asm2015
115th General Meeting | American Society for Microbiology
May 30–June 2, 2015 | New Orleans, Louisiana

IQCP – GUIDELINES and TEMPLATE FOR GETTING STARTED

Linda C. Bruno, M.A., MT(ASCP)
Director, Microbiology and Molecular Labs
ACL Laboratories, Rosemont, IL
June 1, 2015

Disclosures

- No disclosures

IQCP – OUTLINE

- IQCP applications in Microbiology
- Current and future CMS QC standards for Microbiology
- Getting started on sample IQCP template

GOING AWAY 12/31/2015

Equivalent Quality Control (EQC)

Aka: QC performed once every 30 days and any frequency other than each day of patient testing

COMING 1/1/2016

Individualized Quality Control Plan (IQCP)

Aka: QC frequency will need to be determined based on IQCP Risk Assessment

IQCP Applications in Microbiology?

Microbiology – Test Systems where IQCP May Apply

All QC not performed each day of testing for **NON-WAIVED** tests:

- ID systems (M50 Streamline), including Yeast ID systems
- Sensitivity testing (eg Vitek, MicroScan, Etests, Disk diffusion testing)
- Rapid/Direct antigen kits (eg Rotavirus, RSV, Strep A, Legionella Urinary Antigen, Strep pneumoniae urinary Antigen, Flu)
- Reagent tests (Refer to current CMS reqs)
- Exempt Culture Media
- Rapid Molecular tests (eg Illumigene, BioFire, Cepheid)

Let's look what is in CMS/CLIA Standards And What CLSI documents are being DELETED from the Standards

Current CMS Laboratory Standards

*SubPart K - Quality System for Nonwaived Testing		QC Pos	QC Neg
QC Frequency:	**Each day of use**		
D5473 493.1256	AFB Stains (eg Kinyoun, Ziehl-Neelsen)	Yes	Yes
D5501 493.1261	Beta-lactamase other than Cefinase	Yes	Yes

*CLIA Advance copy-revised Appendix C-Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services, Jan 9, 2015

Current CMS Laboratory Standards

*SubPart K - Quality System for Nonwaived Testing		QC Pos	QC Neg
QC Frequency: Each time of use			
D5475 493.1256	Fluorescent stains (includes fluorochrome AFB) and immunohistochemical stains	Yes	Yes

*CLIA Advance copy-revised Appendix C-Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services, Jan 9, 2015

Current CMS Laboratory Standards

*SubPart K - Quality System for Nonwaived Testing		QC Pos	QC Neg
QC Frequency:	**Each new batch, lot #, and shipment**		
D5471 493.1256 (e)(1)	Bacitracin	Yes	Yes
	Catalase	Yes	Yes
	Cefinase	Yes	Yes
	Coagulase plasma	Yes	Yes
	Germ Tube test	Yes	No

*CLIA Advance copy-revised Appendix C-Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services, Jan 9, 2015

Current CMS Laboratory Standards

*SubPart K - Quality System for Nonwaived Testing		QC Pos	QC Neg
QC Frequency:	**Each new batch, lot #, and shipment**		
D5471 493.1256 (e)(1)	ONPG	Yes	Yes
	Optochin	Yes	Yes
	Oxidase	Yes	Yes
	Spot indole	Yes	Yes
	X and V factor strips and disks	Yes	No

*CLIA Advance copy-revised Appendix C-Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services, Jan 9, 2015

CLSI M50 being DELETED from CMS Laboratory Standards

*SubPart K - Quality System for Nonwaived Testing		QC Pos	QC Neg
QC Frequency:	**Each new lot # and shipment**		
D5471 493.1256 (e)(1)	**Identification systems**	Yes	Yes
	Check (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity of each substrate (includes mycology ID systems)		

*CLIA Advance copy-revised Appendix C-Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services, Jan 9, 2015

DELETED from CMS/CLIA

- CLSI M50 – Quality Control for Commercial Microbial Identification Systems
- Are you doing Stream-line QC ?
- If so, to continue stream-line QC you will need to do an IQCP

CLSI M22 being DELETED from CMS Laboratory Standards

*SubPart K - Quality System for Nonwaived Testing	Checks
QC Frequency: Each <u>new batch, lot #, and shipment</u> – check before or concurrent with initial use	
D5477 493.1256 (e)(4)	**Media** - Sterility - Ability to support growth - Select or inhibit specific organisms - Produce biochemical response - Document…when compromised…deterioration…

*CLIA Advance copy-revised Appendix C-Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services, Jan 9, 2015

Deleted from CMS/CLIA

- CLSI M22 – Quality Control for Commercially Prepared Microbiological Culture Media (since 1986)
- Exempt culture media listed in Table 1B of M22 will require IQCP (eg Blood agar, Thio broth, urease agar, blood culture media, CNA, MacConkey etc)
- NOTE: CMS does not distinguish between exempt and non-exempt culture media

Current CMS Laboratory Standards

*SubPart K - Quality System for Nonwaived Testing		QC Pos	QC Neg
QC Frequency:	**Each week of use**		
D5503 493.1261 (a)(2)	Gram stain	Yes	Yes

*CLIA Advance copy-revised Appendix C-Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services, Jan 9, 2015

