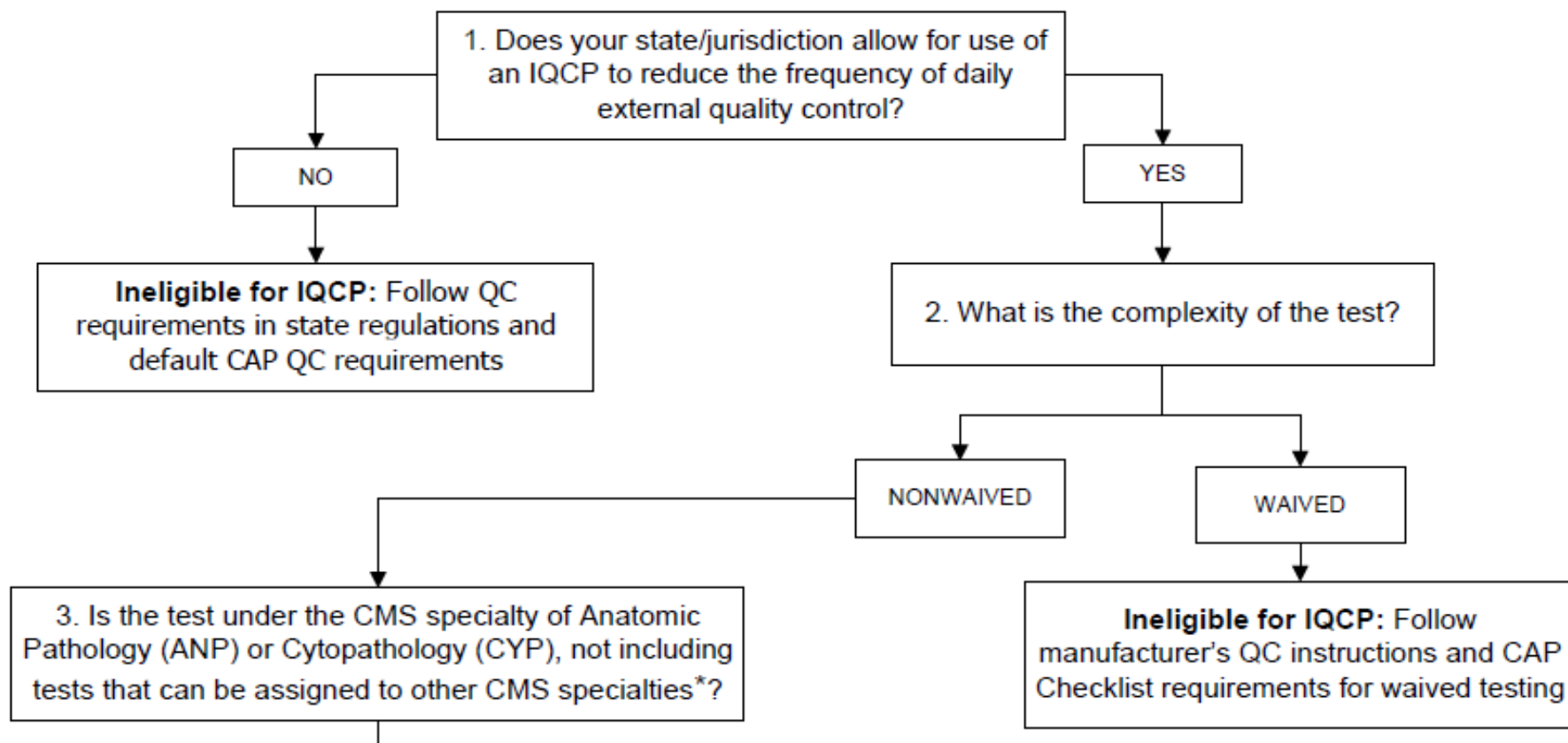
Eligibility for IQCP Use

- **Nonwaived test systems**
 - **Subspecialties other than pathology and cytology**
 - **Exception for those that can come under multiple subspecialties (eg, FISH can be assigned to either histopathology or cytogenetics)**
 - **Follow manufacturer's instructions at minimum**
 - **Must follow local laws and regulations**
 - **Testing employs an internal quality control system (electronic, procedural, or built-in control)**
 - **Exception: Microbiology media and reagents used for microbial identification and susceptibility testing**
- IQCPs in use that do not reduce the QC frequency below the minimum default QC requirement are not inspected with the IQCP checklist requirements***

