IQCP – What Is It? A Guide for Implementation

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IQCP - OUTLINE

- Explanation of current QC options for Microbiology
- IQCP overview
- Microbiology tests that do NOT require IQCP
- Microbiology tests that are eligible for IQCP
- Sample template
- CAP Requirements/Checklist questions relating to IQCP

TWO THINGS GOING AWAY 1/1/2016

1. **Equivalent Quality Control (EQC)**

   (Ex. QC performed once every 30 days as in kits/cartridges with internal controls)

2. **All references to CLSI documents in CMS CLIA standards:**
   - **QC susceptibility testing – weekly (M100)**
   - **QC exempt media- not required by end user (M22)**
   - **Streamline QC on Identification Systems (M50)**

COMING 1/1/2016

Individualized Quality Control Plan (IQCP)

(AKA: QC frequency will need to be determined based on Risk Assessment)

So what's the difference between EQC and IQCP?

EQC vs IQCP (CMS/CLIA)

Current EQC	Future IQCP – coming 1/1/16
Transitional	Updated Solution
Standardized	Customizable
Rigid	Flexible
Narrow scope Limited regulations Limited specialties	Broader scope More regulations Applicable to all except Path
Applies to Analytic phase only	**Applies to Pre-Analytic, Analytic and Post-Analytic**
Requires Internal QC Decreases External QC	Does not require Internal QC May/may not decrease QC

IQCP

What is the rationale for moving to IQCP?

- Changes in healthcare environment & delivery of services
- Advances in technology
- Regulatory ‘one-size-fits –all’ no longer suitable
- Equivalent Quality Control (EQC) as an alternative was a 1st step; proved too limited & rigid
- Need a flexible program & plan for the future that evaluates the entire testing process

IQCP

Why should labs use IQCP?

- Provides customizable framework for unique QC plan for each test Includes specimen, environment, test system, personnel, etc.
- Uses data & information already available
- Is broad in scope: considers all phases of test process & specialty requirements
- Risk Assessment review & documentation lead to comprehensive Quality Control Plan with appropriate controls & quality activities, Quality Assessment and continually monitoring
- Can be used for compliance w/ future technology

LET'S TAKE A CLOSER LOOK AT IQCP

CMS IQCP – WHAT IS IT?

IQCP consists of three key parts:

1. Risk Assessment (RA)

   Identifies areas where errors or failures could occur in entire workflow path

   (pre-analytical, analytical, post-analytical); and assesses risk for harm to the patient if an error would occur and be reported

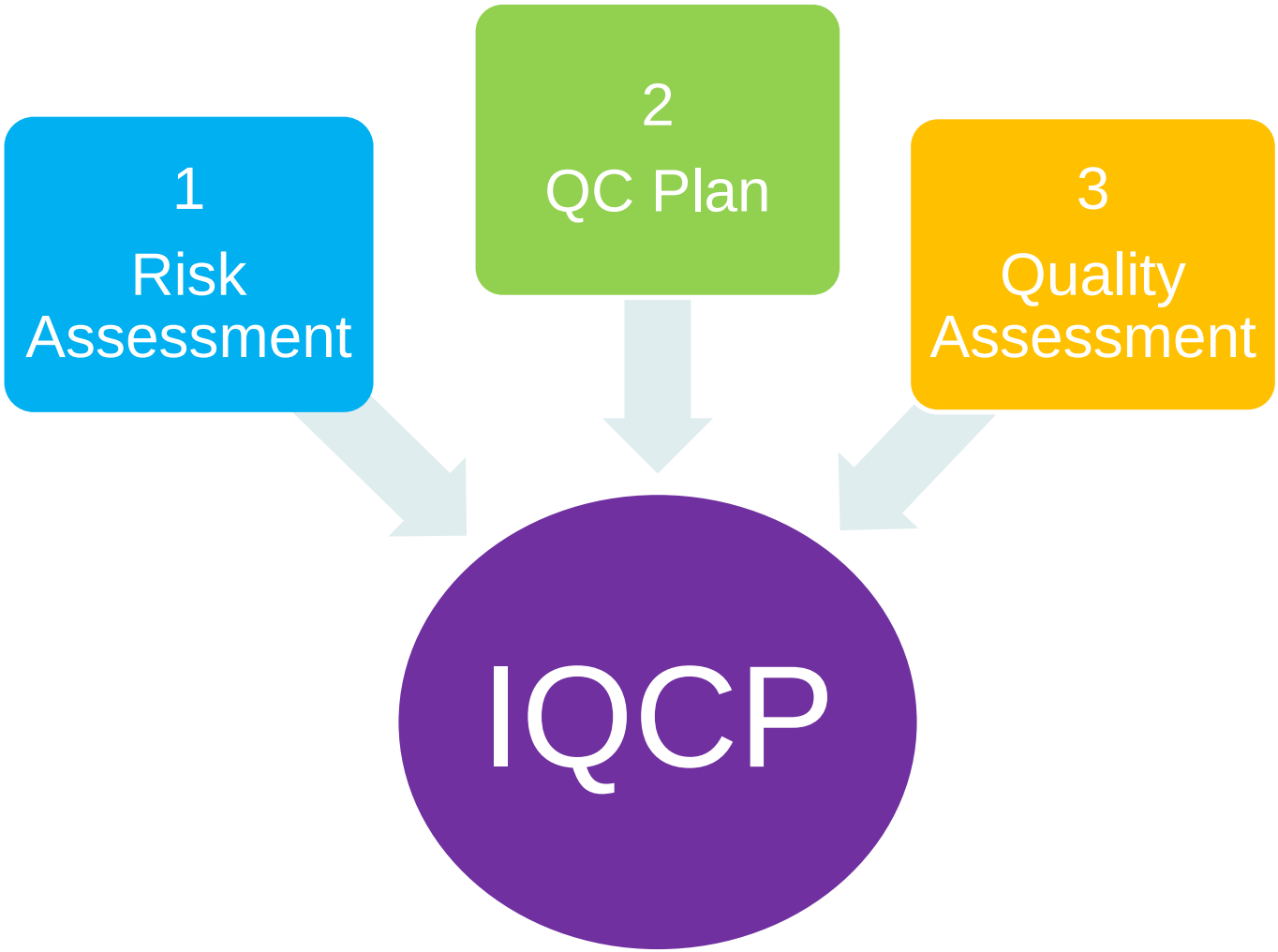
2. Quality Control Plan (QCP)

   Defines the control mechanisms in place for detecting or preventing errors

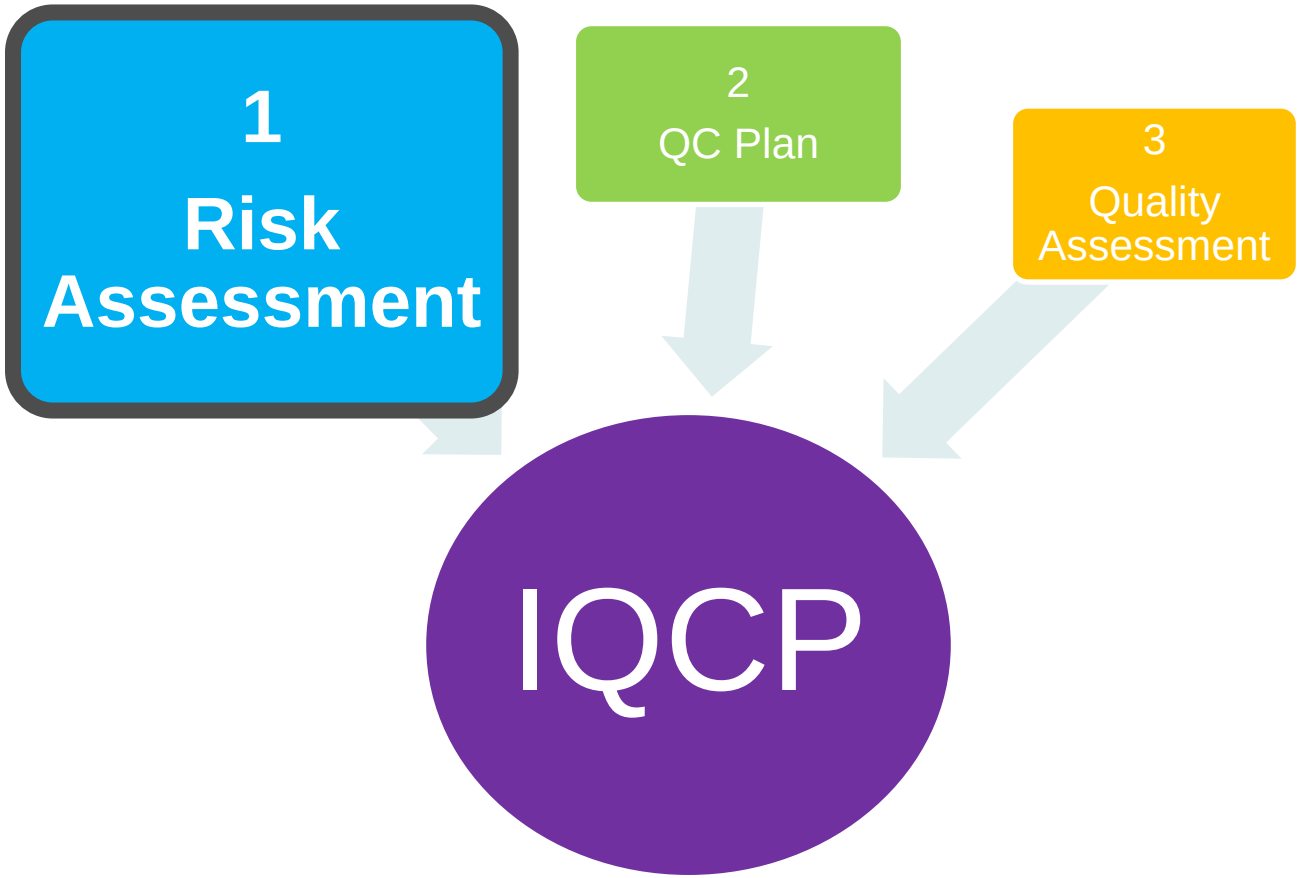
3. Quality Assessment (QA)

   Continually monitors effectiveness of QCP

Individualized Quality Control Plan (IQCP)



Individualized Quality Control Plan (IQCP)



What is IQCP – Part 1

1. **Risk Assessment (RA)** – looks at entire testing process from:

   specimen collection → test result

   to identify sources of potential failures and/or errors

   - **Pre-analytical**—sample collection through storage
   - **Analytical**—testing process & system
   - **Post Analytical** —result reporting

IQCP – Risk Assessment (RA)

1. **Risk Assessment (continued):**
   - 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..)

