# IQCP

## It's here! Now what?

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# Quality Control?

- What?
  - Set of procedures designed to monitor the test method & results to ensure appropriate test system performance
- WHY?
  - Ensure day-to-day consistency of measurements

excerpted from CLSI Harmonized Terminology Database

# POCT QC – in the beginning

- Two levels of liquid QC available from manufacturers
  - Recommended frequency often missing
  - End users often unaware that QC is required
  - Process not reflective of patient test performance
    - Still true for many systems
- Haphazard implementation

# 1990's

- POCT awareness increased
  - Inspectors take active look at POC processes
  - Increased implementation of QC programs
    - Compliance difficult
    - Expense of POCT greatly increased
- Introduction of Electronic QC
  - 1994 ESVT cleared for Hemochron tube system
  - 1998 HepTrac cleared for HMS system
  - Others cleared with instrument

# Alternative QC Expansion

- QC designed to replace liquid controls
  - Generally only a partial replacement
  - Designed to insure system performance without surrogate sample (LQC) testing
- Electronic QC
  - Internal or external
  - Evaluates instrument function only
  - Includes dry cartridge QC alternatives

# Other Alternative QC

- On-board
  - Generally references internal reagent controls
  - Evaluates instrument and reagent function
  - Some also evaluate operator technique
- Equivalent QC
  - Term coined by CMS to reference any non-surrogate sample QC

# What is Required?

- CLIA Regulations
  - Subpart K--Quality Systems for Nonwaived Testing
  - Sec. 493.1256 Standard: Control procedures
    - monitor the accuracy and precision of the complete analytical process
    - **lab** must establish the number, type, and frequency of testing control materials
    - control procedures **must**–

      (1) Detect immediate errors that occur due to
      - test system failure
      - adverse environmental conditions
      - and operator performance.

      (2) Monitor over time the accuracy and precision of test performance

# Is there a required frequency?

- CLIA Regulations
  - Unless CMS approves a procedure … that provides equivalent quality testing, the laboratory must …
    - For each test system, perform control procedures … At least once each day patient specimens are assayed
      - Hematology and Blood Gas require at least once per eight hour shift
    - Each quantitative procedure, include two control materials of different concentrations
    - Each qualitative procedure, include a negative and positive control material

# Equivalent Quality Testing

- Since 2003, this has been the CMS approved procedure.
  - Three options, specific implementation instructions
- Option 4
  - CLSI undertook the charge to develop a risk based method for determining QC procedures and frequency
    - EP-23 Laboratory Quality Control Based on Risk Management
    - Forms the basis for IQCP
      - CLSI. *Laboratory Quality Control Based on Risk Management; Approved Guideline.* CLSI document EP23-A. Wayne, PA: Clinical and Laboratory Standards Institute; 2011.

# IQCP ≠ EP23

- EP23 is a tool, but not required
  - Provides tool kit to perform risk analyses
  - Explains how risk assessment can affect Quality Plan
  - Does not provide guidance on QC frequency
- How to implement IQCP is site and test system dependent

# IQCP Implementation

- IQCP will be voluntary
  - Default QC requirement will be 42 CFR 493.1256(d)(3)
- IQCP phase-in has begun
  - Continue as now until IQCP Plans ready
  - Implement for each test as Plans available
- Education and Transition Period
- IQCP implementation deadline January 2016
  - Equivalent QC **NOT** acceptable
  - IQCP **only** option to
    - 2 levels QC each day of patient testing
      - every 8 hours for blood gases and coagulation

# Individualized Quality Control Plan (IQCP)

# CLIA

- ✔ **Customizes** QC Plan for each test in its unique environment
- ✔ **Optimizes** use of electronic/integrated controls
- ✔ **Offers** laboratories **flexibility** in achieving QC compliance
- ✔ **Adaptable** for future advancements in technology
- ✔ **Incorporates** other sources of Quality Information
- ✔ **Strengthens** Manufacturer/Laboratory partnerships
- ✔ **Formalizes** risk management data already maintained within the laboratory
- ✔ **Provides** equivalent quality testing to meet the CLIA QC regulations