Current CMS Laboratory Standards

*SubPart K - Quality System for Nonwaived Testing		QC Pos	QC Neg
QC Frequency: every 6 months	**Each lot # and shipment, and once**		
D5505 493.1261 (a)(3)	Salmonella and Shigella antisera, streptococcal serotyping systems	Yes	Yes

*CLIA Advance copy-revised Appendix C-Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services, Jan 9, 2015

CLSI M100 being DELETED from CMS Laboratory Standards

*SubPart K - Quality System for Nonwaived Testing		QC Organisms
QC Frequency: Each batch of media AND each lot # and shipment of antimicrobial agents before, or concurrent with initial use		
D5507 493.1261 (b)	**Antimicrobial susceptibility test**	Yes

*CLIA Advance copy-revised Appendix C-Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services, Jan 9, 2015

CLSI M100 being DELETED from CMS Laboratory Standards

*SubPart K - Quality System for Nonwaived Testing		QC Organisms
QC Frequency: Each day tests are performed, must use appropriate control organisms to check procedure		
D5507 493.1261 (b)(1)	**Antimicrobial susceptibility test**	Yes

*CLIA Advance copy-revised Appendix C-Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services, Jan 9, 2015

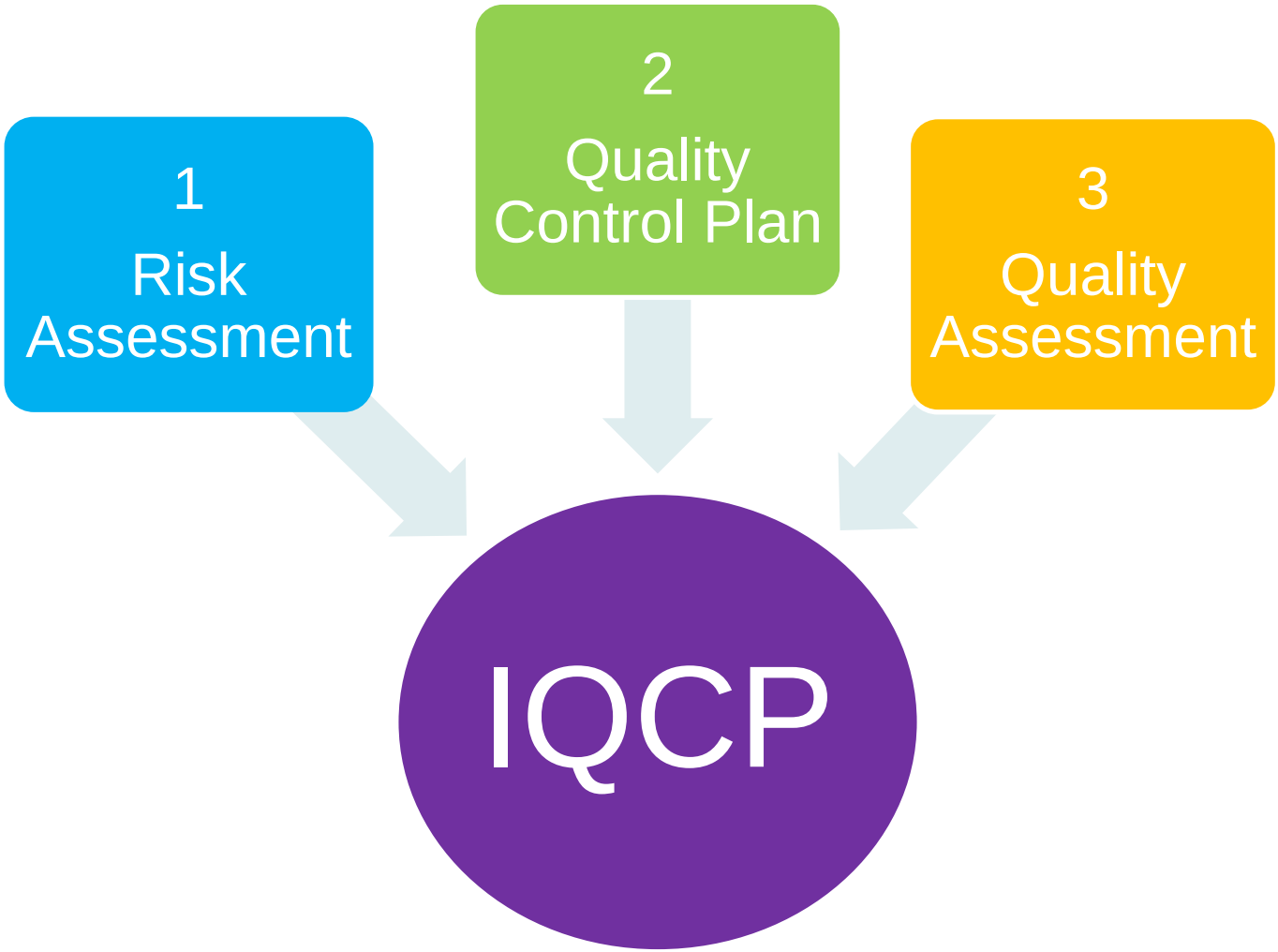
Deleted from CMS/CLIA

- CLSI M100 – Performance Standards for Antimicrobial Susceptibility Testing
- All disk diffusion and MIC susceptibility testing with weekly QC will need IQCP
- Labs performing gradient MIC susceptibility testing with weekly QC will need IQCP