Risk Assessment

Reference:

- See page 3 of this link to CMS information on areas to include for potential sources of error for the 5 risk assessment components

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

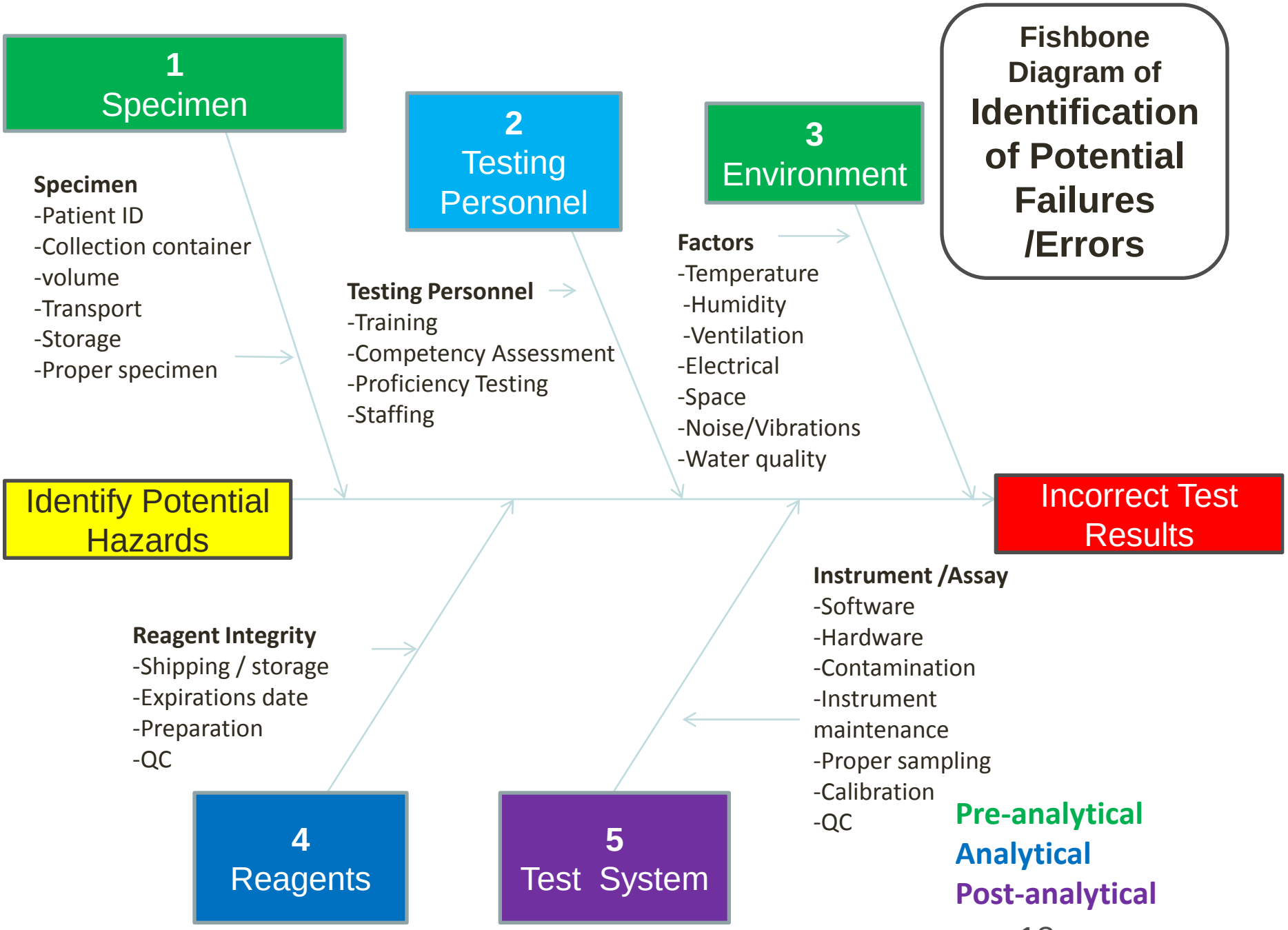
RISK ASSESSMENT- Overview

- Gather pertinent information and data
- Review for areas of risk/error

- Document the review
- Identify potential areas of risk that may cause failure or be sources of error within the entire testing system/process
- Evaluate the frequency of those failures/errors
- Weigh the severity those failures/errors could have on causing harm to patients

RISK ASSESSMENT

Tools you can use


Fishbone Diagram of Identification of Potential Failures /Errors
1 Specimen
2 Testing Personnel
3 Environment
Specimen
-Patient ID
-Collection container
-volume
-Transport
-Storage
-Proper specimen
Testing Personnel
-Training
-Competency Assessment
-Proficiency Testing
-Staffing
Factors
-Temperature
-Humidity
-Ventilation
-Electrical
-Space
-Noise/Vibrations
-Water quality
Identify Potential Hazards
Incorrect Test Results
Reagent Integrity
-Shipping / storage
-Expirations date
-Preparation
-QC
Instrument /Assay
-Software
-Hardware
-Contamination
-Instrument maintenance
-Proper sampling
-Calibration
-QC
4 Reagents
5 Test System
Pre-analytical
Analytical
Post-analytical

RA - Specimen

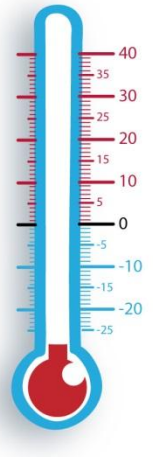
Review all policies and procedures relating to:

- 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

Risk Assessment

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

- Build table(s) or grid(s) for each component and list all risks identified from fishbone diagram or other format used
- Based on documented records of failure or error, determine the "Frequency of occurrence" and the "Possible severity of harm" for each risk identified.

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

Risk Assessment Table

- The following table is an example of how to present the risk. Table/grid represents each of the five components and the identified related risk/error and its associated frequency of occurrence and severity of harm.

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?

