CLSI EP23-A
Laboratory Quality Control Based on Risk Management; Approved Guideline

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EP23 – “The Right QC”

- EP23 IS NOT about reducing quality control

- EP23 IS about understanding where errors can occur, and putting the right “controls” in place to reduce the risk of errors occurring
EP23 – “The Right QC”

• EP23 helps the lab director and the lab staff better understand their entire testing process, from collecting the sample to reporting the result.

• EP23 stresses the importance of, identifies, and formalizes all of the other activities that labs do to ensure quality results.

• EP23 expands the concept of what constitutes “quality control.”
Overview of the EP23 Process

MEASURING SYSTEM INFORMATION

- Medical Requirements for the Test Results
- Regulatory and Accreditation Requirements
- Measuring System Information
  - Provided by the Manufacturer
  - Obtained by the Laboratory
- Information About Health Care and Test Site Setting

PROCESS
Risk Assessment

OUTPUT
Quality Control Plan

PROCESS
Postimplementation Monitoring

Corrective and Preventive Action and Continual Improvement
How does this work?

- The lab director creates a Quality Control Plan (QCP) based upon their testing processes
  - Includes sample acquisition through result reporting
  - Includes analyzing of all process steps to see where errors could occur, and what actions could prevent or reduce the risk of that error occurring
  - Results in a plan that encompasses all of the identified activities
  - Customized for each specific test, instrument, facility
The Benefits

- CLSI document EP23 provides instruction on developing an appropriate QCP that will:
  - Improve lab efficiency and quality- save time and money through reducing errors
  - Appropriately use electronic and/or integrated QC features
  - Incorporate all actions that ensure quality
  - Be truly customized for the specific laboratory and facility situation
EP23 and The Quality Control Toolbox

- Understand that each QC tool has its strengths and weaknesses (there is no perfect QC tool)

- Implement a combination of tools in order to properly control the test

- EP23 explains the strengths and weaknesses of the different types of QC
Introduces the Concept of Risk Assessment

• Gather information from several sources:
  – Regulatory and accreditation requirements
  – Measuring system information
  – Health care and testing site settings
  – Medical requirements for the test results

• Compile this information together by creating a process map and a fishbone diagram
Identify Key Process Steps

• Once the process map is created, examine it for places where errors could occur.

• Five major areas:
  – Samples
  – Operator
  – Reagents
  – Laboratory environment
  – Measuring system
Group into a Fishbone Diagram

1. Samples
   - Sample Integrity
     - Lipemia
     - Hemolysis
     - Interfering substances
     - Clotting
     - Incorrect tube
   - Sample Presentation
     - Bubbles
     - Inadequate volume

2. Operator
   - Operator Capacity
     - Training
     - Competency
   - Operator staffing
     - Short staffing
     - Correct staffing

3. Reagents
   - Reagent Degradation
     - Shipping
     - Storage
     - Used past expiration
     - Preparation
   - Quality Control Material Degradation
     - Shipping
     - Storage
     - Used past expiration
     - Preparation

4. Laboratory Environment
   - Atmospheric Environment
     - Dust
     - Temperature
     - Humidity
   - Utility Environment
     - Electrical
     - Water quality
     - Pressure

5. Measuring System
   - Calibrator Degradation
     - Shipping
     - Storage
     - Used past expiration
     - Preparation
   - Instrument Failure
     - Software failure
     - Optics drift
     - Electronic instability
   - Inadequate Instrument Maintenance
     - Dirty optics
     - Contamination
     - Scratches

Identify Potential Hazards

Incorrect Test Result
Perform the Risk Assessment

- Identify the potential hazards and their causes.
- Assess each potential failure.
- Where harm could occur, add an element in the QCP that will reduce the severity of harm, making residual risk acceptable.
  - For some types of failures, the manufacturer’s information may already have a quality check in place.
Perform the Risk Assessment

• Construct a table; see which types of errors are detected and which ones are not.
  – If not detected, it must be included in the QCP.

• For each possible hazard, assess the severity of harm.
  – Do this for each hazard on five-point scales.
  – Use all of the information gathered in order to make these assessments.
Perform the Risk Assessment

## Definitions for categories are from ISO 14971

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<th>Probability of Harm</th>
<th>Negligible</th>
<th>Minor</th>
<th>Serious</th>
<th>Critical</th>
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</table>
Assemble the Quality Control Plan

• Use the chart developed earlier to add all of the identified risks and their control measures.

• Construct the QCP.

• Include each of the identified QCP Actions in the QCP.
Monitor Quality Control Plan for Effectiveness

• Verify that QCP put in place actually works

• Continue to monitor errors and control failures.

• If an error occurs:
  – Take the appropriate corrective action.
  – Investigate the cause of the error.
  – Once the cause is understood, evaluate whether any changes need to be made in the QCP.
Monitor Quality Control Plan for Effectiveness

• Review any complaints that the laboratory receives from health care providers.
  – These complaints may include pointing out another source of QC “failure” that must be addressed.

• For patient safety, review EP23 on a regular basis to ensure an optimal QCP.
EP23 Summary
EP23 Companion Products

- EP23 Implementation Workbook
- EP23 Risk Assessment Worksheet
  - Template and Example
- QCP Examples
  - Blood Glucose is in the EP23 document
  - PT/INR is in the workbook
  - Molecular test is coming soon
  - Blood gas test is in development
- Webinars
  - For labs and for instrument/test manufacturers
Thank you!