Quality Control and Risk Management

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Why Now?

• EP23
  - Laboratory QC Based on Risk Management

• CLIA*
  - Individualized Quality Control Plans based on EP23

• ISO 15189: 2012
  - References to Risk Assessment & Risk Management

• ISO 22870: POCT: Personnel & Quality
  - Follows 15189

* Appendix C/State Operators Manual
What is Risk Management?

Use of policies / procedures designed to minimize the occurrence of patient harm due to an incorrect test result

Example:

• Run QC material to ensure the instrument is performing properly

• Monitoring refrigerator temp where reagents are stored
What is Risk Management?

- Risk Perception
- Risk Assessment
- Risk Management
Key Concepts for Risk Management

- Know your risks (hazards)
- Remove, minimize, or monitor risks (hazards)
- Monitor process to ensure risk remains acceptable
QC Based on Risk Management

Goal

• Appropriate use of QC material and activities that deliver quality patient results

Activities

• Identify, Assess, Treat / Mitigate / Control, Monitor
  - Process Mapping, Fishbone Analysis, FMEA, etc.

Deliverable

• QC Plan
What is in a QC Plan?

Control Steps and Frequency They are Performed

Example:

• **Electronic controls** – auto - every 24 hrs
• **Liquid QC**
  - 2 levels before & after Calibration or Maintenance
  - 2 levels every 200 patient tests
  - New lot of reagents….etc.
• **EQA**
• **Calibration**
• **Maintenance**
Risk Approach Has Many Names

• Patient Focused QC
• Patient Safety
• Patient Centered
• The Right QC
• TQM
How much QC is appropriate?

“The clinical use of the test result, the impact of errors on patient care, test stability, number of patients between QC events, and frequency of calibration influences the maximum interval between control events.”

EP23 5.1.1
Risk Management Impact on a QC Plan

• Considers 3 phases of testing
  – Pre-analytical, analytical, post-analytical

• QC rules
  – How many QC’s and Accept / Reject policy

• Frequency

• Monitoring
  – Periodic review of QC Plan & activities: ensures adequacy
The Right QC

• Based on instrument / test method quality

• Test volume

• Might be more QC – Might be less QC

• Balanced approach
What is the purpose of QC?

Are you interested in ensuring the instrument is likely to run correctly?

or

Are you interested in ensuring the patient tests you ran are likely to be correct?

Does your car only run function tests when you start it?
When do labs run QC?

Each morning?
After maintenance?
After Calibration?

If a failure occurred mid-day –
How would they know?

What are lab’s philosophies about QC frequency and why?
What is your customer’s comfort level?

“How many patient results can be at risk before you start getting nervous?”

What’s required to recover?

Mayo Clinic reports ~ 15 events per year that affect more than 20 patients per event

Large-Scale Testing Errors
Tips on How Labs Can Prepare and Recover
An Interview with Nikola Baumann, PhD, DABCC
Risk Management – Minimize Exposure

Legacy QC:
Rules for each analytical run

Modern Labs: What is an analytical run?
What is your answer to these questions?

• If I’m running QC only in the morning, how do I know the results are still acceptable at the end of the day?

• What’s my comfort level for # of test results to go back and assessing when I have a failure? Does my QC match that?
The [CLIA] requirement for testing two levels of liquid QC every day a test is run comes from the days when labs ran just a few batches of patient samples a day.

With the new, more automated analyzers, there is no longer batch analysis and patient samples are run continuously.

So now, the question is, do we hold those samples until the next QC run, or do we run QC continuously every 10, 20, or 50 samples and release results in small batches?

These operational considerations lead to turn around time issues, cost issues and resource issues.

For more detailed information

- Type “Risk Management” in the search field of the QCNet home page
Risk Management Resources

Patient Risk Management

Looking Ahead to Patient Risk Management

We're now living in a time when sophisticated automated systems continuously produce patient test results. Yet typical QC practices are based around a batch of patient samples, or are set by default to a once daily regulatory minimum. Take your laboratory into the era of patient risk management – with Bio-Rad as your partner.

In this article you will learn about building a QC system based around patient risk management. Related articles provide more detail on key concepts. There are links to useful references and resources. You also have links to: a catalog of independent third party Bio-Rad control materials, Product Insights with Levels, Mean Values and Ranges; and the Unily™ Interlaboratory Program.

Regulation is changing from “one-size-fits-all QC” to doing the “Right QC”

Regulation is changing. Centers for Medicare & Medicaid Services (CMS), has recognized that “one-size-fits-all QC” is no longer appropriate due to newer technologies now available in the laboratory. What is needed is “design of an appropriate and effective GCP (QC Plan) for each laboratory and each specific test; that is the ‘Right QC’” This new QC protocol will not necessarily reduce QC requirements, but instead, will be the “Right QC” for [each] laboratory, its environment, patients, personnel, test systems, etc. 1 For more information on Right QC see the related article “One-size-fits-all QC vs. Right QC.”

1 DHSS, CMS, Office of Clinical Standards and Quality/Survey and Certification Group, Ref. S&C: 12-03-CLIA, November 4, 2011.

Related Articles

One-size-fits-all QC vs. Right QC
Expected Number of Patients Compromised by Failure
Concentrations of Control Materials
Six Sigma Background

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