Eligibility Determination

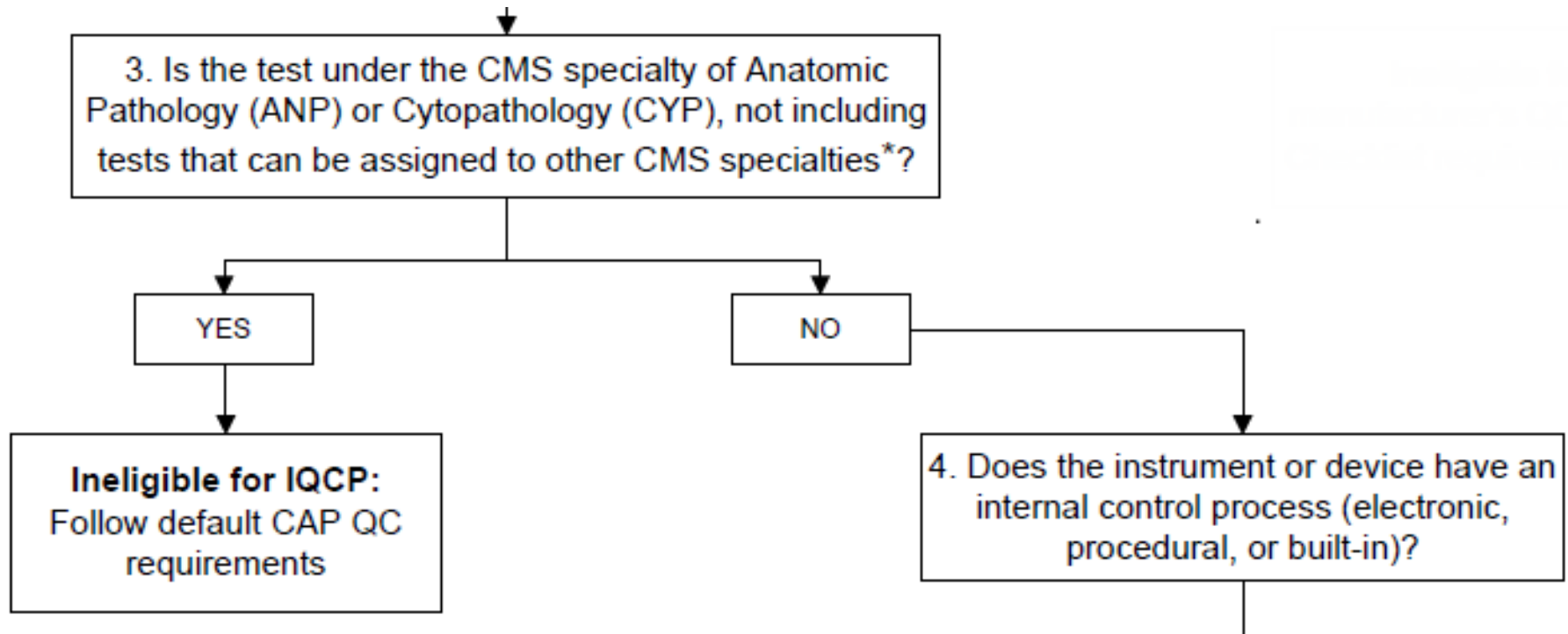
CAP Website Tool

Eligibility Determination for Individualized Quality Control Plan (IQCP) Option



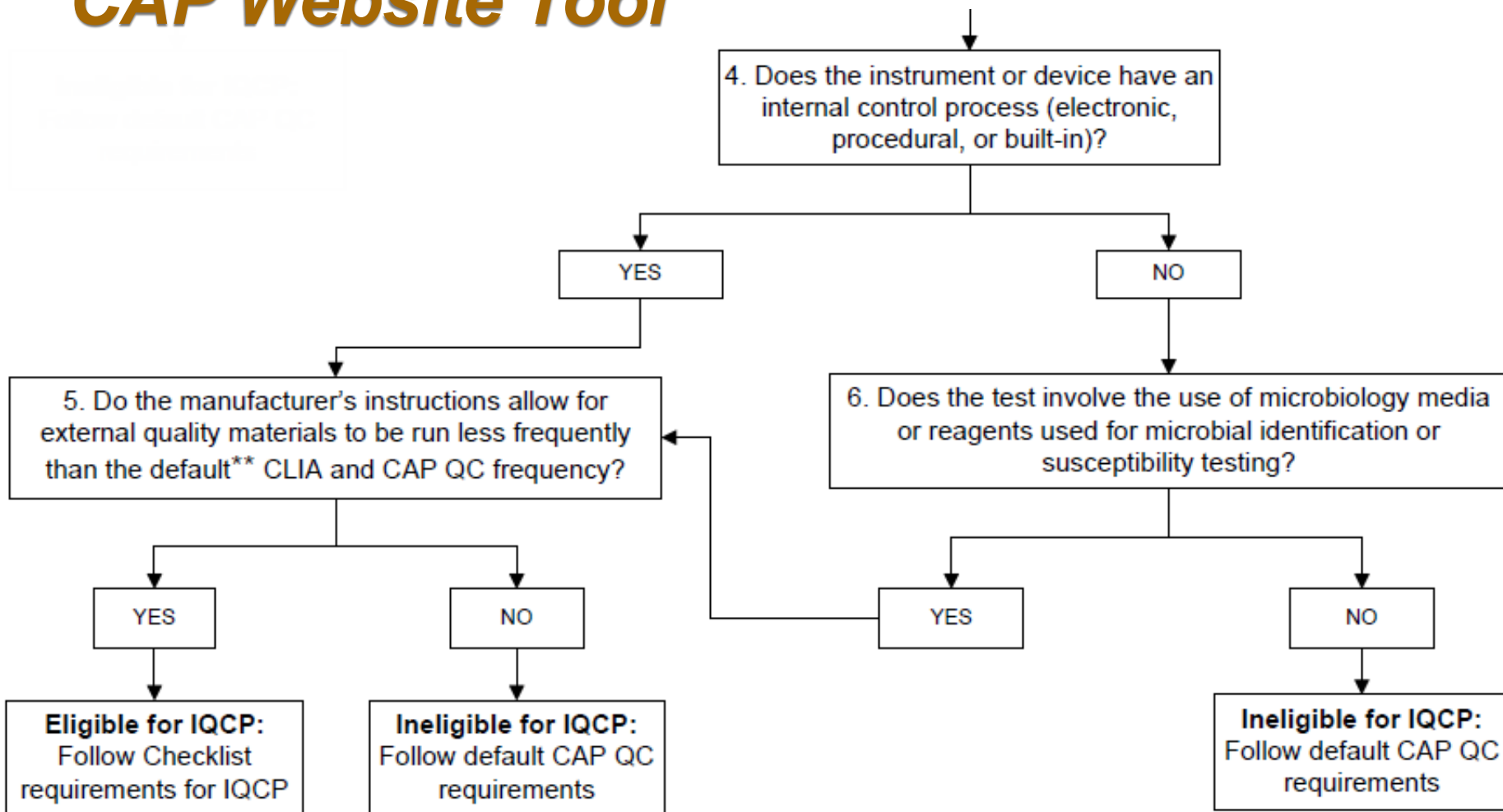
Eligibility Determination

CAP Website Tool



Eligibility Determination

CAP Website Tool



CAP eligibility to use IQCP

- **An IQCP is NOT needed if at least two levels of external QC for a nonwaived test is performed each day of patient testing (or more frequently as defined by manufacturer)**
- **An IQCP is voluntary...*however*, without an IQCP, laboratories must follow the minimum daily QC requirements and default regulations for daily QC of nonwaived testing**

IQCP Elements

Risk Assessment

- Identifies and evaluates potential failures and sources of errors in the testing process
- Must include evaluation of specimen, test system, reagent, environment, and testing personnel

Quality Control Plan

- A written document describing practices and procedures performed by your lab to reduce the chance of possible failures and errors in your test processes
- Ensures accurate, reliable test results
- PT, maintenance, and training are components

Quality Assessment

- Process of monitoring effectiveness of QCP
- QC reviews, PT performance, and complaints

Risk Assessment— *What could possibly go wrong?*



Beginning the Risk Assessment

Gather information to assess risks

- **Regulatory and accreditation requirements**
 - **Mandated QC procedures**
 - **Device failure notifications**
- **Measuring system information**
 - **Intended use**
 - **Instructions for calibration, maintenance, use, reagent storage**
- **Laboratory information**
 - **Environmental conditions**
 - **Operator training and competency**