CLSI EP-23 document: **Risk Matrix**

	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

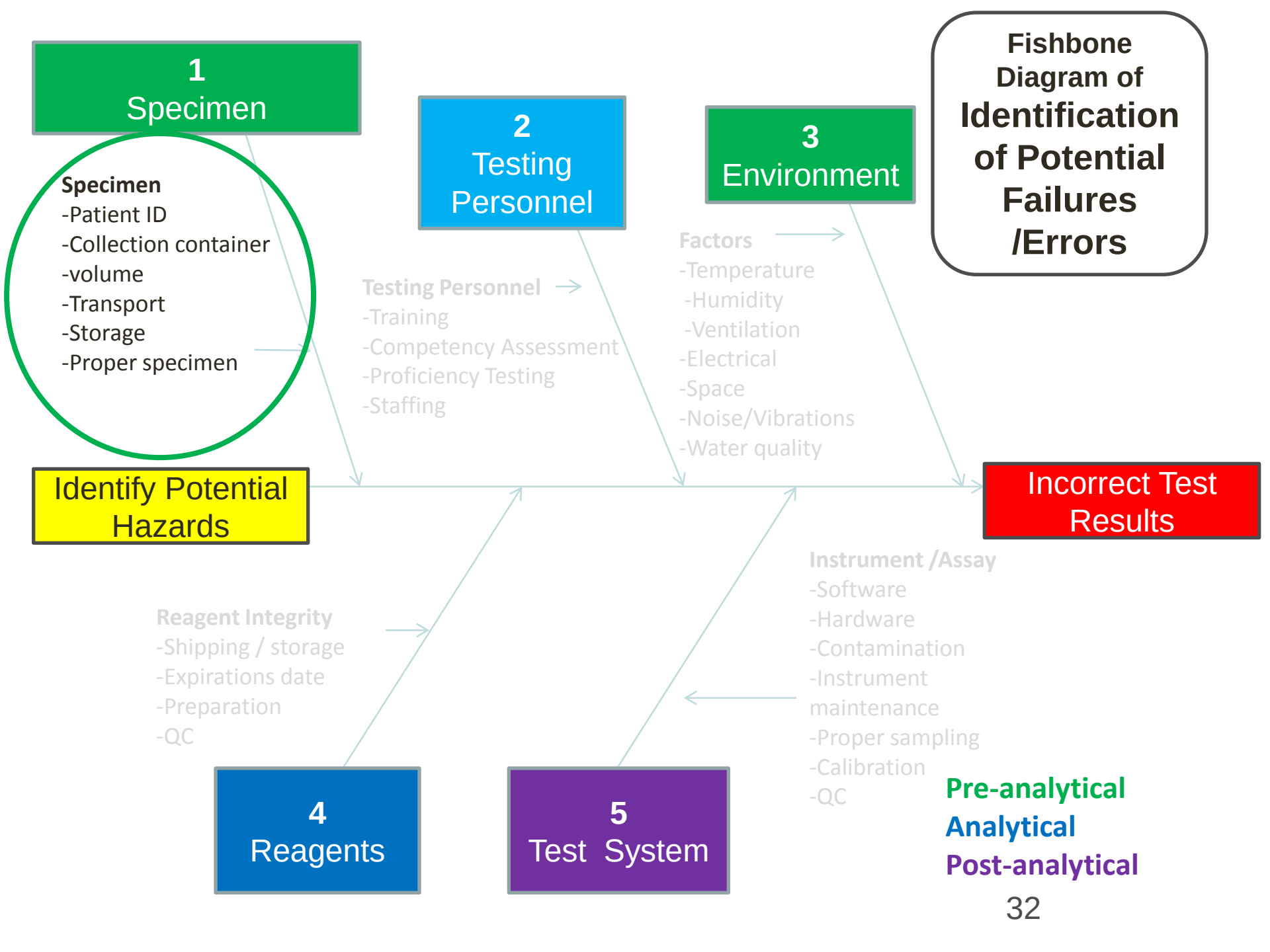
U = Unacceptable risk

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)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Analytical
Post-analytical

Risk Assessment – Specimen
EXAMPLE of TABLE FORMAT

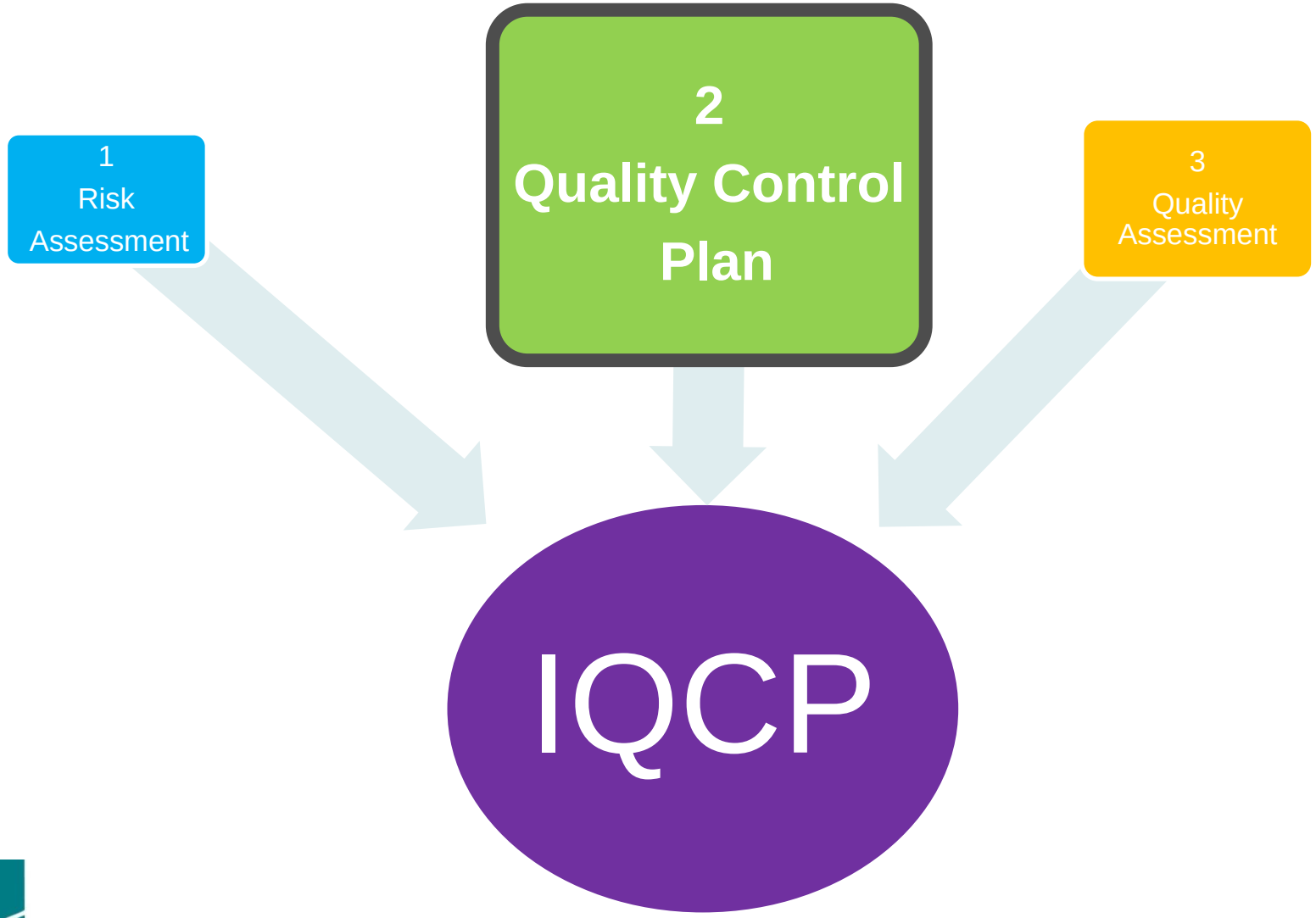
1 Specimen	Frequency of Occurrence	Severity of Harm	Measures to control risk	Relevant SOP
Patient identification	Occasional	Minor-Critical	Patient identification criteria defined; acceptability defined; competency assessment performed	SOP# SOP# SOP#
Collection/ Container/ Volume	Occasional	Minor-Critical	Collection/ container criteria defined per source; acceptability defined; competency assessment performed	SOP# SOP# SOP#

Risk Assessment (and then what?)

Resulting “Risk Assessment” is then used to develop the Quality Control Plan (QCP)

- 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?

Individualized Quality Control Plan (IQCP)



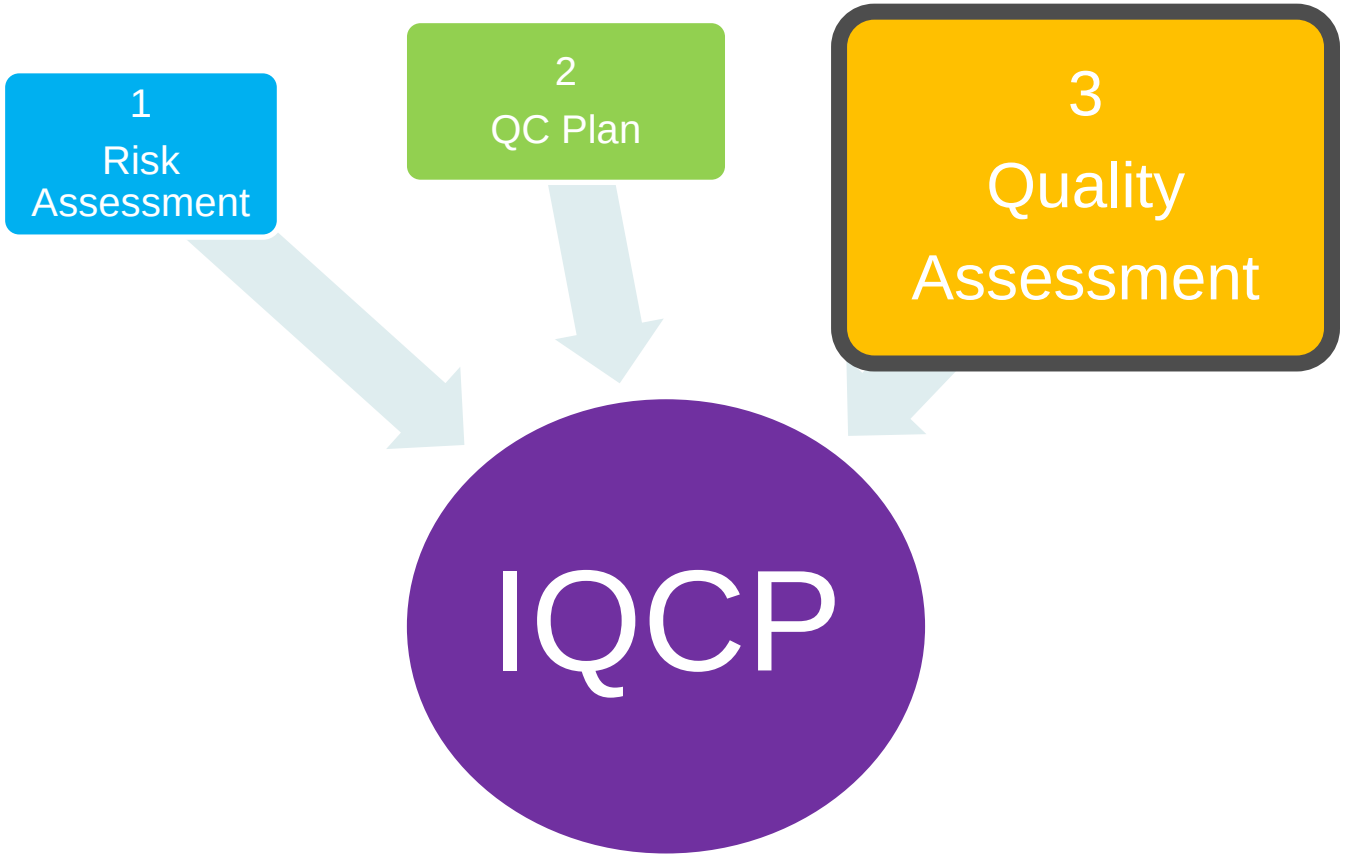
Quality Control Plan (QCP) - Overview

What is QCP?

