Connecting Analyzer Risk Mitigation Features to Your IQCP

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Disclosures

Not a representative of CLSI or CMS

Content reflects my views

Presentation is sponsored by
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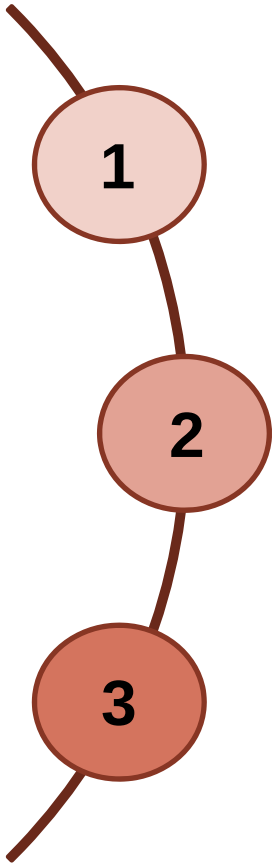
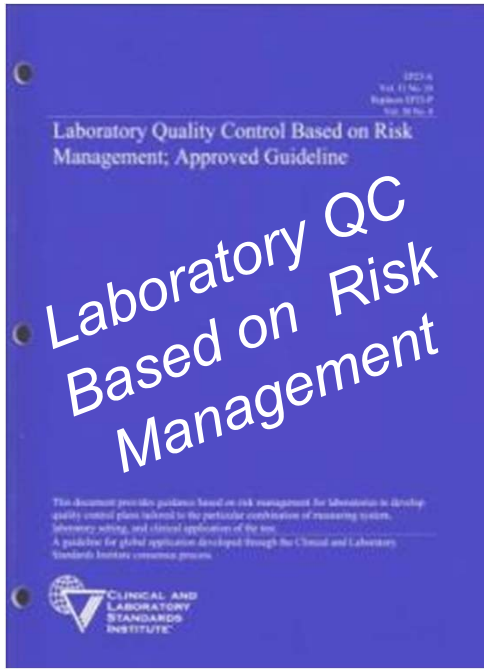
Goals for today



1. Simplify development of a CMS defined Individualized Quality Control Plan (IQCP)
2. Provide an “easy” approach to risk assessment (RA)
3. Capitalize on testing device’s risk management features

CLIA's New QC Option – Jan. 1, 2016



Quality control plan development based on risk management (RM)

Systematic approach to analyze, evaluate, control, and monitor risks

CMS' *new* CLIA IQCP option incorporates RM concepts

ISO14971:2007. Application of risk management to medical devices. www.ISO.org ;
Clinical and Laboratory Standards Institute. www.CLSI.org;
http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/ Downloads/Survey-and-Cert-Letter-13-54.pdf

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CMS goals for IQCP-*new* QC option?

