Quality Control Based on Risk Management and Its Role in Quality Management Systems for Laboratory Accreditation

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Agenda

- About CLSI
- Risk management's fit within a quality management system (QMS) framework
- Risk management and CLSI document EP23™
- CMS requirements and the use of EP23 concepts to create individualized quality control plans (IQCP's)

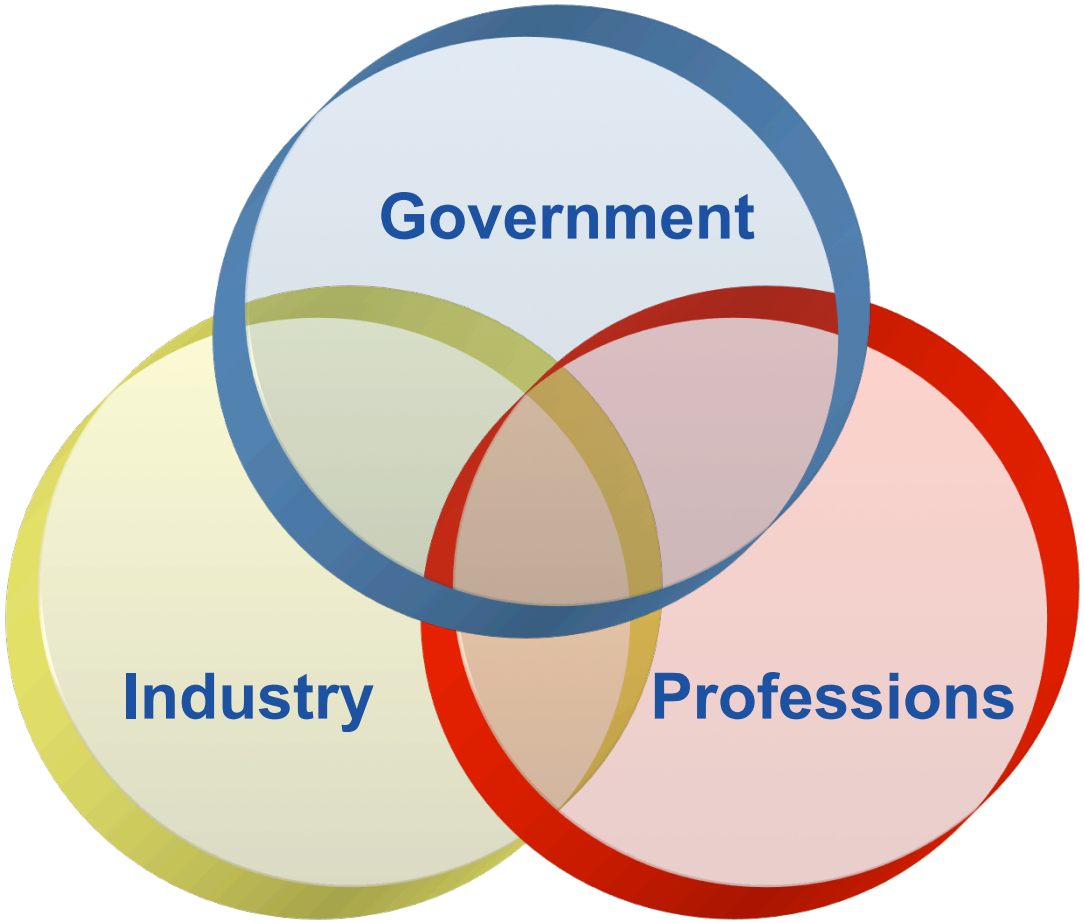
CLSI

We develop clinical and laboratory best practices and promote their use worldwide.





CLSI Tripartite Constituencies



Risk management's fit within a quality management system framework

Risk Management

- *Risk management* is a formal term for what clinical laboratories are already doing every day.

- Risk management is not a new concept; laboratories:
  - Evaluate performance of new devices.
  - Troubleshoot instrument problems.
  - Respond to physician complaints.
  - Estimate harm to a patient from incorrect results.
  - Take actions to prevent errors.