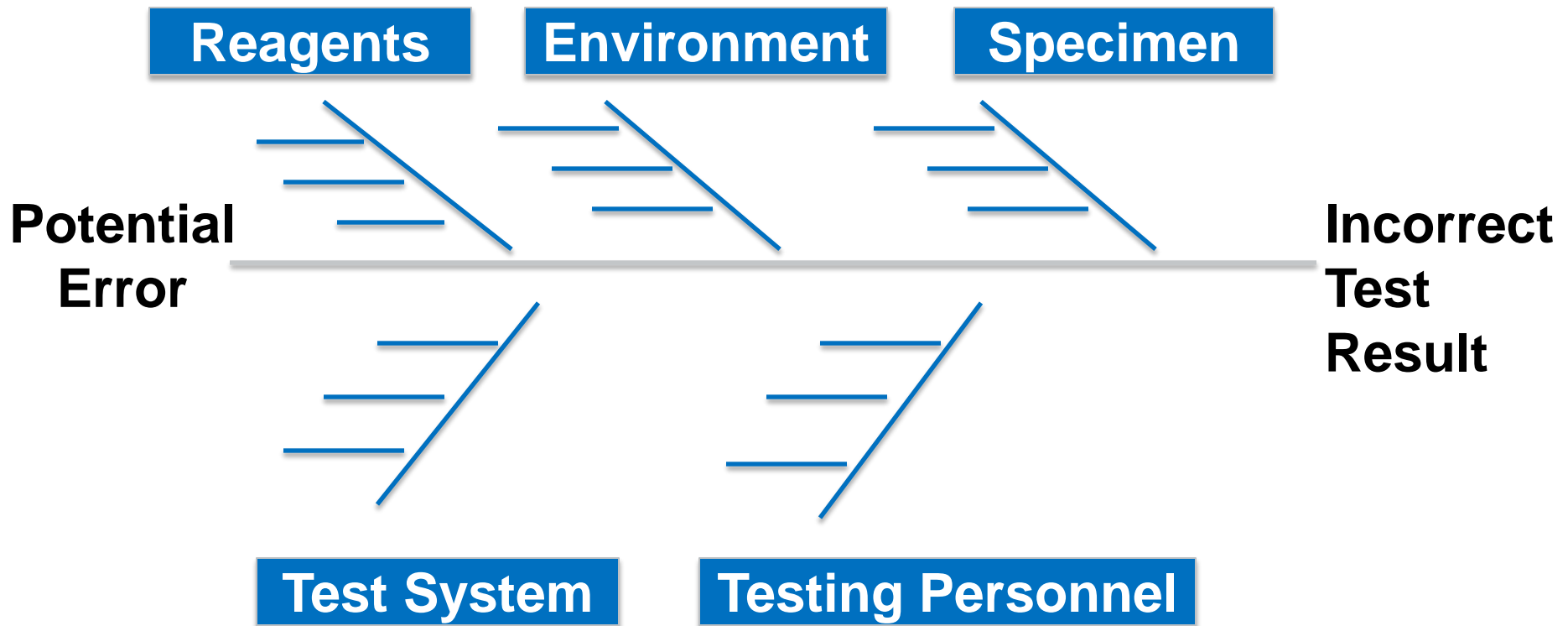
Beginning the Risk Assessment

Gather information to assess risks (cont.)

- **Publications and laboratory peers**
 - **Published performance evaluations**
 - **Published clinical studies**
- **Clinical information**
 - **Clinical applications for use of test result**
 - **Foreseeable medical errors that could result from incorrect, delayed, or no result**