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:

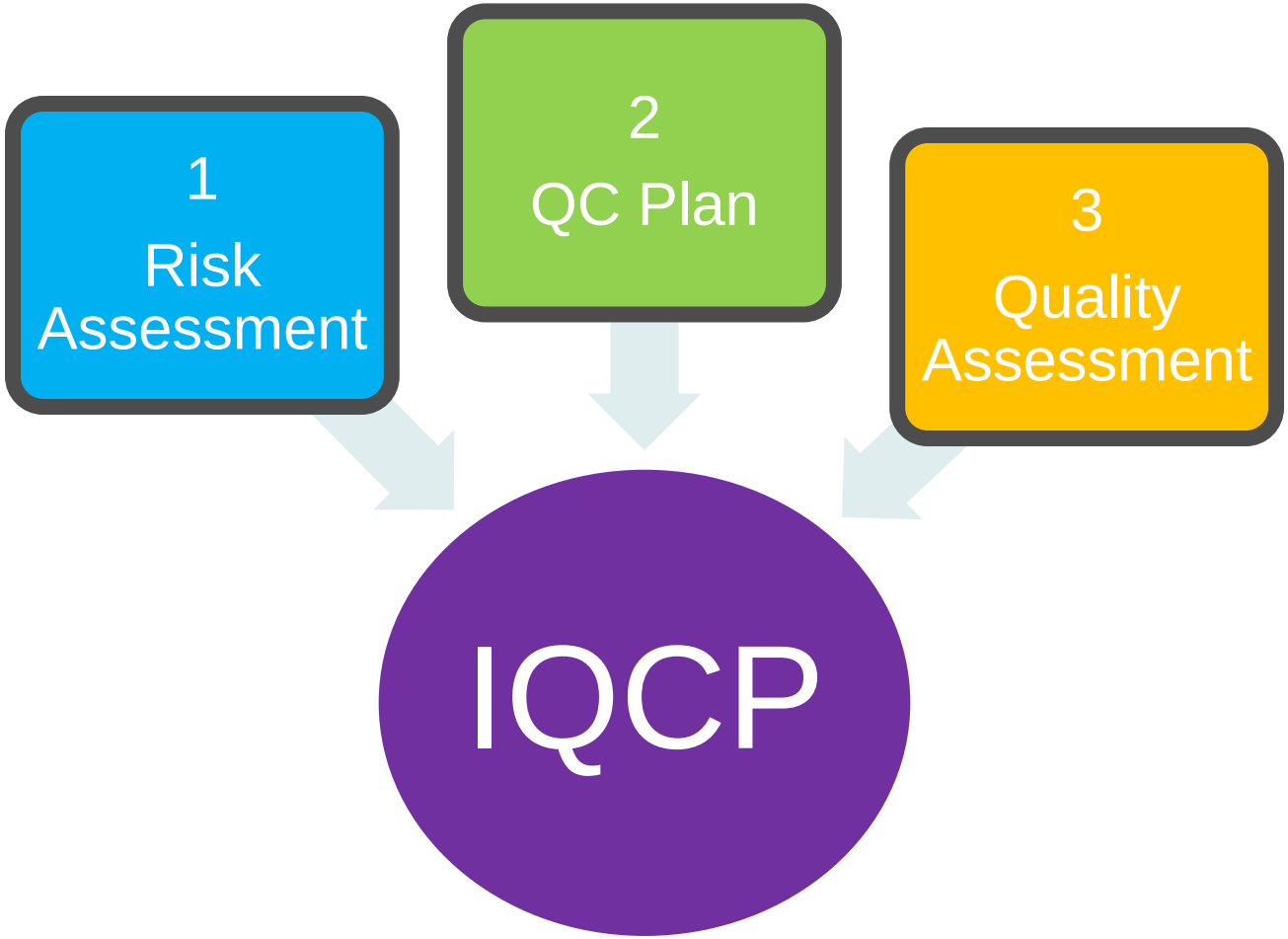
- testing personnel
- testing environment
- specimens
- test reagents
- test system

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 should be approved by Lab Director
- May want to have QCP signed / dated again

Individualized Quality Control Plan (IQCP)



Implementation of IQCP

CMS IQCP Education & Transition - Two years long

- 2014 and 2015, during this time labs may implement

Until December 31, 2015: Microbiology Labs may use:

- CLIA QC regulations (QC each day of testing),
- EQC
- CLSI M100, M22, and M50
- or IQCP

By January 1, 2016: Laboratories must follow:

- CLIA QC regulations 'default' or
- IQCP
- **All new / existing test systems must be in compliance**

Mandatory vs. Voluntary

IQCP is voluntary for laboratories, however

Current CMS/CLIA control “default” regulations will continue to be in effect

EQC will be discontinued, as well as the references to CLSI M100, M22 and M50 in CMS CLIA standards January 1, 2016

What Specialties / Subspecialties Are Eligible for IQCP

IQCP – Applicable to CLIA-Certified Labs

Specialties/subspecialties ELIGIBLE -IQCP		Not Eligible - IQCP
Bacteriology	Urinalysis	Pathology
Mycobacteriology	Endocrinology	Histopathology
Mycology	Toxicology	Oral Pathology
Parasitology	Hematology	Cytology
Virology	Immunohematology	
Syphilis Serology	Radiobioassay	
General Immunology	Clinical Cytogenetics	
Routine Chemistry	Histocompatibility	

Ref: CMS Memo S&C: 13-54-CLIA

What Does IQCP Apply To 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, Disk diffusion testing)
- Rapid/Direct antigen kits (eg Rotavirus, RSV, Strep A, Legionella Urinary Antigen, Strep pneumoniae urinary Antigen, Flu)
- Exempt Culture Media
- Rapid Molecular tests (eg Illumigene, BioFire, Cepheid)

Let's look at the 'default'
CMS/CLIA Standards
(and CAP requirements)
Relating to
Microbiology
(These do NOT need an IQCP)

Continue performing

QC frequency as you are currently doing as

outlined in the

next few slides

CMS and CAP QC Requirements – These do NOT need IQCP

Test	QC Frequency CMS/CLIA	QC Frequency CAP
Gram stain	Weekly	Weekly
AFB Stain (Kinyoun)	Each day of use	Each day of use
AFB Fluorescent stain	Each time of use	Each time of use
Beta Lactamase other than Cefinase	Each day of use	Each day of use

CMS and CAP QC Requirements – These do NOT need IQCP

Test	QC Frequency CMS/CLIA	QC Frequency CAP
Bacitracin	Each new batch, lot # and shipment	
Catalase	Each new batch, lot # and shipment	
Cefinase	Each new batch, lot # and shipment	
Coagulase Plasma	Each new batch, lot # and shipment	
Staph latex	Each new batch, lot # and shipment	

CMS and CAP QC Requirements – These do NOT need IQCP

Test	QC Frequency CMS/CLIA	QC Frequency CAP
ONPG	Each new batch, lot # and shipment	
Optochin	Each new batch, lot # and shipment	
Oxidase	Each new batch, lot # and shipment	
Spot indole	Each new batch, lot # and shipment	
X and V factor strips and disks	Each new batch, lot # and shipment	

CMS and CAP QC Requirements – These do NOT need IQCP

Test	QC Frequency CMS/CLIA	QC Frequency CAP
Salmonella and Shigella antisera, streptococcal serotyping systems	Each lot # and shipment, and once every 6 months	
LactoPhenol Cotton Blue	Each lot number (commercially prepared), and shipment	
Parasitology permanent stain(s)	Each month of use, the laboratory must check permanent stains using a fecal sample control material that will demonstrate staining characteristics	

CMS and CAP QC Requirements – These do NOT need IQCP

Test	QC Frequency CMS/CLIA	QC Frequency CAP
Antimycobacterial susceptibility test	Each week tests are performed, laboratory must use the appropriate control organism(s) to check the procedure	
	Each batch of media and each lot number and shipment of antimycobacterial agent(s) before, or concurrent with, initial use, using an appropriate control organism(s)	

CMS and CAP QC Requirements – These do NOT need IQCP

Test	QC Frequency CMS/CLIA	QC Frequency CAP
Antifungal susceptibility tests	Each day tests are performed, laboratory must use the appropriate control organism(s) to check the procedure	
	Each batch of media and each lot number and shipment of antimycobacterial agent(s) before, or concurrent with, initial use, using an appropriate control organism(s)	