Sources of Laboratory Error

- Environmental
  - Temperature, humidity, lighting
- Operator
  - Improper specimen preparation, handling, test system operations
- Specimen
  - Clots, incorrect tube additive, speed of delivery
- Reagents
  - Shipping, storage, expiration date
- Measuring system
  - Optics, contamination, mechanical failure

The Purpose of a Quality Management System

The fundamental purpose of a quality management system (QMS) is to reduce errors in the delivery of health care.

QMS Framework: the CLSI Model

The Quality Hierarchy

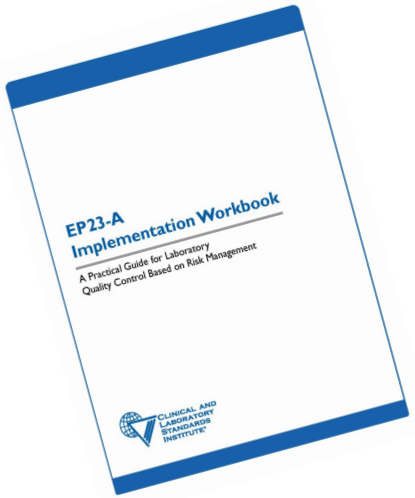
Stage	Activities Performed
Total Quality Management	Management approach centered on sustained high quality by focusing on long-term success through customer satisfaction
Quality Cost Management	Measurement system for the economic aspects of the "cost of quality"
Quality Management System	Systematic, process-oriented approach to meeting quality objectives
Quality Assurance	Planned systematic activities to provide confidence that an organization fulfills requirements for quality
Quality Control	Organizational process control techniques to fulfill quality requirements for regulatory compliance and accreditation

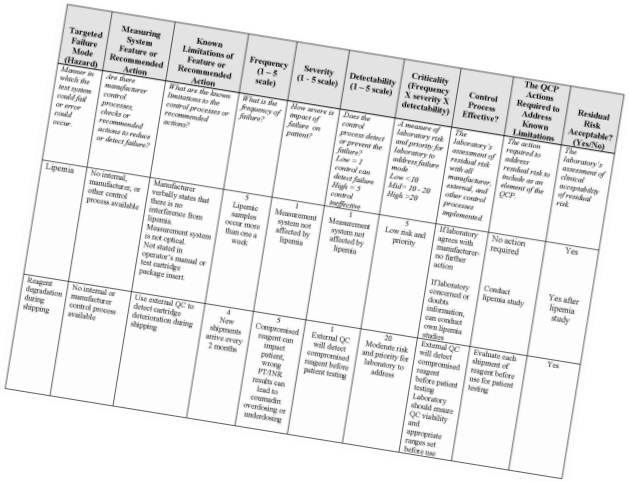
CLSI Guideline EP23

- *Laboratory Quality Control Based on Risk Management; Approved Guideline EP23-A™*
- A quick history….

EP23 Statistics

- CLSI has held seven workshops with CMS on EP23 concepts.
  - Over 160 individuals have attended.
  - All have had hands-on experience in the development of an IQCP.
  - The use of the EP23 Workbook and the EP23 Worksheet have proven helpful.