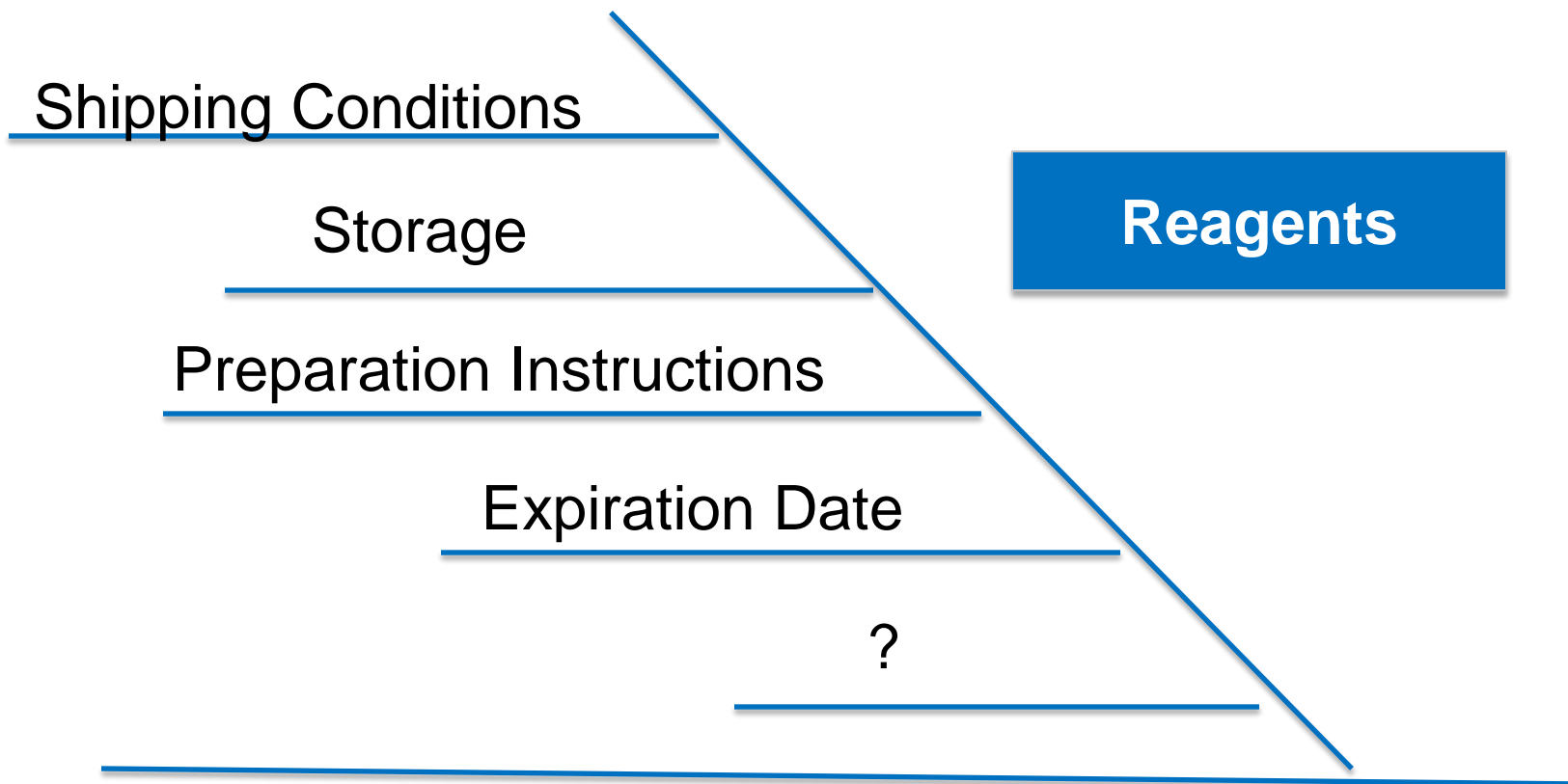
TOOL: CLSI Guideline

Five-Component Risk Assessment Using a Fishbone Diagram



Risk Assessment Components

Reagents



CDC/CMS Handbook: Developing an IQCP

A Step-by-Step Guide

Risk Assessment Worksheet

Laboratory Name _____ Test System Name _____

1	2	3	4
Risk Assessment Components	What are our possible sources of error? What can go wrong?	Can our identified sources of error be reduced?	How can we reduce the identified sources of error?
	Gather information, from the manufacturer's instructions and other resources, on how we should be performing the testing process.	Yes/No Not Applicable (N/A)	Indicate how to reduce possible error sources. <ul style="list-style-type: none"> • Internal controls • Actions taken by laboratory • Safeguards in the test system or laboratory practices
SPECIMEN			



Risk Assessment Components

Reagents

Possible Sources of Error	Can the sources of error be reduced?	How can we reduce the identified sources of error?
Reagent stability compromised during shipping of new lots and shipments of reagent	Yes	Check each new lot and shipment of reagent with two levels of external control materials prior to use
Manufacturer requires storage at 2-8 °C	Yes	Monitor refrigerator storage temperatures daily to confirm that temperatures are maintained within the required range
Reagents must be brought to room temperature prior to use.	Yes	Include instructions in the laboratory procedure and train testing personnel on reagent preparation
Reagents placed at room temperature (20-24 °C) are stable for 14 days and may not be refrigerated again.	Yes	Include instructions in the laboratory procedure and train testing personnel to record a 14-day expiration date on reagents placed at room temperature and check dates prior to use.