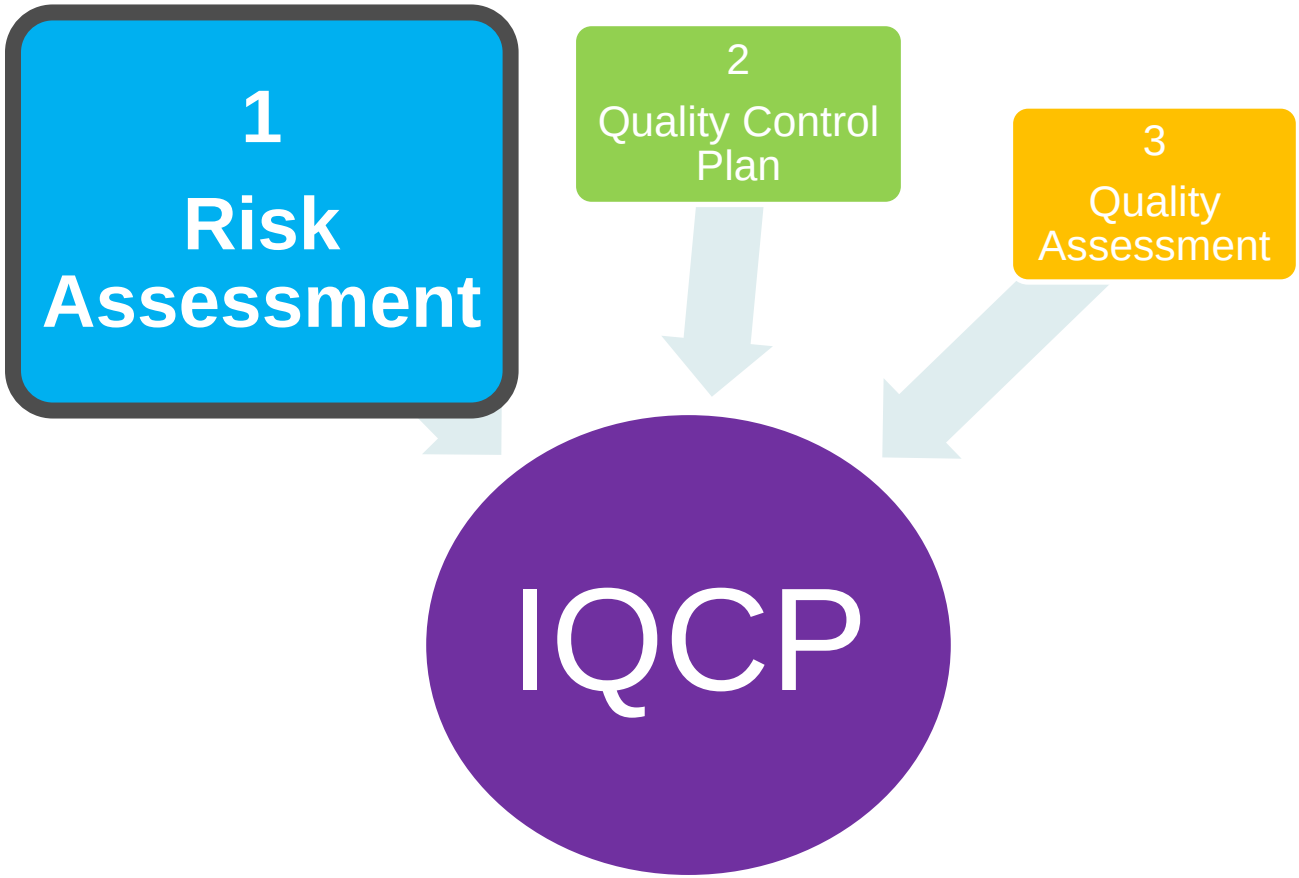
CLSI References being DELETED
CMS/CLIA Clinical Lab Standards

- M100 Sensitivity QC
- M22 Media QC
- M50 Microbial ID Systems – Streamline QC

Individualized Quality Control Plan (IQCP)



Individualized Quality Control Plan (IQCP)