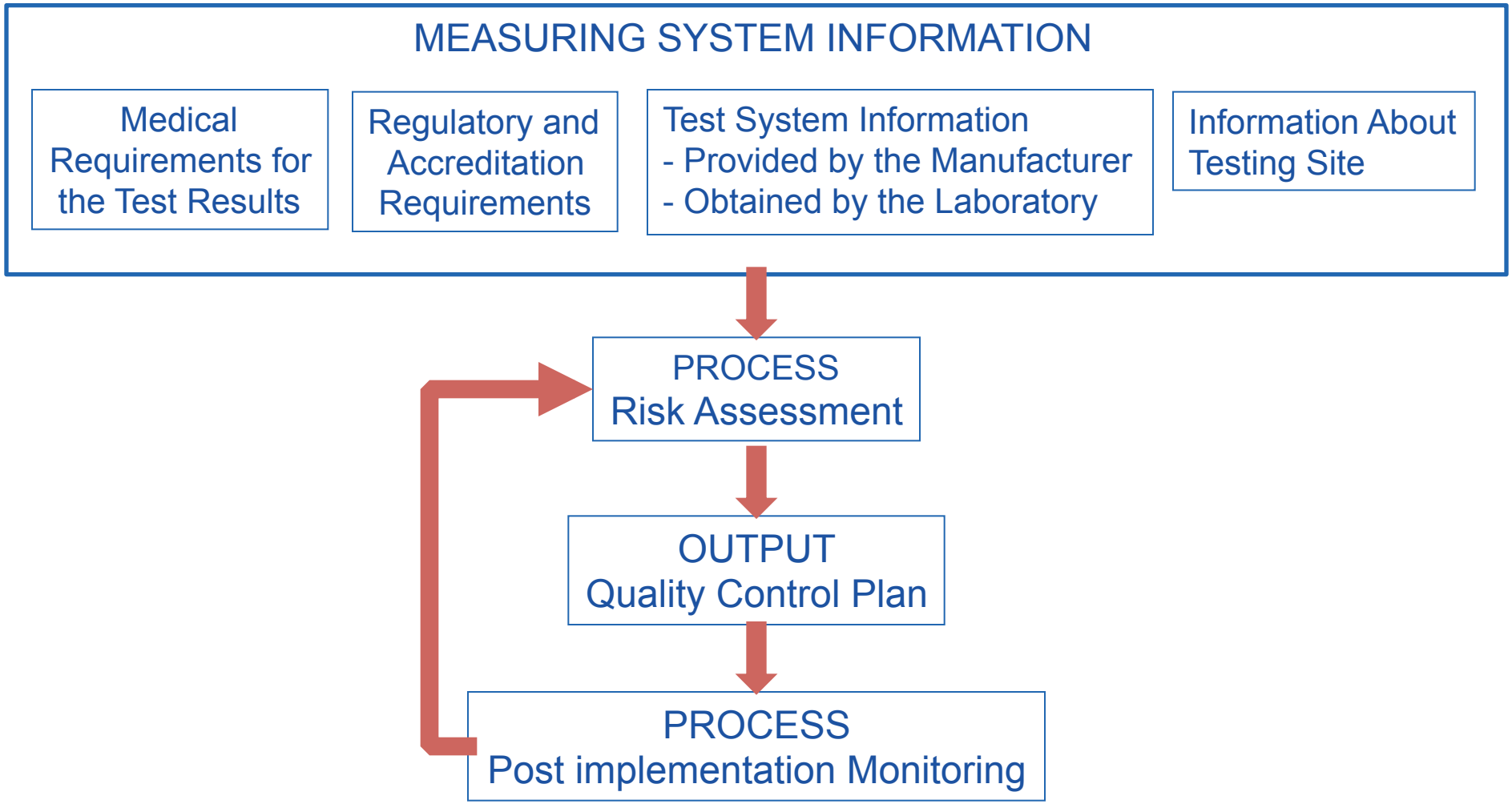
Targeted Failure Mode (Hazard)	Measuring System Feature or Recommended Action	Known Limitations of Feature or Recommended Action	Frequency (1 – 5 scale)	Severity (1 – 5 scale)	Detectability (1 – 5 scale)	Criticality (Frequency X severity X detectability)	Control Process Effective?	The QCP Actions Required to Address Known Limitations	Residual Risk Acceptable? (Yes/No)
Manner in which the test system could fail or error could occur.	Are there manufacturer control processes, checks or recommended actions to reduce or detect failure?	What are the known limitations to the control processes or recommended actions?	What is the frequency of failure?	How severe is impact of failure on patient?	Does the control process detect or prevent the failure? Low = 1 control can detect failure High = 5 control ineffective	A measure of laboratory risk and priority for laboratory to address failure mode Low <10 Mid= 10 - 20 High >20	The laboratory's assessment of residual risk with all manufacturer, external, and other control processes implemented.	The action required to address residual risk to include or an element of the QCP.	The laboratory's assessment of clinical acceptability of residual risk
Lipemia	No internal, manufacturer, or other control process available	Manufacturer verbally states that there is no interference from lipemia. Measurement system is not optical. Not stated in operator's manual or test cartridge package insert.	5 Lipemic samples occur more than once a week	1 Measurement system not affected by lipemia	1 Measurement system not affected by lipemia	5 Low risk and priority	If laboratory agrees with manufacturer- no further action If laboratory concerned or doubts information, can conduct own lipemia studies	No action required. Conduct lipemia study	Yes Yes after lipemia study
Reagent degradation during shipping	No internal or manufacturer control process available	Use external QC to detect cartridge deterioration during shipping	4 New shipments arrive every 2 months	5 Compromised reagent can impact patient, wrong PT/INR results can lead to commedin overdosing or underdosing	1 External QC will detect compromised reagent before patient testing	20 Moderate risk and priority for laboratory to address	External QC will detect compromised reagent before patient testing Laboratory should ensure QC viability and appropriate ranges set before use	Evaluate each shipment of reagent before use for patient testing	Yes