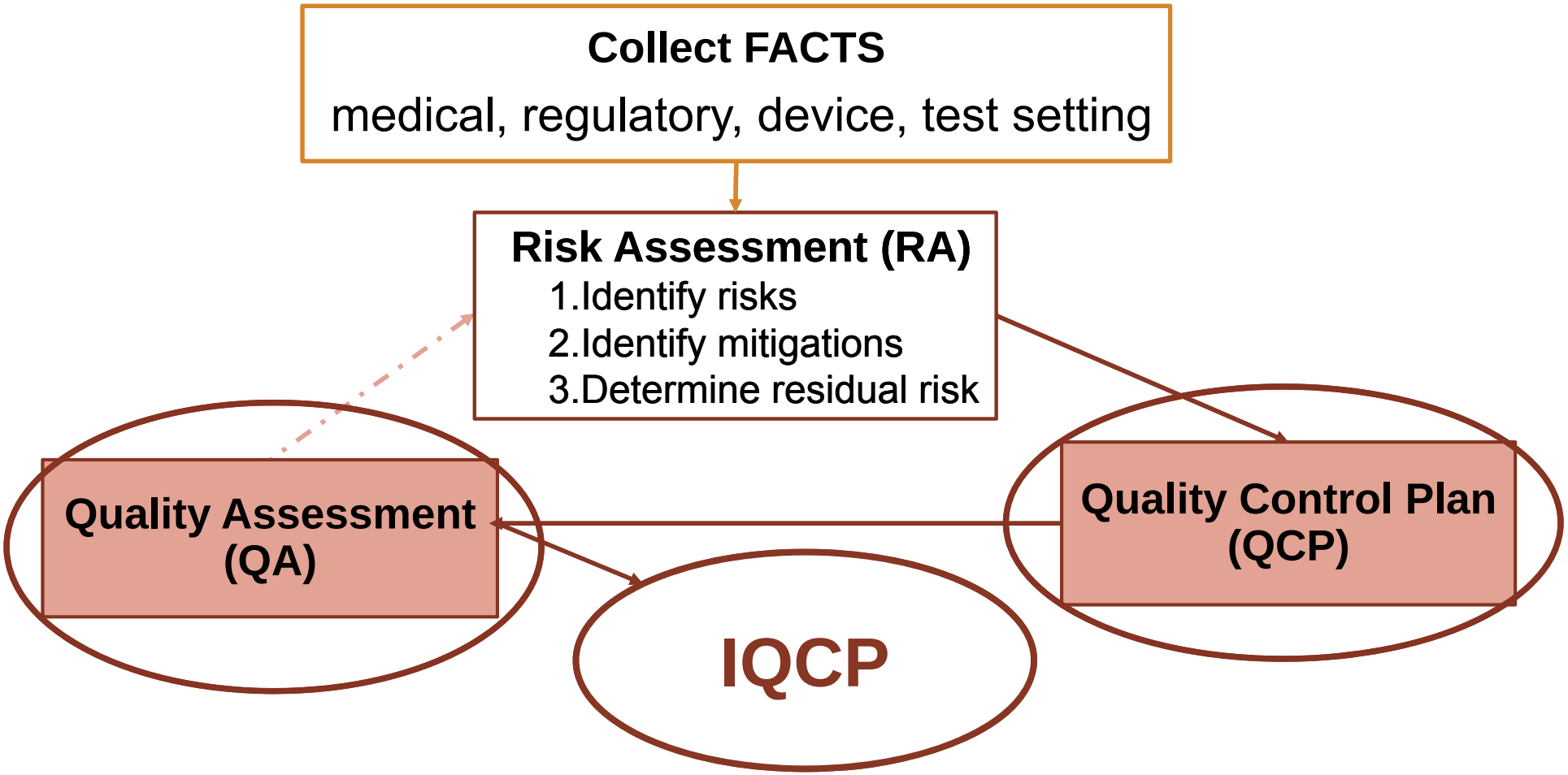
Address concerns with “built-in, quality assessment” technology in evaluating test quality

- IQCP validates, at a minimum, that manufacturer recommendations adequately **ensure analytical quality**

Ensure test result quality by eliminating significant risk in the entire testing process

Allow sites flexibility to develop quality strategies appropriate for their specific testing situation

