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The Road to Risk Management: From Paper to Practice
Brief History

Need for QC frequency rationale led to CLSI guideline EP23

- Focus on failure mode and effects analysis (FMEA)

CMS responded with individualized quality control plan (IQCP)
What is IQCP intended to be?

Uncomplicated

Critical and honest

Review and evaluation of known and potential risks in the lab

Planned

Well-documented
When is an IQCP needed?

Totally voluntary unless:

- You want to reduce QC for a test or a device to less than 2 times per day
- The manufacturer (product insert) recommends less than 2 times per day
What about just using an IQCP prepared by the manufacturer?

Not allowed

Provides a good baseline though
So how do we identify risks in the lab?

Form a small group

Start small

Brainstorm

Map the process

• Look for hazards (potential failures that could cause harm)

• Assess the associated risk (next slide)
Assessing the risk

How probable is it that the failure will occur?

What degree of harm would come to the patient if a bad result were reported and acted upon?

How many patients might be affected?
Then what?

Establish causes of the potential failures (hazards)

• Use a cause and effect analysis
  o Ishigawa chart, fishbone diagram
Cause and effect

Classic
Method
Measurement
Man
Materials
Machine
Environment

IQCP
Specimen
—
Testing personnel
Reagents
Test system
Environment
Prioritize risks using FMEA

Identify and put controls into place that will:

- Eliminate the cause of the failure (and/or)
- Reduce the potential the failure will happen (and)
- Effectively detect the failure should it occur

Follow-up six months later

- Evaluate effectiveness
- Document
Summary

Keep it simple
Do the work
Ask the hard questions
Be able to accept results you don’t expect
Perform an honest assessment
References

Medical devices – Application of risk management to medical devices (ISO 14971: 2007).

Medical laboratories – Requirements for quality and competence (ISO 15189: 2012).