EP23 and Development of an IQCP

CLSI document EP23 provides guidance on developing an appropriate IQCP that will:

- Save time and money.
- Use electronic and/or integrated QC features.
- Use other sources of QC information.

Developing a Quality Control Plan



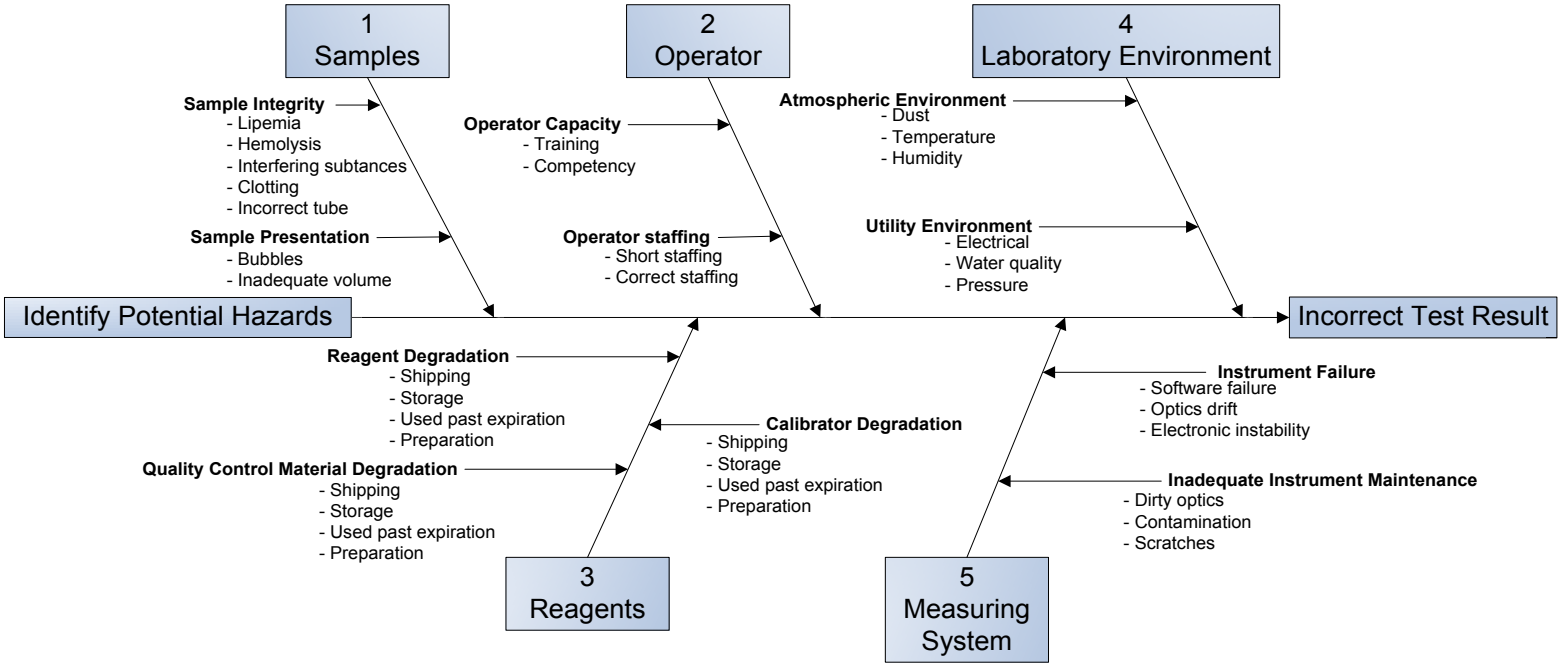
The Risk Assessment

CMS lists these possible sources for information for conducting a risk assessment:

