IQCP
How We Can Help Our Customers

andy quintenz

BIO-RAD

BIO-RAD LABORATORIES – QUALITY SYSTEMS DIVISION

Agenda

- How We Got Here
- IQCP Requirements & Timeline
- Laboratory Response
- Manufacturer Response

FDA & Quality Control

- Quality control (QC) … monitors the analytical performance of that test system. It may monitor the entire test system or only one aspect of it.
- FDA regulates the *material or mechanism* as a medical device; it does not monitor how a QC component is used within a laboratory (i.e. how often other QC types should be run, or whether the QC replaces other, more traditional external types of QC).
- FDA makes sure that products have QC materials, reviews labeling for accuracy, and determines if manufacturers have protocols to ensure stability.
- How a QC component is used within a laboratory is not within FDA's jurisdiction. Other Agencies, such as of the Centers for Medicare and Medicaid Services (CMS), the College of American Pathologists (CAP), or the Joint Commission Accrediting Hospital Organization (JCAHO) have jurisdiction over the procedures and practices within laboratories.

http://www.fda.gov/medicaldevices/deviceregulationandguidance/ivdregulatoryassistance/ucm123682.htm#11

ISO Guidance

- ISO 15189:2004
  Validation of user quality control procedures by the manufacturer

- ISO 14197:2012
  Application of risk management to medical devices

How Much QC?

- CLIA regs mandated min. performance
  - Typically: 2 levels / day
- No QC rules or other frequency guidance
- CMS: ‘it was supposed to be the floor’
- Batch testing era

- CLIA 2003: Equivalent QC
  - Intended to allow for advances in technology
  - Heavy push by POCT
  - Allowed for weekly or monthly QC under certain conditions

Equivalent QC

- Scientific validity questioned
  - Intense debate
- CLSI stepped in to develop guidance practice for QC frequency
  - Laboratory QC Based on Risk Management
  - Presentation of a Manufacturer's Risk Mitigation Information for Users of In Vitro Diagnostic Devices

EP23 and CMS

- CMS proposed EP23 as new requirement
  - No objective criteria for determining QC frequency
- Morphed into EP23 based requirements
  - Individualized Quality Control Plan

- Narrative:
  - How one might go about creating one
  - Components & Elements of IQCP
  - No objective criteria for determining QC frequency

IQCP Timeline

- Jan 1, 2014
  - Begin Educational Phase
  - May start IQCP any time
  - No citation unless “serious quality problems” exist
- Jan 1, 2016
  - End Educational Phase
  - End Equivalent QC

Accrediting Organizations

- COLA adopting with no modifications
- TJC adopting, details not released
- CAP ‘evaluating’

AABB, A2LA, AOA, ASHI to be determined

Mandatory IQCP Components

- 3 Phases
  - Pre, analytic, post
- 5 Elements
  - Environment, Personnel, Specimen, Test System, Reagents
- 3 Parts
  - Risk Assessment, Control Plan, Quality Assurance
- …For QC Frequency

http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/IQCP-announcement-letter-for-CLIA-CoC-and-PPM-labs.pdf

Labs Are Asking for Help

- Little to no experience in FMEA / RA
- Staff overwhelmed
- Where to begin?
- Templates?
- How to objectively make decisions?

Where Labs Need Help - RA

- IQCP provides overview of process
  - No details
  - EP23 $50 - $170 - Companion Products extra
- Risk Assessment for lab processes still new
  - Manufacturer resources
  - Process mapping and hazard identification
- Unsure what instruments internal checks do
- Fairly subjective guidance runs counter to lab's need for black / white answers

Where Labs Need Help - QCP

- No guidance on:
  - Format
  - What is acceptable data to support decision
    - For Risks
    - For control activities
    - For QC frequency
- Do Manufacturer's have recommended QC checks?

Where Labs Need Help - QA

- When reviewing the process, what should lab look for other than blatant failures?
- If I have no complaints from clinicians, is everything okay?
- How do I review my post-analytic process?