Tests Eligible for IQCP

For these tests –labs may do 'default' QC listed on this slide or IQCP

Test	QC Frequency CMS/CLIA	QC Frequency CAP
Identification Systems	**Each new lot # and shipment**	
	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)	

For these tests –labs may do 'default' QC listed on this slide or IQCP

Test	QC Frequency CMS/CLIA	QC Frequency CAP
Antimicrobial Susceptibility testing	**Each batch of media AND each lot # and shipment of antimicrobial agents before, or concurrent with initial use**	
	QC Frequency: **Each day tests are performed**, must use appropriate control organisms to check procedure	

For these tests –labs may do 'default' QC listed on this slide or IQCP

Test	QC Frequency CMS/CLIA	QC Frequency CAP
Media	**Each new batch, lot #, and shipment – check before or concurrent with initial use**	
	- Sterility - Ability to support growth - Select or inhibit specific organisms - Produce biochemical response - Document…when compromised…deterioration…	

AGAIN

Microbiology Tests That Do NOT Need An IQCP

CMS Standards - Summary of What Does NOT Need IQCP

- Gram Stain
- AFB Kinyoun Stain
- AFB Fluorescent stain
- Beta Lactamase other than Cefinase
- Bacitracin
- Catalase
- Cefinase
- Coagulase plasma
- Staph latex

Summary of What Does NOT Need IQCP

- Germ Tube test
- ONPG
- Oxidase
- Spot Indole
- X and V factor strips and disks
- Identification systems (if NOT using streamline QC)
- Non-exempt media (as defined in CLSI M22)
- Salmonella and Shigella antisera
- Streptococcal serotyping systems

CMS Standards - Summary of What Does NOT Need IQCP

- EIA testing in 96 well format, or break away wells (Manufacturers recommended positive and negative controls run with each batch)
- Non-exempt culture media (keep performing QC as currently doing – no change)
- Antimycobacterial susceptibility test (continue performing frequency)
- Lactophenol Cotton Blue

CMS Standards - Summary of What Does NOT Need IQCP

- Antifungal susceptibility tests (continue performing each day tests are performed)
- Parasitology permanent stains (monthly)

What is Eligible for IQCP in Microbiology

- Tests that have an internal control
- Exempt culture media
- Antimicrobial susceptibility testing
- Identification Systems (for Streamline QC)

Something to think about …

Manufacturer's Instructions

Laboratories performing non-waived tests must follow all manufacturers instructions.

When the manufacturer's instructions for QC are absent or less stringent than the "default" CMS/CLIA control procedures

(e.g.For tests with an internal control - performing 2 levels of QC each day of patient testing)

- The laboratory must choose to either:
  - follow CMS/CLIA 'default' QC regulations
  - or develop an CMS/CLIA IQCP

Example

IQCP

Example - IQCP

Remel
Commercially Prepared
CLSI-exempt media

List of CLSI-exempt media consists of the following Remel products used in our laboratory:

- Blood agar
- MacConkey agar
- PEA agar
- CNA agar
- Mannitol salt agar
- Blood/SXT agar
- CIN agar
- Brucella agar
- Blood culture media
- Middlebrook agar
- Lowenstein-Jensen agar
- IMA
- Saboaraud’s dextrose agar
- LIM broth
- Selenite broth
- Thioglycolate broth
- TSI agar
- Urease agar

Information Review

- *CMS regulatory guidelines*
- *Certifying/accreditation requirements*
- *Be in compliance w/ manufacturer instructions and recommendations*

Information Review

- *CMS regulatory guidelines*
- *CAP accreditation requirements*
- *Be in compliance w/ the manufacturer instructions/recommendations*

CMS regulatory guidelines:

CMS's FAQ for IQCP, revised April 2015, Question 42 – states in part:

"For example, laboratory documentation showing visual quality checks of media are acceptable in-house data. The laboratory may also include manufacturer's quality certificates as part of the information considered in its risk assessment."

Reference
http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/FAQs-IQCP.pdf

Information Review

- *CMS regulatory requirement*
- *Certifying/accreditation requirements*
- *Be in compliance w/ the manufacturer instructions/ recommendations*

*For CAP accredited labs, refer to 2015 Microbiology and All Common Checklists**

(Certifying or accrediting organizations may require quality checks that differ from this example. Be sure to do a thorough review of your accreditation requirements for media QC)

*Reference http://www.cap.org

Information Review

- *CMS regulatory requirement*
- *Certifying/accreditation requirements, and*
- *Be in compliance w/ manufacturer instructions/recommendations*

Manufacturer information:

- Remel's "Certificates of Quality" (CoQ)certify that specific lot numbers of exempt media have met all performance and QC criteria for the product. CoQs can be found in supervisor's office filed under media quality records.
- No additional risks were identified from review of the Remel's IFU (Instructions For Use), alerts or bulletins associated with these media products. All alerts and bulletins pertaining to these media can be found in the microbiology laboratory's media QC files.
- Remel has no recommendation for end-user QC of CLSI exempt media.

Example Summary of Historical In-house QC data

Example summary may include:

- QC data for the past [XX] months (1/1/XX - 12/31/XX) were reviewed
- Visual inspection records of exempt media as listed in NCCLS / CLSI M22 document were reviewed
- Testing was performed as outlined in the QC section of SOP.xxxx.

Summary of Historical In-house QC data

- Reference used is NCCLS M22-A3 – "Quality Control for Commercially Prepared Microbiological Culture Media; Approved Standard – Third Edition

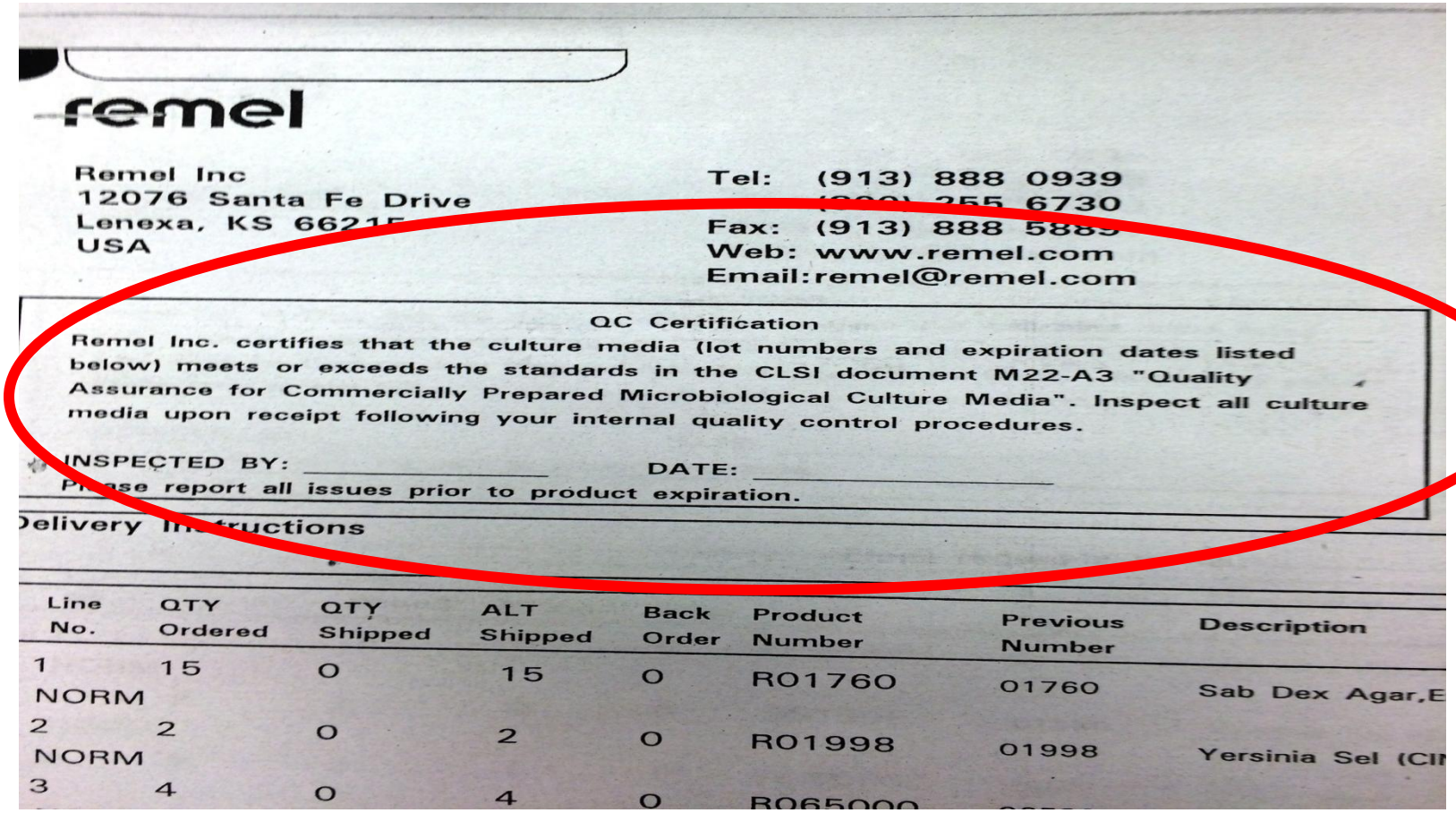
  - Table 1 - College of American Pathologists Extrapolated Failure Rates (EFR) of Media from 3 surveys (1984, 1988 and 2001)

  - Exempt media has EFR <=0.5%, quality control is not required unless used for fastidious organisms

Summary of Historical In-house QC data

- QC reviewed were for exempt media as defined in NCCLS M22-A3-Table 1A for:
  - Blood culture media
  - Bacteriology culture media
  - Mycology culture media
  - Mycobacteriology culture media
- Documentation reviewed were:
  - Visual inspection (in accordance with CMS/CLIA and CAP) records
  - Vendor QC/Performance statements in accordance with NCCLS M22-A3

Vendor – QC CLSI M22 Statements



remel

Remel Inc
12076 Santa Fe Drive
Lenexa, KS 66215
USA

Tel: (913) 888 0939
(800) 255 6730
Fax: (913) 888 5885
Web: www.remel.com
Email: remel@remel.com

QC Certification

Remel Inc. certifies that the culture media (lot numbers and expiration dates listed below) meets or exceeds the standards in the CLSI document M22-A3 "Quality Assurance for Commercially Prepared Microbiological Culture Media". Inspect all culture media upon receipt following your internal quality control procedures.

