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

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

*CLIA Advance copy-revised Appendix C-Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services, Jan 9, 2015
<table>
<thead>
<tr>
<th>*SubPart K - Quality System for Nonwaived Testing</th>
<th>QC</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>QC Frequency:</strong> Each <strong>time</strong> of use</td>
<td>QC</td>
<td></td>
</tr>
<tr>
<td>D5475 493.1256</td>
<td>QC</td>
<td></td>
</tr>
<tr>
<td>Fluorescent stains (includes fluorochrome AFB) and immunohistochemical stains</td>
<td>QC</td>
<td></td>
</tr>
</tbody>
</table>

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

*Yes - Yes
# Current CMS Laboratory Standards

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

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

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

*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**

<table>
<thead>
<tr>
<th>SubPart K - Quality System for Nonwaived Testing</th>
<th>QC Frequency: Each new lot # and shipment</th>
</tr>
</thead>
<tbody>
<tr>
<td>D5471 493.1256 (e)(1) Identification systems</td>
<td>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)</td>
</tr>
</tbody>
</table>

*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

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

*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 (e.g., 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

<table>
<thead>
<tr>
<th><strong>SubPart K - Quality System for Nonwaived Testing</strong></th>
<th>QC</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>QC Frequency:</strong> Each <strong>week</strong> of use</td>
<td><strong>Pos</strong></td>
</tr>
<tr>
<td>D5503 493.1261 (a)(2) Gram stain</td>
<td>Yes</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>*SubPart K - Quality System for Nonwaived Testing</th>
<th>QC Frequency: Every 6 months</th>
<th>QC Pos</th>
<th>QC Neg</th>
</tr>
</thead>
<tbody>
<tr>
<td>D5505 493.1261 (a)(3)</td>
<td>Each lot # and shipment, and once every 6 months</td>
<td>Salmonella and Shigella antisera, streptococcal serotyping systems</td>
<td>Yes</td>
</tr>
</tbody>
</table>

*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

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

*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

<table>
<thead>
<tr>
<th>*SubPart K - Quality System for Nonwaived Testing</th>
<th>QC Organisms</th>
</tr>
</thead>
<tbody>
<tr>
<td>QC Frequency: <strong>Each day</strong> tests are performed, must use appropriate control organisms to check procedure</td>
<td></td>
</tr>
<tr>
<td>D5507 493.1261 (b)(1)</td>
<td><strong>Antimicrobial susceptibility test</strong></td>
</tr>
</tbody>
</table>

*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)

1. Risk Assessment
2. Quality Control Plan
3. Quality Assessment

IQCP
Individualized Quality Control Plan (IQCP)

1. Risk Assessment
2. Quality Control Plan
3. Quality Assessment

IQCP
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

1 Specimen
Specimen integrity

2 Environment
Factors

3 Testing Personnel
Operator Function

Identify Potential Hazards

4 Reagents
Reagent Integrity
QC Organism(s)

5 Test System
Instrument QC organism

6 Test Results
Reported Results

Incorrect Test Results

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

<table>
<thead>
<tr>
<th>Frequency of Occurrence</th>
<th>Severity of Harm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unlikely (once /2-3 yrs)</td>
<td>Negligible (temporary discomfort)</td>
</tr>
<tr>
<td>Occasional (1/yr)</td>
<td>Minor (temporary injury; not requiring medical intervention)</td>
</tr>
<tr>
<td>Probable (1/mo)</td>
<td>Serious (impairment requiring medical intervention)</td>
</tr>
<tr>
<td>Frequent (1/wk)</td>
<td>Critical (permanent impairment requiring medical intervention)</td>
</tr>
</tbody>
</table>
Determining Risk – Example 5 levels

<table>
<thead>
<tr>
<th>Frequency of Occurrence</th>
<th>Severity of Harm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rare (once /2-3 yrs)</td>
<td>Negligible (temporary discomfort)</td>
</tr>
<tr>
<td>Unlikely (1/yr)</td>
<td>Minor (temporary injury; not requiring medical intervention)</td>
</tr>
<tr>
<td>Possible (1/mo)</td>
<td>Moderate (may require medical intervention)</td>
</tr>
<tr>
<td>Likely (2/mo)</td>
<td>Serious (impairment requiring medical intervention)</td>
</tr>
<tr>
<td>Almost certain (1/wk)</td>
<td>Critical (permanent impairment requiring medical intervention)</td>
</tr>
</tbody>
</table>
# Risk Matrix from CLSI EP-23

## Severity of harm (Impact)

<table>
<thead>
<tr>
<th>Probability of harm (Frequency)</th>
<th>Negligible</th>
<th>Minor</th>
<th>Serious</th>
<th>Critical</th>
<th>Catastrophic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequent</td>
<td>U</td>
<td>U</td>
<td>U</td>
<td>U</td>
<td>U</td>
</tr>
<tr>
<td>Probable</td>
<td>A</td>
<td>U</td>
<td>U</td>
<td>U</td>
<td>U</td>
</tr>
<tr>
<td>Occasional</td>
<td>A</td>
<td>A</td>
<td>A</td>
<td>U</td>
<td>U</td>
</tr>
<tr>
<td>Remote</td>
<td>A</td>
<td>A</td>
<td>A</td>
<td>U</td>
<td>U</td>
</tr>
<tr>
<td>Improbable</td>
<td>A</td>
<td>A</td>
<td>A</td>
<td>A</td>
<td>A</td>
</tr>
</tbody>
</table>

*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

1 Specimen
- Specimen Integrity

2 Environment
- Factors

3 Testing Personnel
- Operator Function

4 Reagents
- Reagent Integrity
- QC Organism(s)

5 Test System
- Instrument QC organism

6 Test Results
- Reported Results

Incorrect Test Results

Pre-analytical
Analytical
Post-analytical
Risk Assessment – Specimen EXAMPLE of TABLE FORMAT

<table>
<thead>
<tr>
<th>1 Specimen</th>
<th>Frequency of Occurrence</th>
<th>Severity of Harm</th>
<th>Measures to control risk</th>
<th>Relevant SOP</th>
</tr>
</thead>
<tbody>
<tr>
<td>List each risk identified</td>
<td>List frequency of occurrence</td>
<td>List degree of severity of harm</td>
<td>List how risk will be controlled</td>
<td>Reference SOP that support control measure</td>
</tr>
</tbody>
</table>

- 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)

1. Risk Assessment

2. Quality Control Plan

3. Quality Assessment

IQCP

A partnership of the Advocate and Aurora Health Care System
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)

1. Risk Assessment
2. Quality Control Plan
3. Quality Assessment

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
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)

1. Risk Assessment
2. QC Plan
3. Quality Assessment
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

Have a Nice Day