## The Right Quality Control

CMS

# Don't Panic

- Lots of help available:
  - CMS
    - IQCP downloads: http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Individualized_Quality_Control_Plan_IQCP.html
    - FAQ: www.cms.gov/clia
    - questions: IQCP@cms.hhs.gov
  - CLSI
    - Workshops Webinars
    - Workbook Worksheet
    - FAQ: http://clsi.org/edu/workshops/ep23-qa/
  - POCC group webinars
    - Whitehat Communications
      - http://www.whitehatcom.com/POC_Group_Webinars_2014.htm

# IQCP Must Include:

- Risk Assessment (RA)
  - The bulk of the up-front effort
- Quality Control Plan (QCP)
  - What needs to be done moving forward
- Quality Assessment (QA)
  - Looking back to ensure efficacy

# Risk Assessment

- Across entire testing process
  - Pre-analytic, analytic, post-analytic
  - Specimen
  - Environment
  - Reagent
  - Test system
  - Testing personnel

# QC Plan

- Practices, resources, and procedures to control the quality of a particular test process
  - Ensure accuracy, reliability & result quality appropriate for patient care
  - Include the number, type, frequency of control
    - Criteria for acceptable results of the quality controls
    - May include:
      - Electronic controls
      - Procedural controls
      - Training and competency assessment
      - Other specified quality control activities
- Development and implementation of QCPs may be delegated (in writing) to a qualified individual

# Quality Assessment

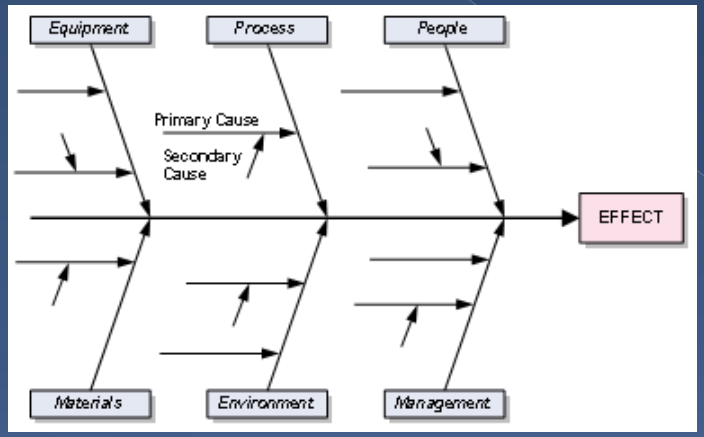
- Review system for monitoring IQCP effectiveness
- Review may include, but is not limited to:
  - QC
  - Proficiency testing records
  - Patient results review
  - Specimen rejection logs
  - Turnaround time reports
  - Records of preventive actions, corrective actions, & follow-up
  - Personnel Competency Records

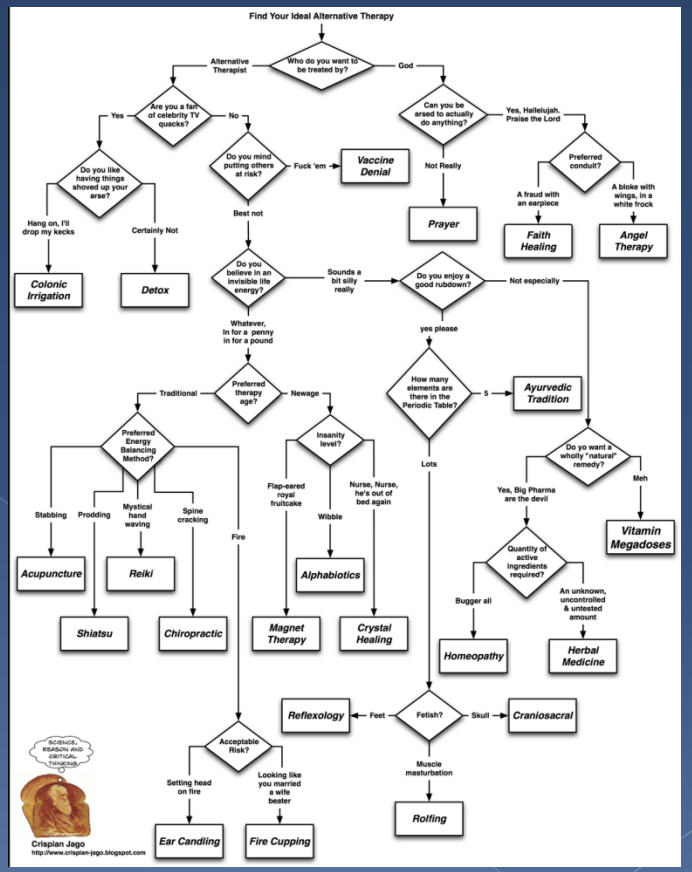
# What does it all mean?