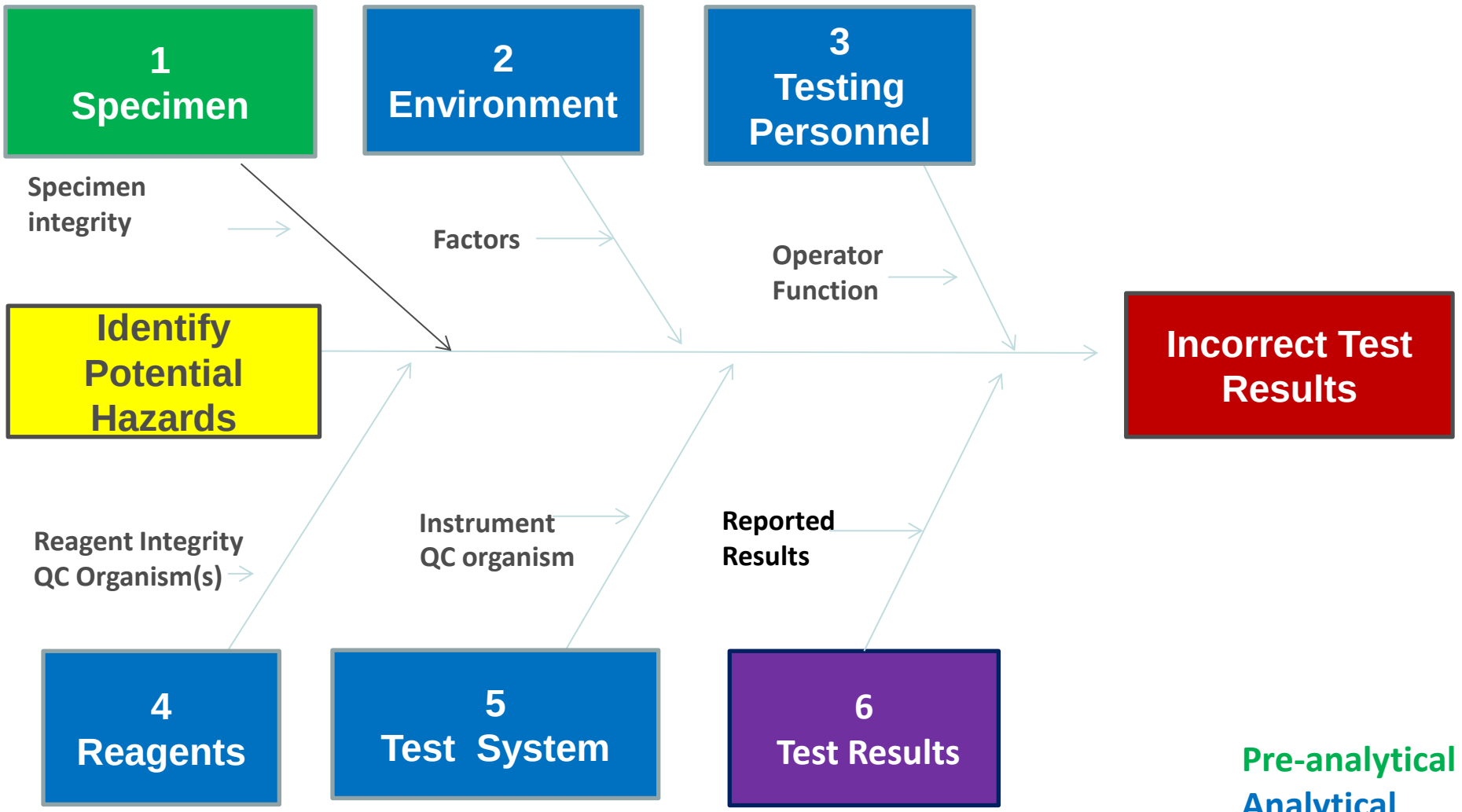


IQCP – Risk Assessment (RA)

1. **Risk Assessment:**
   - Five components that MUST be covered are:
     - **Specimen** (collection, transport, integrity, receiving, processing …)
     - **Lab Environment** (temperature, humidity, power failure …)
     - **Testing personnel** (training, competency, proficiency testing, staffing…)
     - **Reagent/QC** (shipping, storage, preparation, expiration date …)
     - **Test system** (sample failure, reagent failure, software failure, hardware failure..)
     - **Test results** (transmission of results…)

   NOTE:May be separated out from Test System

RISK ASSESSMENT:
Identification of Potential Failures



Pre-analytical
Analytical
Post-analytical

RA - Specimen

Review all policies and procedures relating to:

- Patient identification
- Collection containers
- Specimen collection
- Specimen rejection criteria
- Labelling of containers
- Specimen volume
- Transport
- Storage
- **HOW OFTEN WERE THERE ERRORS? AND**
- **WHAT WAS SEVERITY OF PATIENT HARM?**

RA – Environment

Factors that may affect test system:

- Temperature – review records
- Humidity – review records
- Ventilation
- Electric – are there power surges?
- Space – If cramped, could test system be compromised?
- Noise / vibration
- Water quality – does test system require DI water? If so, review those records
- **HOW OFTEN DID ISSUES OCCUR? AND WHAT WAS THE SEVERITY OF PATIENT HARM?**

RA – Testing Personnel

Are there records / documentation for:

- Training – checklists for each person trained to perform test?
- Competency assessment – is there documentation for each person performing this test system or assay?
- Proficiency Testing –is there PT for this test system and is there remedial action for unsatisfactory results? Is it reviewed?
- Staffing –
- **HOW OFTEN WERE THERE ISSUES? AND WHAT WAS THE SEVERITY TO PATIENT HARM?**

RA - Reagents

Reagent Integrity:

- Shipping and storage – any documented issues?
- Expiration dates – review policy and procedure – any issues?
- Reagent preparation – review policy and procedure – any issues?
- QC – any issues?
- **HOW OFTEN WERE THERE ISSUES? AND WHAT WAS THE SEVERITY OF PATIENT HARM?**

RA – Test System

Instrument / Assay:

- Software – documentation of installs, validation data afterwards, any issues?
- Hardware or LIS interface – any issues
- Contamination
- Maintenance – review of all records, any trends or recurring issues?
- Proper specimen sampling – any issues
- Calibration – any issues
- QC – any failures, review of all records
- **HOW OFTEN WERE THERE ISSUES? AND WHAT WAS THE SEVERITY OF PATIENT HARM?**