Manufacturer Response

- Good News:
  - No new mandated responsibilities
  - Lab-centric regulation
- Bad News:
  - Labs want information that runs counter to our own RA policies

What We Can Do

- Remind labs: non-waived testing under CLIA certificate or AO equivalent
- Recommend: focus on POCT with EQC
- Template guidance documents:
  - Process Map for analytical phase
  - QC Plan based on IFU

Provide 'Objective'ness

Table 3. Risk Acceptability Matrix

	Severity of Harm				
Probability of Harm	***Negligible***	***Minor***	***Serious***	***Critical***	***Catastrophic***
Frequent	***unacceptable***	***unacceptable***	***unacceptable***	***unacceptable***	***unacceptable***
Probable	acceptable	***unacceptable***	***unacceptable***	***unacceptable***	***unacceptable***
Occasional	acceptable	acceptable	acceptable	***unacceptable***	***unacceptable***
Remote	acceptable	acceptable	acceptable	acceptable	***unacceptable***
Improbable	acceptable	acceptable	acceptable	acceptable	acceptable

EP23-A: 2011
CLSI. Wayne, PA

‘Objective’ Matrix

- 1 failure
  - pre / post analytic phase tends to affect one patient
  - cartridge testing tends to affect on patient
  - could affect multiple patients

Common Terms	Possible Description
Frequent	Once per week
Probable	Once per month
Occasional	Once per year
Remote	Once every few years
Improbable	Once in the life of the measuring system

EP23 –A – WB
CLSI. Wayne, PA

‘Objective’ Matrix

- 1 failure
  - pre / post analytic phase tends to affect one patient
  - cartridge testing tends to affect on patient
  - could affect multiple patients

Common Terms	Possible Description
Frequent	More than 1 in 1000 tests
Probable	Between 1 / 1000 and 1 / 10,000 tests
Occasional	Between 1 /10,000 and 1 / 100,000 tests
Remote	Between 1 /100,000 and 1 / 1,000,000 tests
Improbable	Less than 1 in a million tests

ISO 14971: 2004

‘Objective’ Matrix

Common Terms	Possible Description
Catastrophic	Results in patient death
Critical	Results in permanent impairment or life-threatening injury
Serious	Results in injury or impairment requiring professional medical intervention
Minor	Results in temporary injury or impairment not requiring professional medical intervention
Negligible	Inconvenience or temporary discomfort

- Guide labs to look at outcome as most likely to occur under normal use.
- Goal: Patient Risk. If a failure occurs that is highly likely to be caught or won’t cause harm…

Where Labs Need Help - RA

ELECTRONIC TEMPLATE

EP18/EP23 TEMPLATE

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Sources of Failure Template

A failure modes and effects analysis table may be used as a checklist or as a tool to help identify potential failures in a testing system. These potential failures are then addressed by an appropriate quality assurance program.

1. Sample Collection

Potential Source of Failure				
Step or Component in Which Failure Occurs	Failure	Cause	Effect	Reference Documentation
		1.1 Contamination		
		1.1.1 Alcohol		
		1.1.2 Other		

EP23 –A – Template
CLSI. Wayne, PA

Template IQCP

Famous Hospital Laboratories

PT/INR Quality Control Plan
Effective Date: October 1, 2011
Laboratory Director: Sarah Ryan, MD

1. **Electronic Controls:**
   a. Controls shall be run on each instrument once every eight hours.
2. **Liquid-based QC Samples:**
   a. Analyze two levels of QC samples before and after each change in reagent lot. Do not use QC that was shipped with the reagent being tested.
   b. Analyze two levels of QC after each calibration.
   c. Analyze two levels of QC samples at least weekly.
3. **Proficiency Testing:**
   a. Participate in a proficiency testing program two times per year.
4. **Maintenance:**
   a. Clean the instruments after each use with alcohol wipes, following the instructions in the user's manual.
   b. Check the laboratory refrigerator monitors daily.
   c. Check the room temperature monitors in the outpatient clinic daily.
5. **Training:**
   a. Nurses and laboratory technicians—document proper training for:
      I. Sample collection
      II. Sample placement on reagent test strip
      III. Testing procedures
      IV. Cleaning procedures
      V. Documentation of results
   b. Receiving personnel—document proper training for:
      I. Checking the condition of the cold packs upon receipt
      II. Procedure to follow when cold packs are not present or are no longer cold
      III. Procedure for storing of the reagents

From Risk Assessment

Boilerplate IQCP with information extracted from Instructions from Use / Package Inserts?

EP23 –A – WB
CLSI. Wayne, PA

The Future..

- Standard practice in labs by 2025?
- Risk based approach to QC
  - What is the likelihood a failure will occur?
  - How many patients could it affect?
  - Can my lab recover from that failure?
  - Can my lab absorb that financial impact?

In Summary

- Phase out EQC by Jan 1, 2016
- TJC / CAP requirements still unknown
- Template documents would be helpful
- Labs cannot use mfr data exclusively
- Labs cannot use mfr IQCP as-is
- Reformatting IFU into QC Plan steps – helpful

Thank You

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