- Manufacturer's package insert
- Manufacturer's operator manual
- Troubleshooting guide
- Manufacturers' alerts and bulletins
- Verification or establishment of performance specifications
- Testing personnel qualifications, training, and competency records
- QC data
- Proficiency testing (PT) data
- QA information, including corrective action
- Scientific publications
- Other information as appropriate

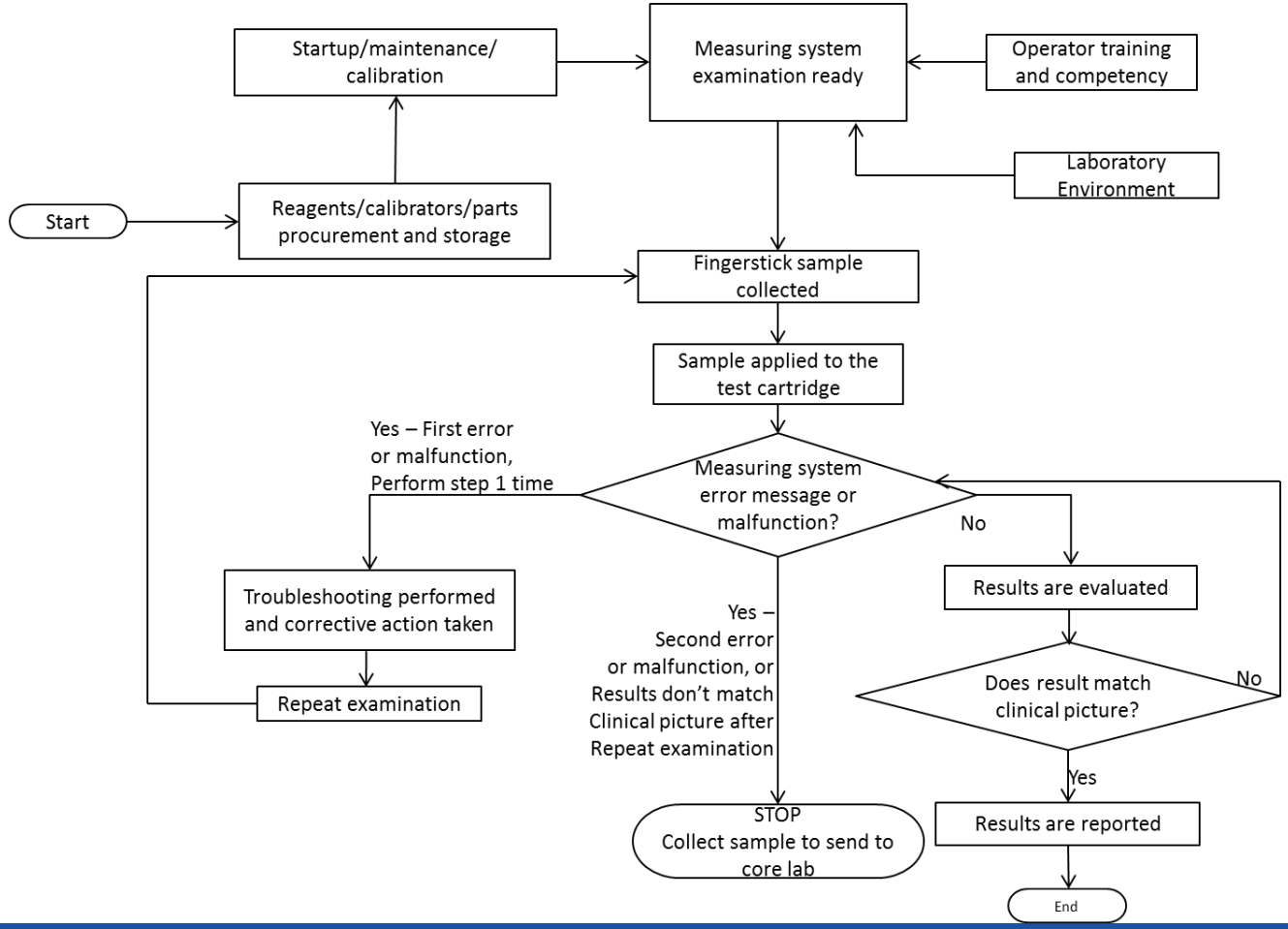
Compile Information

A fishbone diagram is one example



Compile Information

A process map is another example



Risk Assessment Worksheet

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Manner in which the test system could fail or error could occur.	*Are there manufacturer control processes, checks or recommended actions to reduce or detect failure?