INSPECTED BY: _____ DATE: _____

Please report all issues prior to product expiration.

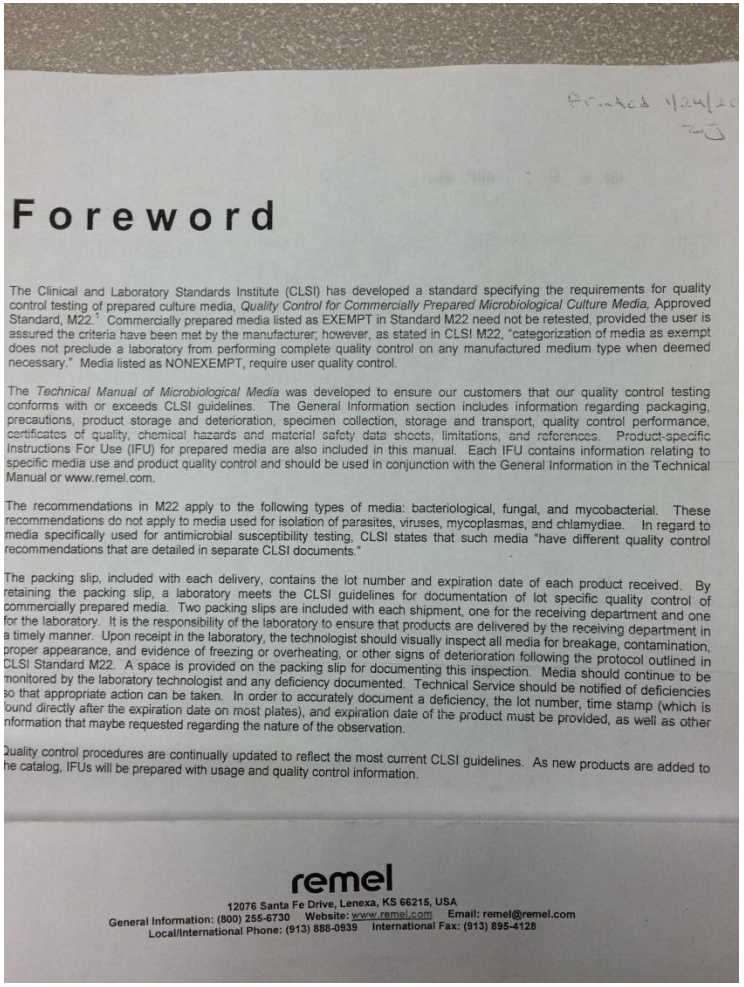
Delivery Instructions

Line No.	QTY Ordered	QTY Shipped	ALT Shipped	Back Order	Product Number	Previous Number	Description
1 NORM	15	0	15	0	R01760	01760	Sab Dex Agar,E
2 NORM	2	0	2	0	R01998	01998	Yersinia Sel (CI
3	4	0	4	0	R065000		

References and data

- Vendor statements – NCCLS M22-A3
- CAP checklist questions – your lab documentation for these questions
- NCCLS M22-A3 document – Table 1A for exempt media

Vendor – QC CLSI M22 Statements



Foreword

The Clinical and Laboratory Standards Institute (CLSI) has developed a standard specifying the requirements for quality control testing of prepared culture media, *Quality Control for Commercially Prepared Microbiological Culture Media*, Approved Standard, M22.[1] Commercially prepared media listed as EXEMPT in Standard M22 need not be retested, provided the user is assured the criteria have been met by the manufacturer; however, as stated in CLSI M22, "categorization of media as exempt does not preclude a laboratory from performing complete quality control on any manufactured medium type when deemed necessary." Media listed as NONEXEMPT, require user quality control.

The *Technical Manual of Microbiological Media* was developed to ensure our customers that our quality control testing conforms with or exceeds CLSI guidelines. The General Information section includes information regarding packaging, precautions, product storage and deterioration, specimen collection, storage and transport, quality control performance, certificates of quality, chemical hazards and material safety data sheets, limitations, and references. Product-specific Instructions For Use (IFU) for prepared media are also included in this manual. Each IFU contains information relating to specific media use and product quality control and should be used in conjunction with the General Information in the Technical Manual or www.remel.com.

The recommendations in M22 apply to the following types of media: bacteriological, fungal, and mycobacterial. These recommendations do not apply to media used for isolation of parasites, viruses, mycoplasmas, and chlamydiae. In regard to media specifically used for antimicrobial susceptibility testing, CLSI states that such media "have different quality control recommendations that are detailed in separate CLSI documents."

The packing slip, included with each delivery, contains the lot number and expiration date of each product received. By retaining the packing slip, a laboratory meets the CLSI guidelines for documentation of lot specific quality control of commercially prepared media. Two packing slips are included with each shipment, one for the receiving department and one for the laboratory. It is the responsibility of the laboratory to ensure that products are delivered by the receiving department in a timely manner. Upon receipt in the laboratory, the technologist should visually inspect all media for breakage, contamination, proper appearance, and evidence of freezing or overheating, or other signs of deterioration following the protocol outlined in CLSI Standard M22. A space is provided on the packing slip for documenting this inspection. Media should continue to be monitored by the laboratory technologist and any deficiency documented. Technical Service should be notified of deficiencies so that appropriate action can be taken. In order to accurately document a deficiency, the lot number, time stamp (which is found directly after the expiration date on most plates), and expiration date of the product must be provided, as well as other information that maybe requested regarding the nature of the observation.

Quality control procedures are continually updated to reflect the most current CLSI guidelines. As new products are added to the catalog, IFUs will be prepared with usage and quality control information.

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Media – CAP Checklist Questions

MIC.21220 Media Visual Inspection I

- The laboratory has documentation that each shipment of purchased media is examined for breakage, contamination, appearance, and evidence of freezing or overheating.

- Reference: CLSI M22-A3

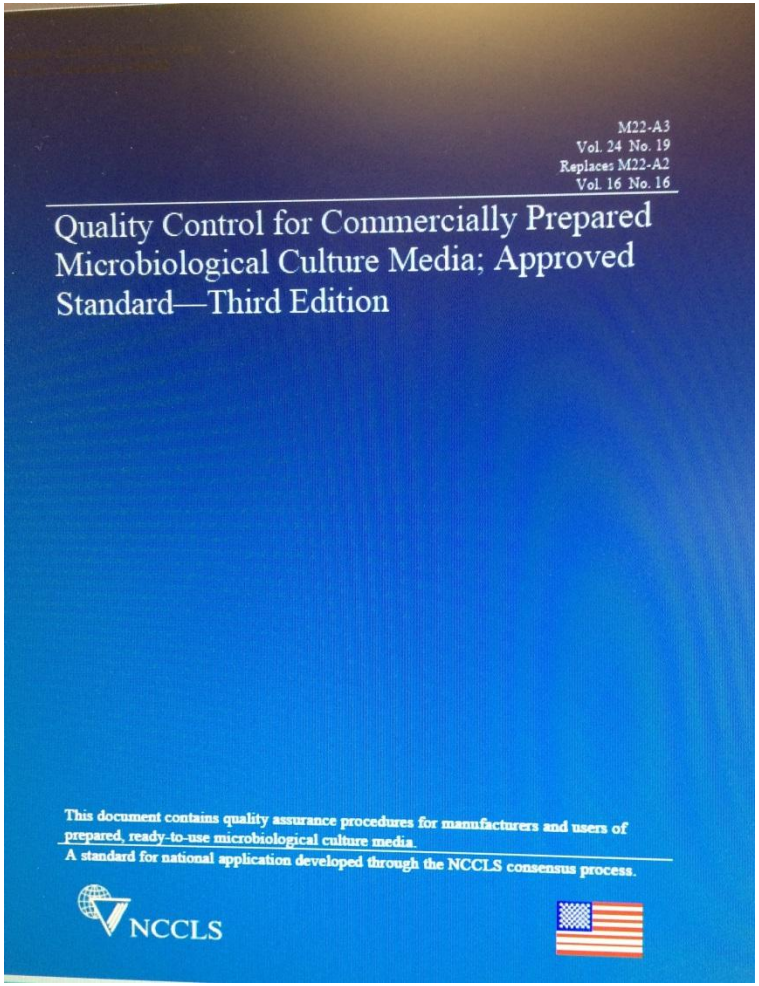
Media – CAP Checklist Questions

MIC.21420 Media Visual Examination II

- All media are in visibly satisfactory condition (with expiration date, plates smooth, adequately hydrated, uncontaminated, appropriate color and thickness, tubed media not dried or loose from sides).