- Requires review of current practices
  - Modify if needed
- Allows each location to have different QC requirements
- No QC tool consistently prevents or detects all failures
  - What is needed for your site?

# Look at the Process

- Process mapping
  - Fishbone Diagram




>Flow Charts

  - Tables
  - Whatever you feel comfortable using

# What is the Process?

| Preexamination (Preanalytical) Processes | Examination (Analytical) Processes | Postexamination (Postanalytical) Processes |
|---|---|---|
| • Ordering<br>• Sample collection and labeling<br>• Sample transport<br>• Sample receipt and accessioning<br>• Preexamination sample processing | • Examination<br>• Results review and follow-up<br>• Medical review | • Results reporting<br>• Results archiving<br>• Sample archiving<br>• Chargings, where applicable |

# Look at the Process - POCT

| Preexamination (Preanalytical) Processes | Applies? | Risk/ Mitigation |
|---|---|---|
| • **Ordering** | • Yes | Standard ordering process<br>Part of a predefined algorithm |
| • **Sample collection and labeling** | • Yes | Wrong sample type; delay in testing; unlabeled sample |
| • **Sample transport** | • No | |
| • **Sample receipt and accessioning** | • No | |
| • **Preexamination sample processing** | • **?** | Sample tube not mixed; Multi-step analysis not performed correctly |

# Pre-Analytic Phase

| | Specimen | Environment | Reagent | Test System | Testing Personnel |
|---|---|---|---|---|---|
| **Ordering** | Type | Not applicable | | | Trained in order system |
| **Sample Collection** | Source; type; collection technique | Temperature / humidity control required | Stored properly At room temp Pre-warm | Ready to accept sample | Trained in sample collection and system prep |
| **Sample Processing** | Mixing/ sending to another location? | Not applicable | | | Trained in processing |

# Preanalytical Processes

- All risks mitigated by training
  - Does training cover all identified risks?
  - Does competency cover all identified risks?
  - Are errors found in clinical use that suggest training needs to be modified?

# Look at the Process - POCT

| Examination (Analytical) Processes | Applies? | Risk/ Mitigation |
|---|---|---|
| • **Examination** | Yes | Quality Control processes must be designed specific to each system |
| • **Results review and follow-up** | Yes | Does operator recognize results inconsistent with patient presentation? Are repeats performed as defined by policy? |
| • **Medical review** | Yes | Was clinician notified as per policy? |

# Analytic Phase

| | Specimen | Environment | Reagent | Test System | Testing Personnel |
|---|---|---|---|---|---|
| **Examination** | Visible problems with sample? | Temperature/ humidity control required? | QC appropriate? Specimen added properly No flags/ warnings or errors | | Proficient in running specimen |
| **Results review & follow-up** | Not applicable | | | Data displayed/ stored as expected | Inconsistent results flagged / repeated |
| **Medical review** | Not applicable | | | Proper cut-offs / reference range | Clinician Notified |

# QC for Analytical Process

- Evaluate current procedures:
  - If using Built In Controls
    - Information on effectiveness in risk mitigation should be obtained from the manufacturer.
    - Often does not control for entire process
  - Liquid QC
    - Is frequency sufficient to identify problems with reagent?
  - Proficiency studies
    - Does performance suggest accurate results being obtained

# QC for Analytical Process 2

- Evaluate current procedures:
  - Evaluate Complaint history
    - Do end users / clinicians question the results?
    - Does frequency suggest problems with system?
  - Evaluate validation performed when current procedure implemented
    - Has frequency of errors changed?
    - Is there reason to believe there are risks that can be better mitigated?

