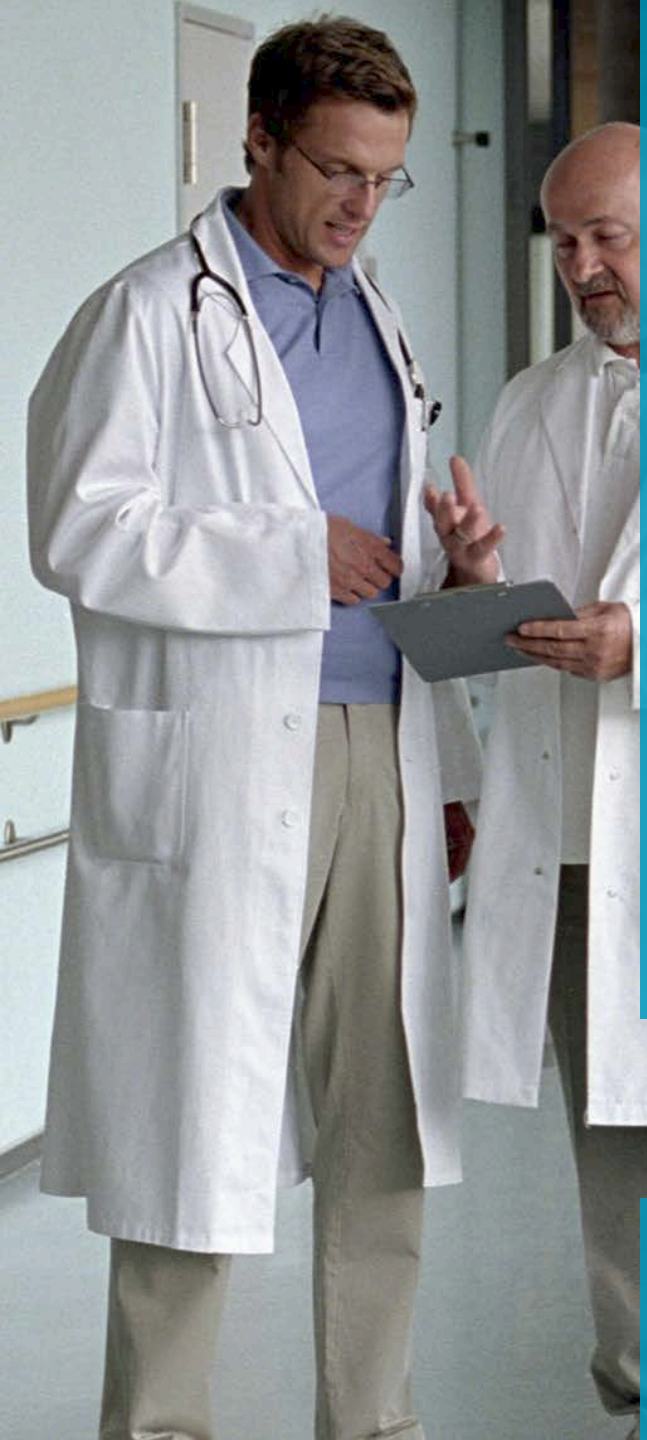

COLLEGE of AMERICAN PATHOLOGISTS

"IQCP – January Is Coming Fast…What Do I Do?!?"

Jean Ball Bold, MBA, MT(HHS), MLT(ASCP

September 9, 2015

Objectives

- **Define what IQCP is**
- **Explain what the requirements are**
- **Learn the steps to formulate an IQCP**

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Polling question

A question for you….