- Reference: CLSI M22-A3

NCCLS – M22- A3 – Table 1B



NCCLS – M22- A3 – Table 1B

- Exempt categories for Media included in CAP Surveys (1984, 1988, 2001)
- Results of the survey of the quality assurance for commercially prepared microbiology media.
- Use NCCLS – M22-A3- Table 1B as a reference

Summary of Historical In-house data for Remel commercially prepared CLSI-exempt media

Media quality data were reviewed for 12 months (4/1/14 - 3/31/15).

When evaluating commercially prepared CLSI-exempt media a visual inspection is incorporated:*

Change in media color	Cracked or damaged plates
Agar detached from plates	Excessive bubbles or rough surfaces
Frozen or melted agar	Excessive moisture/dehydration
Unequal filling of plates	Obvious contamination
Insufficient agar in plates	Presence of precipitates
Hemolysis of blood containing media	

**NCCLS document M22-A3*

Summary of Historical In-house data for Remel commercially prepared CLSI-exempt media

In addition:

- Media is checked for contamination immediately before inoculation with specimens.
- Look for organisms growing on a piece of media and not on others when reading cultures.

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Summary of Historical In-house data for Remel commercially prepared CLSI-exempt media

(continued)

When using the above parameters:

- 0.2% occurrence of unacceptable quality was noted. These plates were not used for patient care but were discarded. This was not associated with any one particular media type. Based on the acceptability criteris described in NCCLS (CLSI) M22-A3, an unacceptable media rate less than 0.5% is allowable.
- At no time when using media was plate contamination suspected upon review of culture results.

RISK ASSESSMENT TABLE

RISK	FREQUENCY OF OCCURRENCE	SEVERITY OF HARM	MEASURES TO CONTROL RISK	RELEVANT SOP
PRE-ANALYTICAL - SPECIMEN				
Identification	Occasional	Critical	Patient and specimen identification acceptability criteria are defined. Competency assessment (CA) performed.	SOP.xxx; CA.xxx
Collection/ Container	Occasional	Minor	Collection criteria are defined. CA performed.	SOP.xxx; CA.xxx
Transport	Occasional	Minor	Transport criteria are defined. CA performed.	SOP.xxx; CA.xxx
Storage	Occasional	Minor	Storage criteria are defined. CA performed.	SOP.xxx; CA.xxx
Volume	Occasional	Minor	Rejection criteria are defined. CA performed.	SOP.xxx; CA.xxx
ANALYTICAL – OPERATOR				
Training	Occasional	Critical	All testing personnel have had training in appropriate utilization of media and media quality parameters.	TR.xxx
CA	Occasional	Critical	All personnel have appropriate CA performed regarding appropriate utilization of media and media quality parameters.	CA.xxx
Proficiency Testing	Occasional	Negligible	All PT failures are addressed with corrective action; media quality is always investigated as deemed necessary.	SOP.xxx
Staffing	Occasional	Minor	Adequate staffing to support appropriate evaluation of media upon arrival and prior to use.	SOP.xxx
ANALYTICAL – REAGENTS				
Receiving/Storage	Occasional	Minor	Media are received and stored according to manufacturer's instructions.	SOP.xxx; manufacturer's PI
Expirations dates	Occasional	Minor	All media are used within expiration dates; no expired media are every used.	SOP.xxx
Visual Inspections	Unlikely	Negligible	Training and procedures are provided for appropriate visual inspection of media upon receipt. CA performed.	SOP.xxx; CA.xxx

RISK	FREQUENCY OF OCCURRENCE	SEVERITY OF HARM	MEASURES TO CONTROL RISK	RELEVANT SOP
PRE-ANALYTICAL - SPECIMEN				
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Collection/ Container	Occasional	Minor	Collection criteria are defined. CA performed.	SOP.xxx; CA.xxx
Transport	Occasional	Minor	Transport criteria are defined. CA performed.	SOP.xxx; CA.xxx
Storage	Occasional	Minor	Storage criteria are defined. CA performed.	SOP.xxx; CA.xxx
Volume	Occasional	Minor	Rejection criteria are defined. CA performed.	SOP.xxx; CA.xxx

ANALYTICAL – OPERATOR				
Training	Occasional	Critical	All testing personnel have had training in appropriate utilization of media and media quality parameters.	TR.xxx
CA	Occasional	Critical	All personnel have appropriate CA performed regarding appropriate utilization of media and media quality parameters.	CA.xxx
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Expirations dates	Occasional	Minor	All media are used within expiration dates; no expired media are every used.	SOP.xxx
Visual Inspections	Unlikely	Negligible	Training and procedures are provided for appropriate visual inspection of media upon receipt. CA performed.	SOP.xxx; CA.xxx

RISK	FREQUENCY OF OCCURRENCE	SEVERITY OF HARM	MEASURES TO CONTROL RISK	RELEVANT SOP
ANALYTICAL – ENVIRONMENT				
Temperature/ airflow/ humidity	Unlikely	Negligible	Appropriate environmental conditions are maintained in the laboratory for proper storage and incubation of media as specified by manufacturer.	SOP.xxx; manufacturer's PI
Utilities	Unlikely	Negligible	Appropriate utilities are maintained in the laboratory for proper storage and incubation of media as specified by manufacturer.	SOP.xxx; manufacturer's PI

ANALYTICAL - TEST SYSTEM				
Contamination	Unlikely	Negligible	Training and procedures are provided to check for contamination prior to plating patient specimens. Visual quality checks are documents. CA performed.	SOP.xxx; QC-Form.xxx; CA.xxx
Organism growth	Unlikely	Negligible	Training and procedures are provided to check for inconsistencies in organisms growth on all media types. Discrepant cultures are review with the supervisor. CA performed.	SOP.xxx; CA.xxx
POSTANALYTICAL - TEST RESULT				
Review results	Unlikely	Negligible	Review of all released results. Appropriate investigation for all reporting errors is undertaken including media quality review as necessary.	SOP.xxx
Clinician feedback	Unlikely	Critical	Appropriate investigation is undertaken for all clinician feedback, issues, complaints, etc., including media quality review as necessary.	SOP.xxx

Quality Control Plan (QCP)

- Upon receipt of exempt media visual inspection will be performed as outlined in the CLSI-M22. Failed media will be brought to the attention of the supervisor or lead technologist and addressed immediately.

- Media will be checked for contamination immediately before inoculation with patient specimens. Contaminated media will be brought to the attention of the supervisor or lead technologist and addressed immediately.

Quality Control Plan (QCP)

- Suspected media contamination when reviewing cultures will be brought to the attention of the supervisor or lead technologist and addressed immediately.

- Remel QC alerts and bulletins will be reviewed and acted on appropriately as necessary.

QC Acceptability Criteria is defined in SOP.xxxx

- **Our post-implementation Quality Assessment (QA) monitoring process will include all of the following:**
- PRE-Analytical
- Media receipt and storage guidelines are reviewed and updated annually as necessary

  See SOP.xxxx
- Staff training documents are reviewed and updated annually as necessary

  See SOP.xxxx

Pre-analytical
Analytical
Post-analytical

Quality Assessment

- ANALYTIC
- Competency assessment for satisfactory media inspection is performed semi-annually and annually as required

  See SOP.xxxx
- Proficiency testing results review and mediated ASAP as required

  See SOP.xxxx
- Media quality information is reviewed and mediated ASAP as required

  See SOP.xxxx, SOP.xxxx. QC-FORM.xxxx, QC-FORM.xxxx
- Unexpected errors investigated ASAP and remediated

  See SOP.xxxx

Quality Assessment

- POST ANALYTIC
- Laboratory error investigation/remediation performed ASAP

  See SOP.xxxx
- Complaint investigation/remediation performed ASAP

  See SOP.xxxx

Quality Assessment

For errors/failures/concerns in any of the above is observed, a reassessment of risk will be performed:

- The reason for failure will be identified and investigated.
- Additional control measures will be implemented if necessary as determined by the new risk assessment.

Commercially prepared Remel CLSI-exempt media

This IQCP/QCP has been reviewed and is approved by the CLIA laboratory director.

_____ _____

(CLIA Laboratory Director signature) (date)

CAP Requirements for IQCP

CAP Requirements for IQCP

New checklist questions:

- **COM.50200 IQCP Test List Phase II**

  "The laboratory has identified all tests using an IQCP and **completed the CAP's forms** for laboratories using an individualized quality control plan."

  - **List of Individualized Quality Control Plans**

    (Listing of all IQCP laboratory performs)

  - **Individualized Quality Control Plan Summary**

    (Must be completed for each IQCP in use)

CAP – Required Forms

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List of Individualized Quality Control Plans

Complete the fields below for each IQCP in use and present to the inspector during the on-site inspection. Fill out a separate Individualized Quality Control Plan Summary form for each IQCP listed.

Laboratory Name:		**CAP Number:**	

1) Laboratory Section/Department	**2) Instrument/Device** Include name, manufacturer, and model	**3) Tests** List all tests included under the IQCP

CAP – Required Forms

COLLEGE of AMERICAN PATHOLOGISTS

Individualized Quality Control Plan Summary

Complete a separate form for each IQCP in use and present to the inspector during the on-site inspection.