Risk Assessment Components

Environment

- **Temperature**
- **Humidity**
- **Altitude**
- **Water**
- **Adequate space**
- **Lighting/intensity**
- **Noise and vibration**
- **Point-of-care testing sites**

Risk Assessment Components

Environment

Possible Sources of Error	Can the sources of error be reduced?	How can we reduce the identified sources of error?
Dropping of the instrument may cause the instrument to malfunction	Yes	Instrument will be stationed on a bench top in the ER
Instrument must be operated at temperatures of 20-30 °C	Yes	Room temperature will be monitored on a daily basis
Testing must be performed on a level, dry surface. It may not be moved during operation	Yes	Instrument will be stationed in a bench top area in the ER away from a sink. Personnel will be trained not to move the instrument during the testing process.

Risk Assessment Components

Specimen

- **Specimen collection**
- **Specimen labeling**
- **Specimen storage, preservation, stability**
- **Specimen transport**
- **Specimen processing**
- **Specimen acceptability and rejection**

Risk Assessment Components

Specimen

Possible Sources of Error	Can the sources of error be reduced?	How can we reduce the identified sources of error?
Only venous whole blood or EDTA plasma specimens may be used	Yes	Specimen collection instructions and criteria for acceptable specimens are defined in the procedure and are covered during training
Test must be performed within 4 hours of collection and be maintained at room temperature	Yes	Test is performed at the point-of-care using whole blood. Procedure requires testing immediately after specimen collection
Hemolysis during specimen collection must be avoided	Yes	Personnel are trained on the appropriate collection techniques.

Risk Assessment Components

Test System

- **Mechanical/electronic failure**
- **Inadequate sampling**
- **Capability to detect interfering substances (eg, lipemia, hemolysis)**
- **Calibration problems**
- **Failure of system controls and function checks**
- **Clot detection capability**

Risk Assessment Components

Test System

Possible Sources of Error	Can the sources of error be reduced?	How can we reduce the identified sources of error?
Overfilling or underfilling of the test cartridge with patient specimen will cause an error with specimen sampling	Yes	Staff training on the filling of the test cartridge. Add a step in the procedure to confirm that specimen is at the fill line prior to testing.
Writing on the front of the test cartridge with brightly colored ink will interfere with the test	Yes	Staff training and procedure will include writing the patient name and medical record number in black ink on the back of the cartridge.
Test cartridge with specimen must be inserted in the instrument within 15 minutes	Yes	Testing is performed at the point-of-care to avoid delays. Timing to be included in staff training and in the procedure.
If built in internal control is not within acceptable limits, no patient result will be reported	Yes	Instrument has a lock out feature. Troubleshooting guide available to staff with contact information for immediate assistance.

Risk Assessment Components

Testing Personnel

- **Appropriate education and experience**
- **Adequate numbers of staff**
- **Training**
- **Competency**
- **Nonlaboratory testing personnel**

Risk Assessment Components



- A. Reagents**
- B. Specimen**
- C. Environment**
- D. Test System**
- E. Testing Personnel**

CLSI EP23-A Guideline

Risk Estimation

- **Assess the likelihood or probability of harm for each failure and the severity of harm to a patient for each failure**
- **ISO 14971 Semi-quantitative approach can be used to estimate the probability of a failure rate; historical data can be used**
 - **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**

CLSI EP23-A Guideline

Risk Estimation

- **What are the consequences of an incorrect result, delayed result, or no result?**
- **Use probability or likelihood of a failure leading to harm combined with severity of that harm to evaluate risk to the patient**

Severity of Harm semi-quantitative scale of severity levels (ISO 14971)

- **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**

Risk Acceptability Matrix

Based on ISO 14971

	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	acceptable	unacceptable
Improbable	acceptable	acceptable	acceptable	acceptable	acceptable



Quality Control Plan

Quality Control Plan (QCP)

- **A QCP is a document that describes the practices, resources, and procedures to control the quality of a particular test process**
- **At a minimum your QCP must include the number, type and frequency of testing control material, as well as criteria for acceptable quality control**

Quality Control Plan

Where to begin

- **List control processes identified from the risk assessment, including:**
 - **External QC**
 - **Internal control processes (built-in/ procedural /electronic)**
 - **Personnel training and competency assessment**
 - **Equipment and environment monitoring**
 - **Result reporting error checks**
 - **Other specified control activities**
- **Ensure that it provides for the immediate detection of errors during the different phases of the testing process**
- **Confirm that the QCP follows manufacturer's instructions and regulatory requirements at minimum**