*	*What are the known limitations to the control processes or recommended actions?*	*What is the frequency of failure?*	*How severe is failure on patient?*	*Does the process detect or prevent the failure? Low = 1 control can detect failure High = 5 control ineffective*	*A measure of laboratory risk and priority for laboratory to address failure mode Low <10 Mid= 10 - 20 High >20*	*The laboratory's assessment of residual risk with all manufacturer, external, and other control processes implemented.*	*The action required to address residual risk to include as an element of the QCP.*	*The laboratory's assessment of clinical acceptability of residual risk.*
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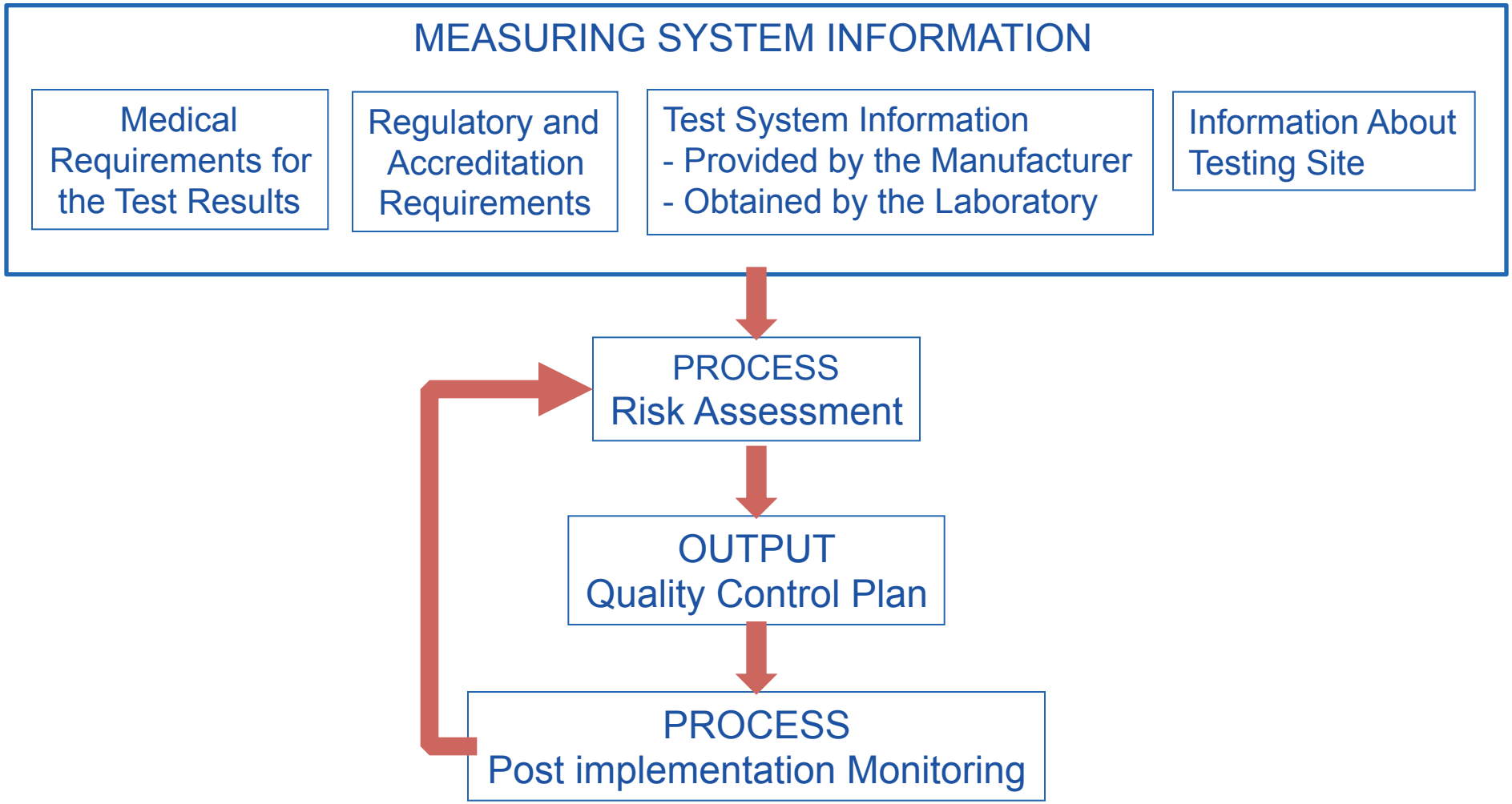
Developing a Quality Control Plan