A step-wise IQCP development approach



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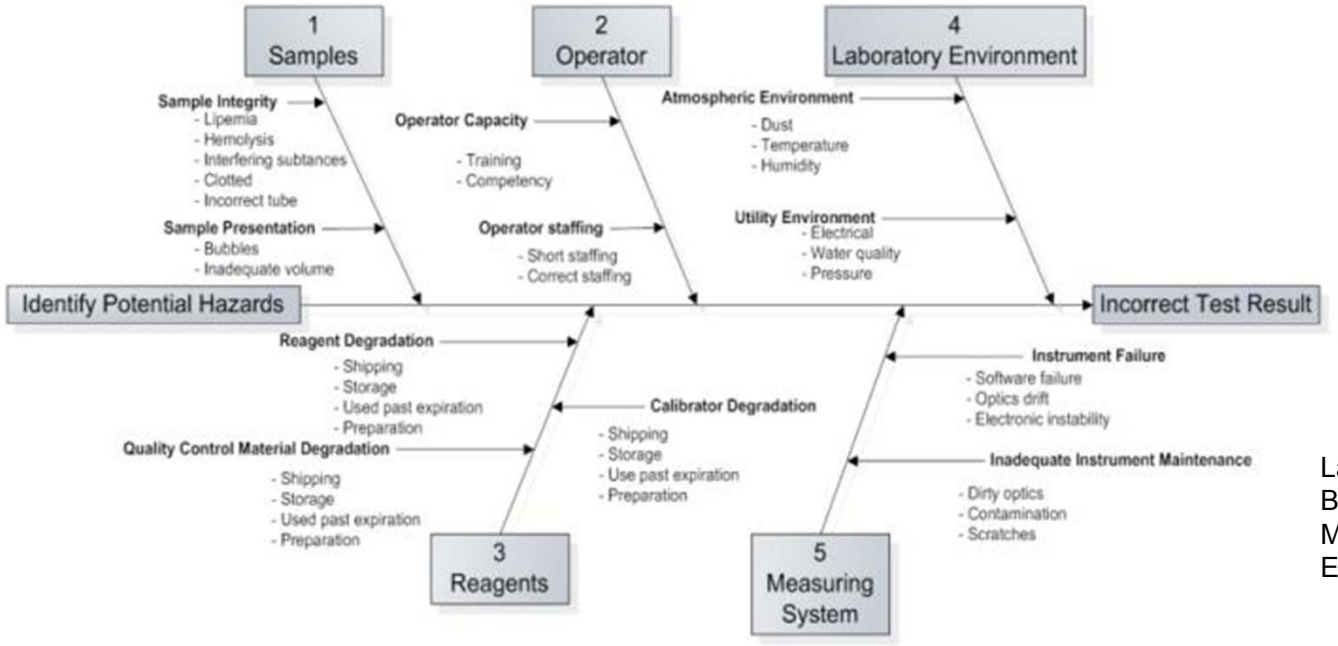
Risk Assessment (RA)
1.Identify risks

Pre-analytical | **Analytical** | **Post-analytical**

- Review the entire testing process to identify sources of *potential risks* that may impact test result quality
  - CMS requires assessment of at least 5 components:



Laboratory QC Based on Risk Management. EP23-A. clsi.org

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Identify Current Risk Mitigation

Risk Assessment (RA)
2. Identify mitigations

Review <u>current</u> *policies/practices* that eliminate or reduce potential risks in all phases of the testing process

- SOPs
- Operator qualifications
- Operator training
- Operatory competency assessment

ENSURE ANALYTICAL QUALITY

- Positive Patient ID
- Right result, patient, time
- Wireless transmission
- Sample result alerts
- Patient History
- Post-analytical reports
  - Sample handling → monitor competency