Example Quality Control Plan

Laboratory Name: Northfield Laboratory CAP#: 11111-11



Type of Control	Frequency	Criteria for Acceptability
Internal QC every time a test is performed	Each time of use	Within manufacturer's limits using automated lockout
Two level of external quality controls from the manufacturer	Each new lot and shipment of reagents Every 31 days Monthly supervisory review	Within defined QC limits
Monitoring of reagent storage areas	Daily Monthly supervisory review	Within 2-8°C
Record and monitor open expiration dates	Each day of use	In date reagents used
Staff training and competency on specimen collecting and testing process	Initial training, 6-month competency for new personnel, ongoing annual competency	Complete training checklist and procedure review. Pass competency assessment with minimum score of 90%.
Monitoring of room temperature		Within 20-24°C
ETC...		

Laboratory Director: Joan Smith, MD Date: 6/5/2015



Quality Control Plan (QCP)

A complete QCP must:

- **Provide for immediate detection of errors for each phase of the testing process**
- **Specify the number, type, and frequency of testing QC material(s)**
- **Contain criteria to determine acceptable QC results**
- **Require the laboratory perform QC as specified by the manufacturer's instructions, but not less than the manufacturer's instructions**
- **Indicate that your laboratory director reviewed, signed and dated the QCP document**



Quality Assessment

Quality Assessment (QA)

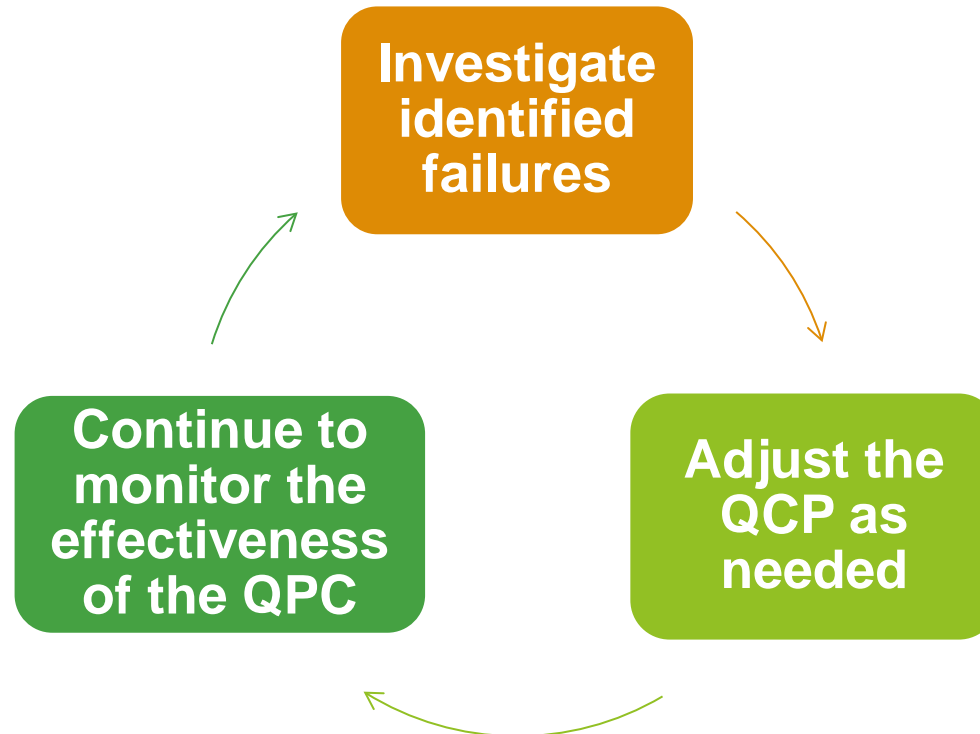
- **Monitoring to include the following: reagents, specimen, environment, test system, and testing personnel**
- **Ongoing assessments may include, but are not limited to, the review of the following records:**

- **Quality control**
- **Proficiency testing**
- **Patient results review**
- **Specimen rejection logs**

- **Turnaround time reports**
- **Error/corrective action logs**
- **Personnel/competency**
- **Instrument maintenance logs**

Quality Assessment Process

- Patients potentially affected by the failure need to be identified and corrective actions taken
- If errors are identified, adjust the QCP to prevent future failures



IQCP Completed!