RA – Test System

Also review:

- Manufacturer's package insert – what are the limitations of the test / assay
- What are the interfering substances?
- Verification/validation data – review, any issues?
- Physician or client complaints

RA – Test Results

Reported results:

- Transmission of results to Hospital Information Systems (HIS)
- Review of released results
- Clinician feedback
- **HOW OFTEN WERE THERE ISSUES? AND WHAT WAS THE SEVERITY OF PATIENT HARM?**

RA - Risk Assessment

After identifying all potential sources of risk/error for each of the five (5) or six (6) components:

- determine the "Frequency of occurrence" and the "Possible severity of harm" for each risk identified, based on documented records of failure or error

RA - Risk Assessment

- Why – do you want to do this?
- Per CMS
- *"To conduct a risk assessment, the laboratory must identify the sources of potential failures and errors for a testing process, and evaluate the frequency and impact of those failures and sources of error."**

* CMS Ref: Survey and Certification: 13-54-CLIA, August 16, 2013

RA – What Determines Frequency of Occurrence and Severity of Harm?

Review all failure/error data, how many times in a week, month, year did a particular failure or error occur? Did it cause harm to the patient?

- Corrective action reports
- Proficiency Testing corrective action
- Retraining of personnel
- Temperature out-of-control records
- QC failures

Determining Risk

- "Frequency of occurrence"

  How often does this error occur? Review all data to determine frequency

- "Severity of harm"

  When error occurred, what was the harm to the patient or possible harm that could be to the patient?

Determining Risk – Example 4 levels

Frequency of Occurrence	Severity of Harm
Unlikely (once /2-3 yrs)	Negligible (temporary discomfort)
Occasional (1/yr)	Minor (temporary injury; not requiring medical intervention)
Probable (1/mo)	Serious (impairment requiring medical intervention)
Frequent (1/wk)	Critical (permanent impairment requiring medical intervention)

Determining Risk – Example 5 levels

Frequency of Occurrence	Severity of Harm
Rare (once /2-3 yrs)	Negligible (temporary discomfort)
Unlikely (1/yr)	Minor (temporary injury; not requiring medical intervention)
Possible (1/mo)	Moderate (may require medical intervention)
Likely (2/mo)	Serious (impairment requiring medical intervention)
Almost certain (1/wk)	Critical (permanent impairment requiring medical intervention)

Risk Matrix from CLSI EP-23

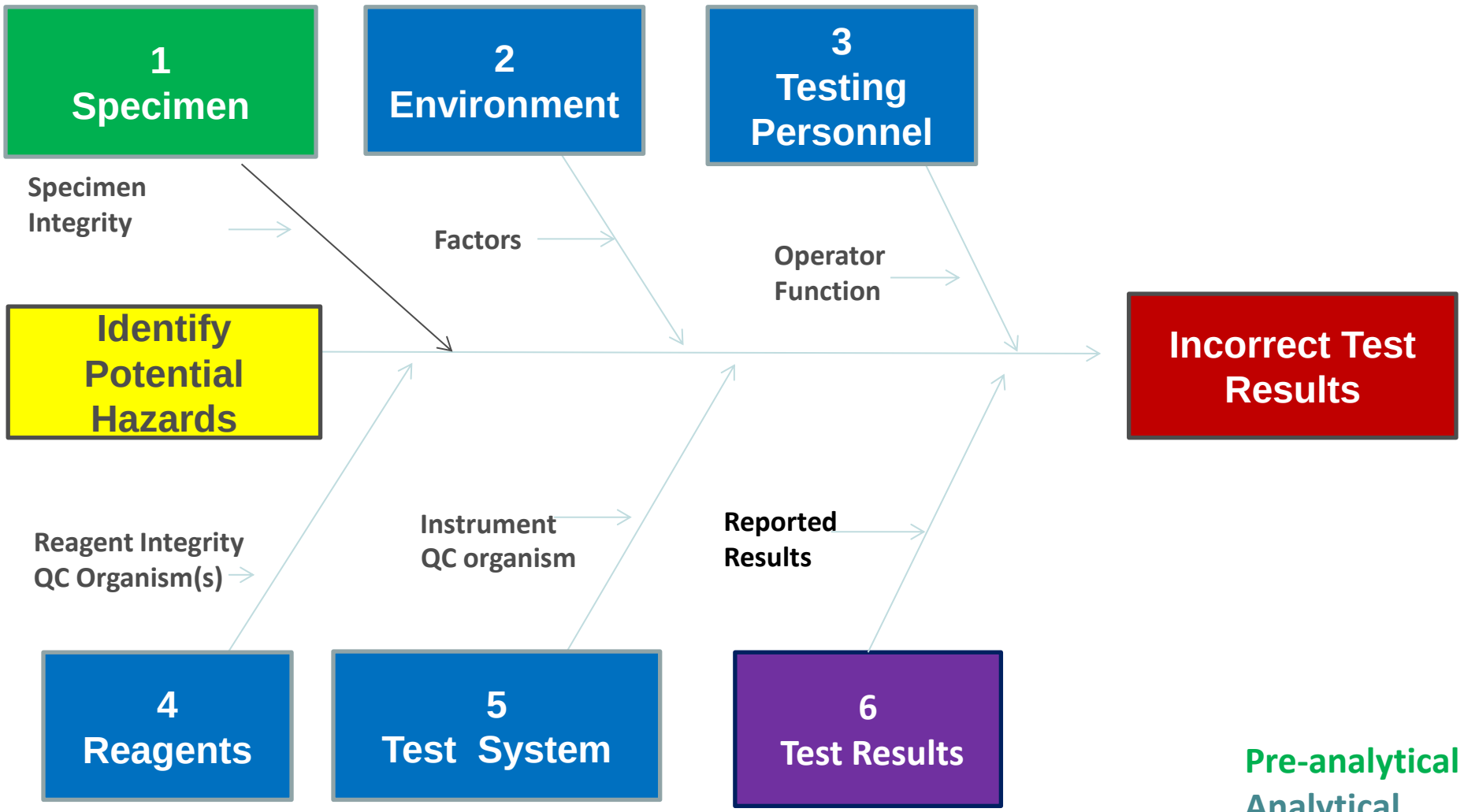
Severity of harm **(Impact)**					
Probability of harm (Frequency)	Negligible	Minor	Serious	Critical	Catastrophic
Frequent	U	U	U	U	U
Probable	A	U	U	U	U
Occasional	A	A	A	U	U
Remote	A	A	A	U	U
Improbable	A	A	A	A	A