Laboratory Name:		**Laboratory Section/Department:**		**CAP Number:**	

1) Instrument/Device Include name, manufacturer, and model	**2) Tests** List all tests included under the IQCP	**3) Number of Devices In Use**	**4) List of Test Sites*** If used in more than one area	**Date of Director Approval**	**Date Implemented**	**Date Retired**
				Click here to enter a date.	Click here to enter a date.	Click here to enter a date.

5) Process Used to Monitor Risk

List control processes put in place based on risk assessment – define the monitor and frequency evaluated.

Reagents	Environment	Specimen	Test System	Testing Personnel	Other

CAP Requirements for IQCP

- **COM.50300 Risk Assessment Phase II**

  "The IQCP for a test/device/instrument includes a risk assessment to evaluate potential sources of error to include the following…."

  NOTE: Lab must involve representative sample of testing personnel in the process of conducting the risk assessment.

CAP Requirements for IQCP

New checklist questions (continued):

- **COM.50400 Quality Control Plan Approval Phase II**

  "The IQCP includes a written quality control plan approved by the laboratory director prior to implementation."

- **COM.50500 Quality Control Plan Elements Phase II**

  "The individualized quality control plan must define all aspects monitored based on the potential errors identified during the risk assessment, including the following parameters…."

CAP Requirements for IQCP

New checklist questions (continued):

COM.50500 Quality Control Plan Elements (cont.)

- Number, type (external and internal QC system), and frequency of QC
- Criteria for acceptable performance
- Monitoring of testing environment and reagents
- Specimen quality
- Instrument calibration, maintenance, and function checks
- Training and competency of testing personnel
- Provisions for multiple identical devices and variation for uses covered under one IQCP

CAP Requirements for IQCP

New checklist questions (continued):

- **COM.50600 Quality Assessment Monitoring Phase II**

  "Ongoing quality assessment monitoring is performed by the laboratory to ensure that the quality control plan is effective in mitigating the identified risks for the IQCP and includes the following:"

CAP Requirements for IQCP

New checklist questions (continued):

- **COM.50600 Quality Assessment Monitoring Phase II**
  - Review of QC and instrument/equipment maintenance and function check data at least monthly
  - Evaluation of errors relating to preanalytic, analytic and post analytic phases of the testing process
  - Review of complaints from clinicians and other healthcare providers regarding the quality of testing to confirm the clinical efficacy of testing, and

CAP Requirements for IQCP

(continued)

COM.50600 **Quality Assessment Monitoring Phase II**

- Evaluation of corrective action taken if problems are identified
- Reapproval of the QC plan by the laboratory director or designee <u>at least annually</u>

Microbiology Checklist Questions with IQCP

MIC.11020 Monthly QC Review:

- "The review of quality control data for tests that have an IQCP approved by the laboratory director **must** include an assessment of whether further evaluation of the risk assessment and quality control plan is needed based on problems identified (e.g. trending for repeat failures, etc.)."

Microbiology Checklist Questions with IQCP

MIC.14583 Direct Antigen Test QC

- **"…**For each test system that requires an antigen extraction phase, as defined by the manufacturer, the system must be checked with an appropriate positive control that will detect problems in the extraction process. If an IQCP is implemented for the test, the laboratory's quality control plan must define how the extraction phase will be monitored….."

Microbiology Checklist Questions with IQCP

MIC.21240 Media QC Purchased

- "….End user quality control must be performed on the following, regardless of the exempt status:
  - Campylobacter agar
  - Chocolate agar
  - Media for selective isolation of pathogenic Neisseria
  - Other media not listed on Table 2 of M22-A3 (e.g. dermatophyte test medium)
  - Media used for..parasites, viruses, Mycoplasmas, Chlamydia
  - Mueller Hinton media used for AST
  - Media commercially prepared and packaged as unit or system consisting of two or more different substrates, primarily used for microbial identification"

Microbiology Checklist Questions with IQCP

MIC.21240 Media QC Purchased

- Must have a copy of CLSI/NCCLS Standard M22-A3
- Media supplier must provide records showing that QC activities meet CLSI/NCLA Standard M22-A3
- Laboratories using exempt media that have not implemented an IQCP
- Or
- Using media that do not qualify for an IQCP

must continue to test each lot and shipment of media and maintain records of such testing

Microbiology Checklist Questions with IQCP

MIC.21240 Media QC Purchased

- Laboratories using exempt media that have not implemented an IQCP
- or
- using media that do not qualify for an IQCP

must continue to test each lot and shipment of media and maintain records of such testing

MIC.31380 Media QC Purchased (Mycobacteriology)

MIC.41200 Media QC Purchased (Mycology)

Microbiology Checklist Questions with IQCP

MIC.21626 Identification System QC

- QC each lot and shipment, with appropriate organisms to get positive and negative reaction with each reagent/substrate
- To qualify for streamline QC, user must fulfill initial and ongoing requirements as defined by manufacturer and CLSI Guideline M50-A,:
  - Retention of test system verification
  - Historical QC review as long as streamlined QC is used

Microbiology Checklist Questions with IQCP

MIC.21910 Susceptibility Test QC Frequency

- Frequency of QC testing may be reduced to weekly… if the laboratory director approves the use of an IQCP,…
- If lab performs QC on antimicrobial screening tests as defined by CLSI standard and manufacturer instructions do not require QC on each day test is performed, lab must have IQCP that meets all requirements defined in All Common Checklist

IQCP – CAP Requirements

Be sure to incorporate the NEW 2015 CAP Checklist questions for IQCP from:

- **Microbiology Checklist**
- **All Common Checklist**

So What Does the Lab IQCP Need to Include?

CMS.gov
Centers for Medicare & Medicaid Services

Clinical Laboratory Improvement Amendments (CLIA)

+

CAP

The Clock is Ticking …..

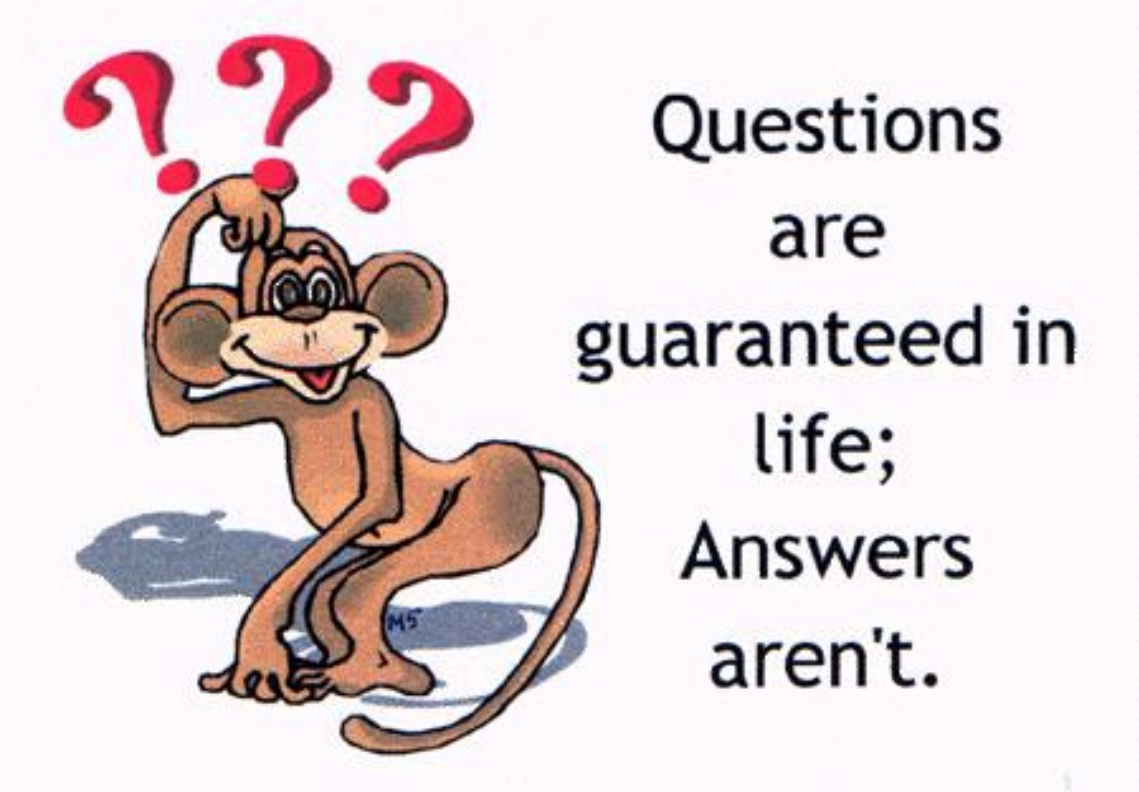
References – CLIA Brochures

- Brochure #11 - CLIA Individualized Quality Control Plan Introduction (IQCP)
- Brochure #12 - CLIA IQCP, Considerations When Deciding to Develop an IQCP
- Brochure #13 - CLIA IQCP, What is an IQCP?
- Brochure #4 - Equivalent Quality Control Procedures

References

- CLIA Advance copy-revised Appendix C-Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services, Jan 9, 2015
- IQCP@cms.hhs.gov
- http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-54.pdf

THANK YOU


Questions
are
guaranteed in
life;
Answers
aren't.

QUESTIONS?