# Look at the Process – POCT

| Postexamination (Postanalytical) Processes | Applies? | Risk/ Mitigation |
|---|---|---|
| • **Results reporting** | Yes | Electronic data transfer or manual?<br>How is accuracy of transfer controlled?<br>How are errors kept from the EMR? |
| • **Results archiving** | Yes | |
| • **Sample archiving** | No | |
| • **Charging for examinations, where applicable** | Yes | Work with IT personnel to ensure transfer to proper billing personnel |

# Post-Analytic Phase

| | Specimen | Environment | Reagent | Test System | Testing Personnel |
|---|---|---|---|---|---|
| **Results reporting** | Not applicable | | | Data recorded/ transmitted as required | Clinician alerted as needed |
| **Results archiving** | Not applicable | | | Data in permanent record / EMR | Verify transfer of results |
| **Charging for examinations** | Not applicable, yet risk exists and must be assessed | | | | |

# Developing a Final QC Plan

- Hazard Identification
  - Analyses just reviewed
- Risk estimation
  - Potential frequency of problem
- Risk evaluation
  - Criticality of problem
- Risk Control
  - Mitigations in place or to be implemented

# Risk Estimation / Evaluation

- Criticality is product of probability (frequency) and severity (consequences)

| | | Severity | | |
|---|---|---|---|---|
| | | Serious Injury | Limited Injury | Negligible Injury |
| Probability | Likely | **High** | Moderate | Low |
| | Remote | Moderate | Low | Low |
| | Improbable | Low | Low | Low |

# Developing a Final QC Plan 2

Sample table format to document findings in EP-23

| Targeted Failure Mode (Hazard) | Measuring System Feature or Recommended Action | Known Limitations of Feature or Recommended Action | Control Process Effective? | The QCP Actions Required to Address Known Limitations | Residual Risk Acceptable? (Yes/No) |
|---|---|---|---|---|---|

- Final plan must show ALL residual risks are acceptable
- If "No", must implement additional mitigation
- Not necessarily increased LQC

# Post-implementation (QA)

- Evaluation of effectiveness
  - Verify identification of errors
  - Review complaints
  - Track complaints and investigations
- Corrective Actions
  - If problem with built-in controls, increase frequency of external controls
  - If operator errors, modify training and procedures

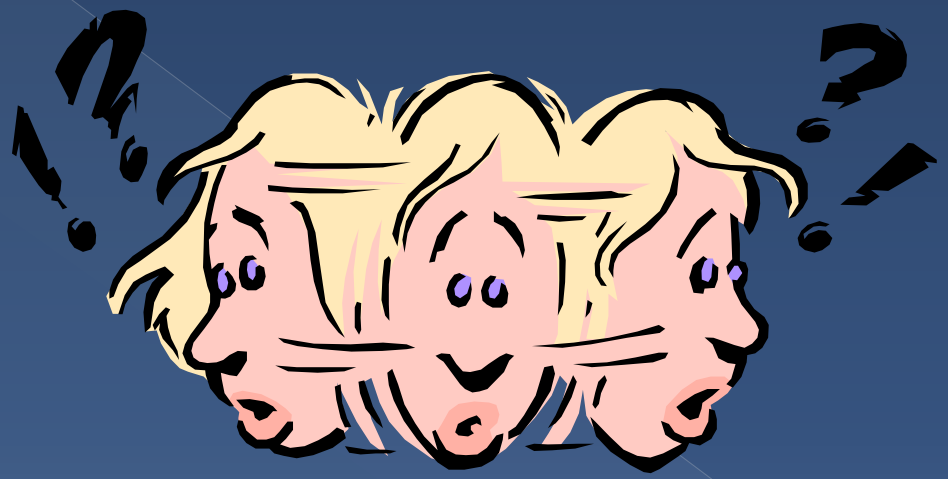
# Impact on your program

- It will take time
  - PAPERWORK, PAPERWORK, PAPERWORK
- Requires:
  - detailed knowledge of system functions
    - ask manufacturers for information
  - detailed understanding of clinical applications
    - ask clinicians for information to aid in identifying risks
      - how "wrong" must a result be to increase risk?
  - Documentation of findings and decisions

# IQCP

- Individualized QC Policy
  - Allows the definition of a policy that fits your institution
    - *e.g.*, Different QC programs for high and low volume tests
  - May not differ from current processes
    - Need to assess efficacy of current processes in light of identified potential risks
    - May need revision if additional risks identified or non-value added steps noted

# QUESTIONS?



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