A = Acceptable risk U = Unacceptable risk

Risk Assessment Table

- The following table is an example of how to present the risk. Table/grid represents each of the five or six components and the
  - identified related risk/error
  - frequency of occurrence and
  - severity of harm
  - Measures to control risk
  - Relevant SOP

RISK ASSESSMENT:
Identification of Potential Failures



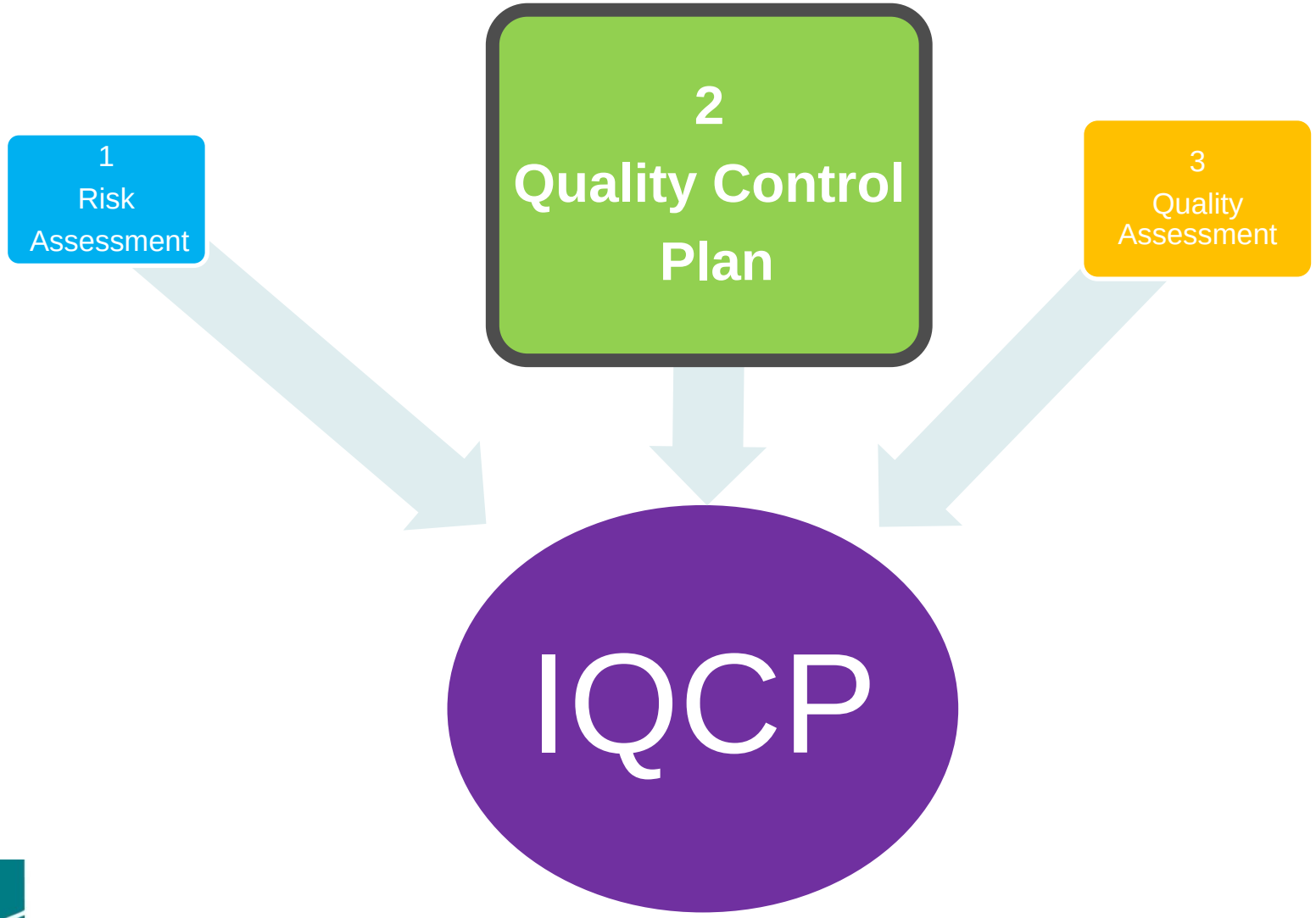
Pre-analytical
Analytical
Post-analytical