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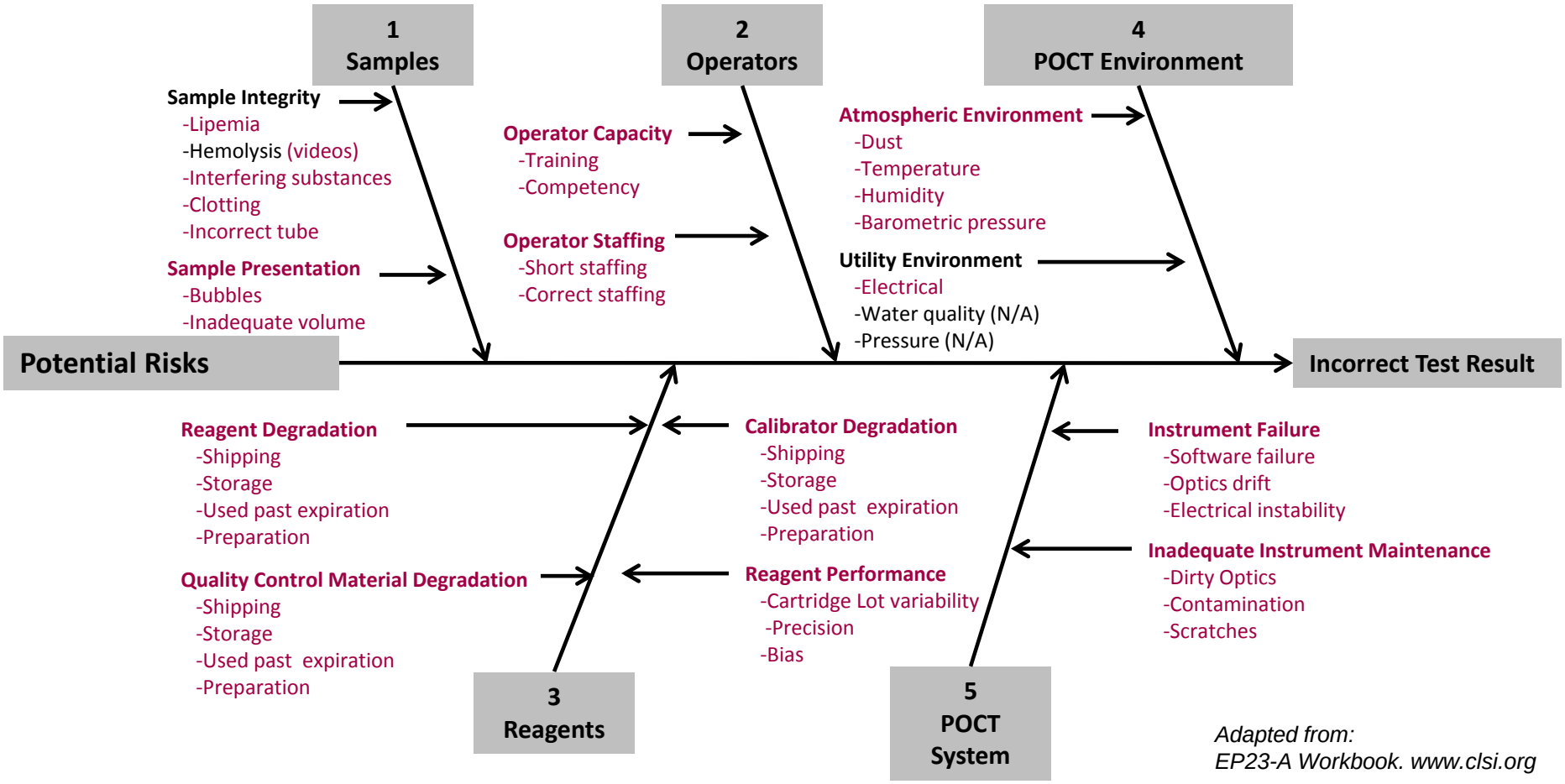
Example -- GEM Premier Systems with iQM: Analytical Error Identification and Mitigation



Adapted from:
EP23-A Workbook. www.clsi.org

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Red = error potential addressed by iQM

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Risk Assessment (RA)
2. Identify mitigations

Pre-analytical | **Analytical** | Post-analytical

Example: Analytical error reduction features - GEM Premier with iQM

Sources of Error	Risk Mitigation Features – SAMPLES
Lipemia*	• Identifies samples with very high lipemia (>4%) • Alerts user and can correct patient results for concentrations ≤4%.
Hemolysis*	• On-board sample collection training videos help reduce error • Patient history includes delta differences for each analyte
Interfering Substances*	• Automatic sample integrity checks on each sample • Alerts user and automatically initiates corrective actions
Clots, bubbles and inadequate volume*	• Automatic sample integrity checks on each sample • Alerts user and automatically initiates corrective actions
Incorrect Patient *	• Barcode scanner ensures proper sample ID • Customizable patient ID entry requirements and configurations for: Pre-Existing Orders, Automatic patient demographic fetch/search functions and ADT/POC order creation (GEMweb Plus)

* Errors can be associated with pre-analytical or analytical phase of testing.

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Risk Assessment (RA)
2. Identify mitigations

Pre-analytical | **Analytical** | Post-analytical

Example: Analytical error reduction features - GEM Premier with iQM

Sources of Error	Risk Mitigation Features – REAGENTS
REAGENT/CALIBARTOR DEGRADITION	
Reagent Deterioration*	▪ Verification of each GEM PAK after insertion; continuous reagent stability checks performed throughout cartridge life with NIST-traceable solutions
Reagent Contamination*	▪ Continuous reagent checks throughout GEM PAK use-life; corrective actions automatically initiated when tolerances are exceeded
Expired Reagents	▪ EEPROM or barcode checks for expiration date, test menu and use-life
REAGENT PERFORMANCE	
Poor Precision/Bias*	▪ Checks continually performed; automatic corrective actions
Lot to Lot Variability*	▪ Checked on PAK insertion and throughout cartridge use-life utilizing NIST-traceable solutions; sensors outside acceptable ranges are disabled
Sensor Malfunction/ QC out of range*	▪ Checks continually performed; automatic corrective actions ***Note: 100's of Process Control Solution performed daily**

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“Leftover,” Residual, Potential Risks?