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Individualized Quality Control Plans – broad strokes

- **Laboratories are free to do traditional QC – IQCP is optional**
- **IQCPs apply only to non-waived testing**
- **Use of IQCP is limited to States that permit an individualized QC Plan**
- **IQCP may not be less frequent than QC printed in the manufacturer's instructions**

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Historical Quality Control Options

- **CLIA 1988 - final regulations published in 1992**
  - **Two levels of QC per day (default QC)**
  - **One-size fits all**

- **Equivalent Quality Control (EQC) option published in CMS Interpretive Guideline in 2004**
  - **First attempt at alternative QC**
  - **Two levels of QC per day or EQC**
  - **Disadvantages**
    - **Limited scope**
    - **Prescriptive**
    - **Analytical focus only**
  - **CMS will discontinue EQC on 1/1/2016**

New QC Option - CMS Individualized Quality Control Plan (IQCP)

- **CMS published new Interpretive Guideline with IQCP option**
- **Voluntary quality control option based on risk management (concepts from CLSI's EP23-A Guideline)**
- **Evaluates the entire testing process**
  - **Pre-analytical, analytical and post-analytical**
- **Customizes the quality control plan for each unique testing environment and setting**
- **Contains some restrictions for eligibility of use**

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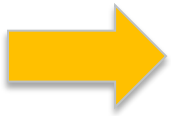
CMS Transition Period for IQCP

- **IQCP is optional, but there will be no grandfathering of test systems already using EQC**

As of January 1, 2014

1. **Default CLIA QC or**
2. **EQC or**
3. **Implement an IQCP**



On or After January 1, 2016

1. **Default CLIA QC or**
2. **Implement an IQCP**

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CMS Eligibility to Use IQCP

- **CMS IQCP option eligibility:**
  - **Non-waived test systems**
  - **CMS subspecialties or subspecialties other than Pathology and Cytology**
    - **Exception for those that can come under multiple subspecialties (e.g. FISH can be assigned to either histopathology or cytogenetics)**
  - **Eligible CLIA regulations**
  - **Follow manufacturer's instructions at minimum**
  - **Follow state laws and regulations**

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CAP Implementation of IQCP

- **Updated IQCP checklist requirements published in July 2015 checklist edition**
  - **All Common Checklist**
    - **New IQCP section with five new IQCP requirements**
  - **Other Checklists (e.g. Chemistry, Microbiology & POCT)**
    - **Revisions to existing QC requirements throughout checklists to allow for use of traditional QC or IQCP**
    - **Provisions for EQC removed**

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CAP Implementation of IQCP

- **Laboratories may develop their own model for designing an IQCP**
- **CAP option for IQCP is more restrictive than the CMS and other accreditors in some areas**