Risk Assessment – Specimen
EXAMPLE of TABLE FORMAT

1 Specimen	Frequency of Occurrence	Severity of Harm	Measures to control risk	Relevant SOP
List each risk identified	List frequency of occurrence	List degree of severity of harm	List how risk will be controlled	Reference SOP that support control measure

- Repeat this process for each component and all risks identified under that component
- **UNACCEPTABLE** risks **must** be included in Quality Control Plan
- **ACCEPTABLE** risks may be included in the Quality Control Plan at the discretion of the Laboratory Director.

Individualized Quality Control Plan (IQCP)



Quality Control Plan (QCP)

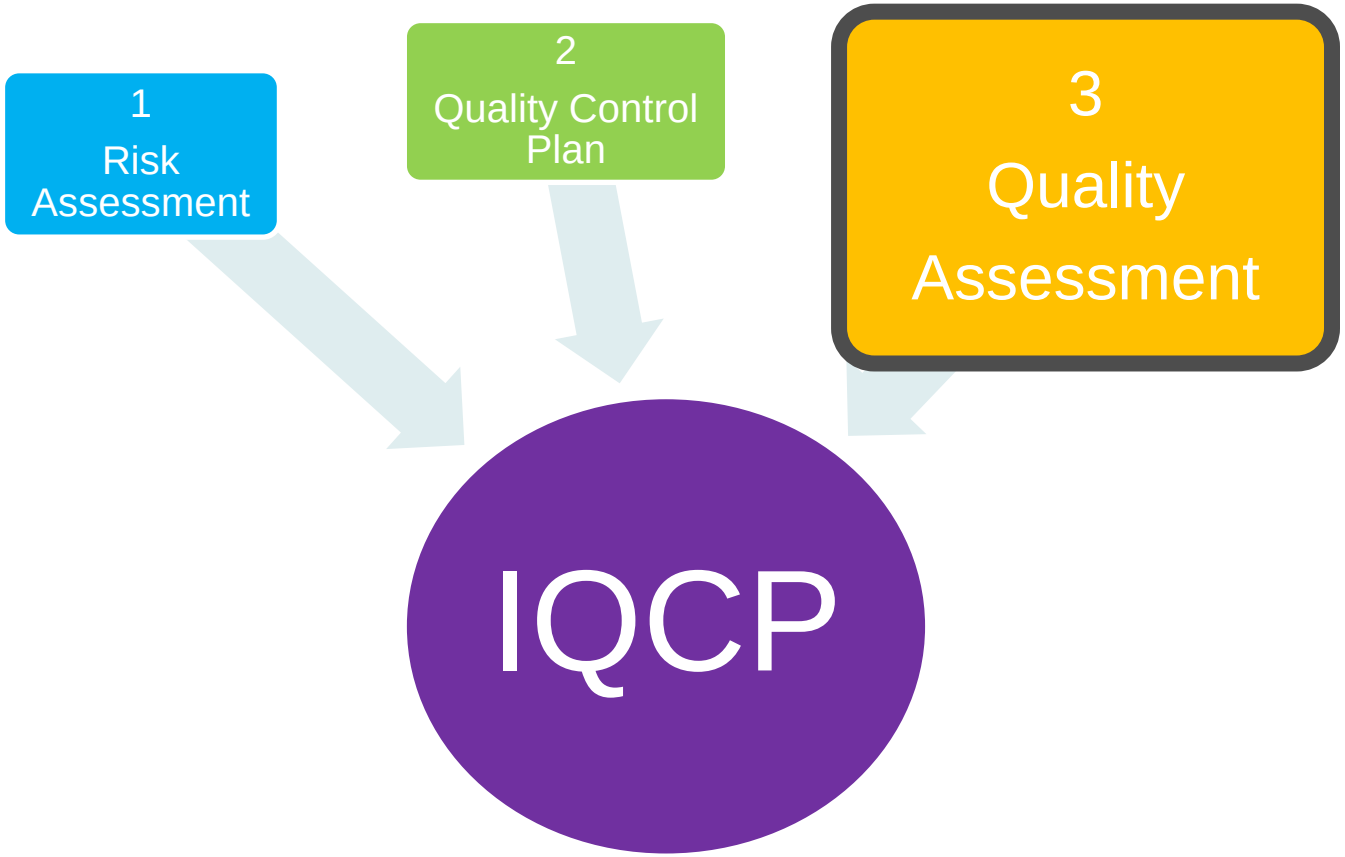
- Resulting "Risk Assessment" is then used to develop the Quality Control Plan (QCP)
- Risks identified as UNACCEPTABLE must be included in QCP and address:
  - How will these risks be controlled?
  - How often does QC need to be performed based on the potential risks identified?
  - What QC material needs to be used?
  - What is the criteria for QC acceptability?