**RA: Risk
Assessment**

**QCP: Quality
Control Plan**

**QA: Quality
Assessment**

IQCP

Requirements Added to the All Common July 2015 Version of the Checklists

- **COM.50200** The laboratory has identified all tests using IQCP and completed the CAP forms
- **COM.50300** The IQCP includes a risk assessment with all required elements
- **COM.50400** The written QCP has been approved by the laboratory director prior to implementation
- **COM.50500** The IQCP defines all aspects monitored and covers the potential errors identified (includes external controls every 31 days for test systems relying on internal controls)
- **COM.50600** Ongoing quality assessment is performed

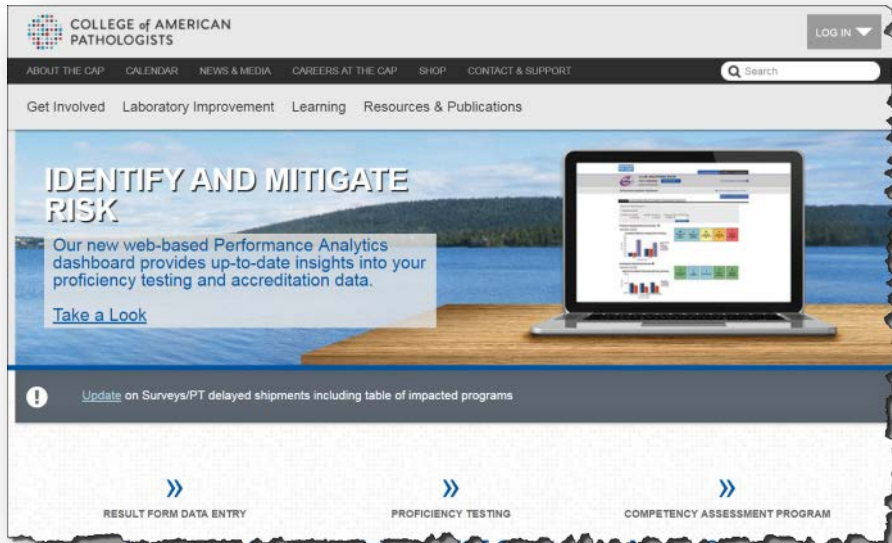
Microbiology and Quality Control

- Since May 2004 Microbiology QC obligations were met with CLSI references
- October 31, 2014, CMS memorandum:
CLSI document references will be removed from the upcoming revision of survey procedures and interpretive guidelines (IGs) for laboratories
- Why did this happen?
 - CMS removed mention of CLSI documents from its interpretive guidelines for QC because government agencies cannot make private guidelines regulatory in effect unless those guidelines are available for free
- What now for labs? 2 options for CLIA QC compliance:
 - *Follow all applicable CLIA QC regulations*
 - OR
 - *Implement IQCP*

IQCP for Microbiology

- **Internal controls as it applies to direct antigen testing and rapid molecular tests**
- **Exempt culture media (defined by CLSI M22)**
- **Antimicrobial susceptibility testing**
- **Identification systems using EQC**





cap.org

Laboratory Improvement >
Accreditation > Individualized Quality
Control Plan (IQCP) Resources

CAP Website Resources

- Eligibility Determination for IQCP Option
- Jointly developed (CAP, ASM, CLSI) templates and examples for microbiology
- CAP IQCP Frequently Asked Questions
- CAP forms and instructions needed for inspection

Summary

- ✓ IQCP is voluntary, but EQC is no longer an option as of September 30, 2016, for international laboratories
- ✓ There are specific eligibility criteria
- ✓ IQCP is developed for each test system/device/instrument for each location
- ✓ Risk assessment must evaluate all phases of testing and include the five components
- ✓ Quality control plan must meet manufacturer's instructions as the starting point
- ✓ Quality assessment is ongoing for continuous improvement

References

- Clinical and Laboratory Standards Institute Guideline EP23-A and companion documents: <http://clsi.org/edu/ep23/>
- CDC/CMS Handbook: Developing an IQCP – A Step-by-Step Guide (<http://wwwn.cdc.gov/CLIA/Documents/IQCP%20Layout.pdf>)
- CMS Guidance and Brochures ([http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Individualized Quality Control Plan IQCP.html](http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Individualized_Quality_Control_Plan_IQCP.html))
- CAP All Common Checklist (July 28, 2015, and August 17, 2016, versions)
- CAP IQCP: cap.org
- ISO 14971: http://iso.org/iso/catalogue_detail?csnumber=38193



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