CAP

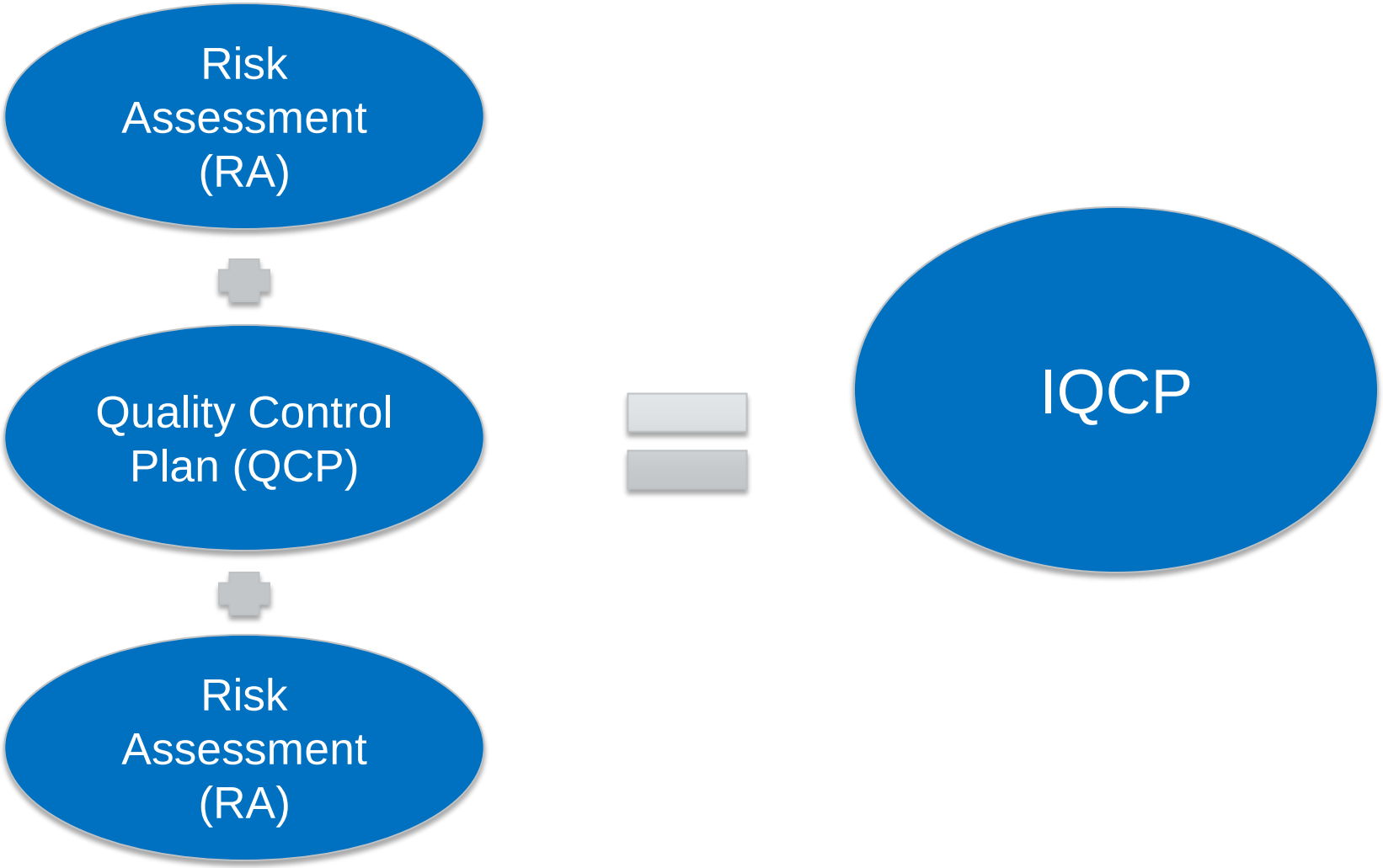
CAP Eligibility to use IQCP

- **CMS IQCP eligibility criteria apply**
- **CAP defines additional criteria:**
  - **Testing must employ an internal quality control system (electronic, procedural, or built-in control)**
    - **Exception: Microbiology media and reagents used for microbial identification and susceptibility testing**

NOTE: IQCPs in use that do not reduce the QC frequency below the minimum default QC requirement are not inspected with the IQCP checklist requirements

CAP

IQCP Option



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IQCP Checklist Requirements – COM.50300

- **COM.50300 – Risk Assessment – evaluate potential sources of errors including:**
  - **Three phases of the testing process – preanalytic, analytic, and postanalytic**
  - **Five components – Reagents, Environment, Specimen, Testing Personnel, Test System**
  - **Variations in the components based on use of test**
  - **Data from the laboratory's own environment, instrument/equipment performance, and testing personnel**
  - **Intended medical uses of the test and impact if inaccurate results are reported (clinical risk)**
  - **Manufacturer’s instructions and recommendations**

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IQCP Checklist Requirements – COM.50500

- **COM.50500 - Quality Control Plan - defines all aspects monitored based on risk assessment**
  - **The number, type (external and internal quality control systems), and frequency of quality control**
  - **Criteria for acceptable performance**
  - **Monitoring of other control processes**
  - **Provisions for multiple identical devices and variation for uses covered under one IQCP**
  - **Follow manufacturer's instructions and recommendations for QC at minimum**
  - **Include the use of external control materials at least every 31 days and with new lots and shipments of reagents**

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Quality Control Plan Approval – COM.50400

- **COM.50400 - Quality Control Plan Approval**
  - **QCP signed and dated by the laboratory director prior to implementation**
  - **No delegation allowed**
  - **Separate approved quality control plan for each laboratory with a separate CAP/CLIA number**