Quality Control Plan (QCP) What Is It?

Document (or chart/table) that describes practices, resources, and procedures used to control the quality of a test system.

- Must monitor accuracy and precision of test performance
- **MUST include:**
  - ✓ **number of QC,**
  - ✓ **type of QC,**
  - ✓ **frequency of QC and**
  - ✓ **define criteria for acceptability of QC**
- MUST have Lab Director's review, approval, signature (this cannot be delegated)
- NOTE: Lab Director is the name on the lab CLIA license

Individualized Quality Control Plan (IQCP)



Quality Assessment - Overview

Laboratory must establish a review system for on-going monitoring of effectiveness of their QCP.

Monitoring must include at least the following:

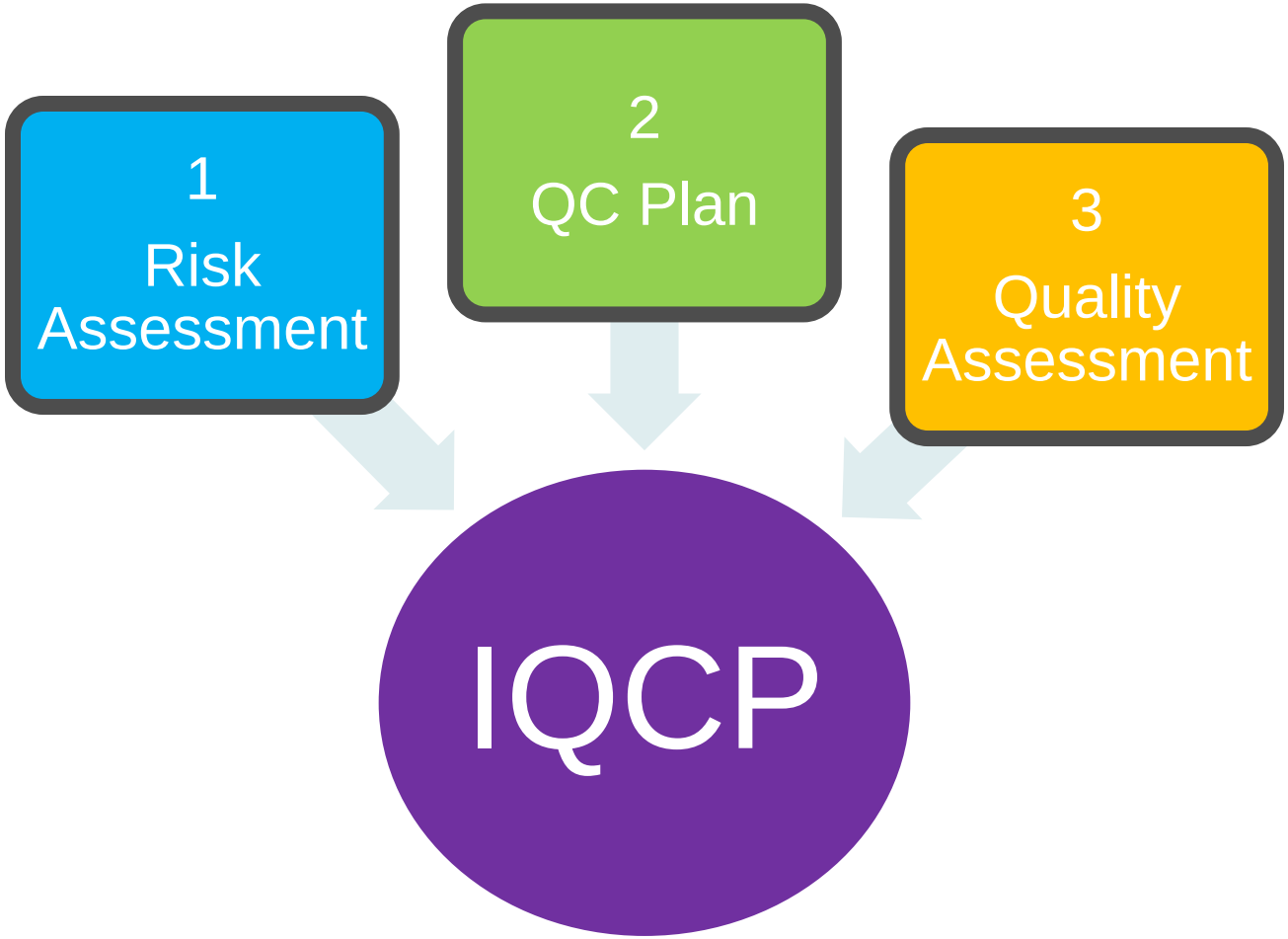
- **Specimens**
- **Testing personnel**
- **Testing environment**
- **Test reagents**
- **Test system**

Quality Assessment – Overview (cont)

When a testing process failure is discovered, lab must conduct and document an investigation to:

- Identify cause of the failure,
- its impact on patient care, and
- make appropriate modifications to their QCP
- Modifications will need review and approval by Lab Director
- QCP signed / dated again

Individualized Quality Control Plan (IQCP)



References

- CLIA Advance copy-revised Appendix C- Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services, Jan 9, 2015
- CMS Ref: Survey and Certification: 13-54-CLIA, August 16, 2013

THANK YOU