For those identified, but NOT currently detected or eliminated, determine which are ***significant***

But how?

Risk Assessment (RA)
3. Determine residual risk

Pre-analytical | Analytical | Post-analytical

Example: rating residual risk

Prior to sample collection, healthcare provider does not draw/discard adequate "waste" blood from a new arterial line

Benzalkonium (interference) in sample causes higher Na^+ value, (e.g.,160 mmol/L versus 140 mmol/L after redraw)

Severity of Harm

Probability	Negligible	Minor	Serious	Critical	Catastrophic
Frequent	**Not OK**	**Not OK**	**Not OK**	**Not OK**	**Not OK**
Probable	OK	**Not OK**	**Not OK**	**Not OK**	**Not OK**
Occasional	OK	OK	OK	**Not OK**	**Not OK**
Remote	OK	OK	OK	OK	**Not OK**
Inconceivable	OK	OK	OK	OK	OK

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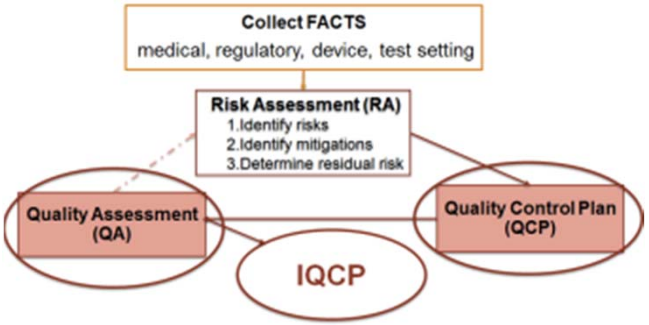
Risk Assessment (RA)
3. Determine residual risk

Pre-analytical | Analytical | Post-analytical

Suggested documentation of RA findings

- Decide how to detect/eliminate risk/failure (modify training, modify policies, etc.)

Phase where failure/error occurs	Potential failure/error	Potential Cause	Mitigated/ Detected?	Changes made to detect/eliminate failure
Pre-analytical	Benzalkonium Interference in Sample	Improper sampling from arterial line (2X waste)	Yes	Analyzer detects Benzalkonium automatically utilizing pattern recognition software
Pre-analytical	Hemolysis (increased K+ results)	Improper sampling	No	Pre-analytical training and competency assessment; documentation
Pre-analytical	Reduced total hemoglobin result	Not mixing sample prior to presenting to device	Yes	On-board training videos, competency assessment; documentation
Analytical	Incorrect CO-Oximetry results	High lipemia	Yes	Analyzer detects lipemia and corrects result automatically or notifies operator



Quality Control Plan
Quality Assessment

- **Quality Control Plan** - Documented strategy (device and site specific) for quality test results
  - Practices, resources and procedures to control quality
    - Ensures accuracy/reliability/appropriate quality for patient care
    - Provides for immediate error detection due to test system failure, adverse environment conditions, operator performance
    - Monitors performance accuracy and precision influenced by changes in test system, environment, and operators
- **Quality Assessment** – Plan-do-check-Act for effectiveness
  - - Nothing new

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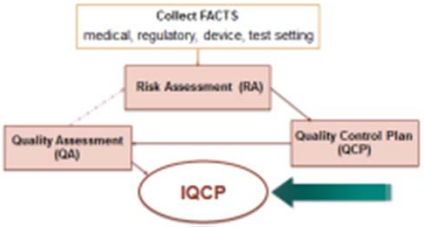

Last Step: The IQCP

Keep it "short" – 1 – 2 pages:

- Begin with the specifics—testing device/analytes; test site's name, address; effective date; CLIA number; director; etc.
- Summarize the Risk Assessment process—steps, staff, information collected, etc.
- Summarize changes in practice(s) for all 3 phases of testing
- Identify location of supporting **documentation/performance data,** SOPs, training/competency, etc.
- Specify QCP—at least include CMS mandates for analytical QC
- Include QA approach—monitors, frequency, follow-up, inclusion into lab's QA plan

Have and show director's approval of the process and plan

Must be maintained like all other lab documents

www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-54.pdf

Q&A

Thank you!