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IQCP Checklist Requirements - COM.50600

- **COM.50600 - Quality Assessment Monitoring - requires ongoing monitoring of the effectiveness of the IQCP**
  - **Review of quality control and instrument/equipment maintenance and function check data at least monthly**
  - **Evaluation of errors relating to all phases of the testing process**
  - **Review of complaints from clinicians and other healthcare providers regarding the quality of testing**
  - **Evaluation of corrective actions taken if problems are identified**
  - **Reapproval of the quality control plan by the laboratory director or designee at least annually**

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Molecular Controls

ANP.22964, CYG.43200, MOL.39146, MOL.34229, MOL.34270

If an internal quality control process is used to meet daily quality control requirements, the laboratory must have an IQCP.

Key points —

- Must include extraction and amplification
- Include a sensitivity control if being used to detect low-level sequences
- Controls should target relevant clinical decision points
- Include a hybridization control for FISH/ISH

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Media QC in Microbiology

MIC.21240, MIC.41200

An appropriate sample of each medium prepared by the laboratory or each lot and shipment of purchased media is checked for each of the following...

Key points —

- The list includes sterility checks, ability to support growth, and biochemical reactivity
- The *previous* reference to M22-A3 is invalid after January 1, 2016 with the expiration of EQC
- An IQCP is required to continue to practice familiar quality checks

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QC of ID Systems and AST in Microbiology

QC of Identification Systems

MIC.21626

Appropriate positive and negative control organisms are tested and results recorded for each new lot and shipment of reagents used in bacterial identification systems.

QC of Susceptibility Testing

MIC.21910

For antimicrobial susceptibility testing by either disk or dilution methods, quality control organisms are tested with each new lot number or shipment of antimicrobials or media, and each day the test is performed thereafter.

- An IQCP is required after January 1, 2016 with the expiration of EQC.
- Any use of CLSI documents M2, M7, M50 and M100 now depend upon the QCP that *you* develop

IQCP Checklist Requirements – COM.50200

- **COM.50200 – IQCP Test List – requires completion of two forms to be provided to the inspection team if IQCP is used**
  - **List of Individualized Quality Control Plans**
    - **The laboratory has identified all tests using an IQCP**
  - **Individualized Quality Control Plan Summary**
    - **The IQCP includes a written quality control plan approved by the laboratory director prior to implementation**
- **Download forms from CAP website (http://www.cap.org) through e-LAB Solutions Suite under CAP Accreditation Resources, Accreditation Forms and Instructions**

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CAP Inspection Preparation

- **All laboratories inspected on or after January 1, 2016 must do the following:**
  - **Discontinue EQC option AND**
  - **Perform external quality following the frequency defined in the CAP inspection checklist (default CLIA QC) OR**
  - **Implement an IQCP, if eligible**

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Frequently Asked Questions

- **Which laboratories should consider implementing an IQCP?**
- **Why would a laboratory want to implement an IQCP?**
- **It’s already August, where should I start?**

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CAP Website Resources

- **The following are available in eLab Solutions Suite under CAP Accreditation Resources – Guidance Documents**
  - **Eligibility Determination for IQCP Option**
  - **CAP/ASM/CLSI Microbiology IQCP template and examples**
  - **IQCP Frequently Asked Questions**
  - **CAP forms and instructions for inspection**
- **CAP IQCP webinar presentation in August**
  - **Webinar is posted to the CAP website under e LAB Solutions, Accreditation Resources, Educational Resources**
  - **Rebroadcast with live Q & A in October**

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Other IQCP Resources

- **Clinical and Laboratory Standards Institute Guideline EP23-A and companion documents**
- **CDC/CMS Handbook: Developing an IQCP – A Step-by-Step Guide (http://wwwn.cdc.gov/CLIA/Documents/IQCP%20Layout.pdf)**
- **CMS Guidances and Brochures (http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Individualized_Quality_Control_Plan_IQCP.html)**
- **Manufacturer tools, if available**

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