Quality Control Plan

- A written document that describes the practices, resources, and procedures to control the quality of a particular test process
- Must include **at least** the number, type, frequency of testing, and criteria for acceptable result(s) of the quality control(s)
- May include:
  - Electronic controls
  - Procedural controls
  - Training and competence assessment
  - Other specified QC activities

Quality Control Plan Monitoring

Monitoring should include, but is not limited to, the following components:

- Testing personnel
- Environment
- Specimens
- Reagents
- Test system

Reevaluation of the IQCP should be considered when changes occur in any of the above components.

Quality Control Plan Monitoring

Documents may include:

- QC review
- PT (scores, testing failures, trends)
- Patient results review
- Specimen rejection logs
- Turnaround time reports
- Records of preventive measures, corrective actions, and follow-up
- Personnel competency records

CMS' Requirements

- On August 16, 2013, CMS CLIA released IQCP interpretive guidelines to laboratories.
- The memo describes and explains CMS' expectations of an IQCP.
- A go-live date is January 1, 2014 with a two-year transition and education period.
- After two years, the lab must either implement IQCP, or revert to two levels of liquid QC each day of use.
- The "equivalent quality control" (EQC) option goes away and IQCP is the official alternative QC method.

CMS' Requirements

Is IQCP intended to reduce the amount of quality control in laboratories?

- It depends.

  IQCP permits a laboratory to develop an effective QC protocol that recognizes technology enhancements that are built into test systems.

  IQCP's are customizable to reflect the laboratory's own unique environment, patients, testing personnel, test systems, etc.

CMS' Requirements

Are CLIA QC regulations changing to accommodate IQCP?

- No, CLIA 2003 QC regulations remain the same.
- All preanalytical, analytical, and postanalytical systems requirements in the CLIA regulations remain in effect.
- CMS is using enforcement discretion to allow laboratories to use the IQCP alternative.

CMS' Requirements

Will accrediting organizations and exempt states be required to accept the use of the IQCP option?

- It will be optional to incorporate IQCP into their standards.
- In general, they will likely follow the current QC requirements during the transition period until IQCP is fully effective, and then follow the new QC protocols subsequently approved by CMS.

CMS' Requirements

Are all specialties and subspecialties eligible for IQCP?

- All CLIA specialties, with the exception of pathology, will be eligible for IQCP. Pathology will be reconsidered at a later date.

CMS' Requirements

Will there be an education and transition period?

- Yes, CMS will be providing an education and transition period to allow laboratories to implement IQCP.

- During this time, survey teams will be instructed not to cite QC deficiencies except in cases of immediate jeopardy or when serious quality problems are identified.

CMS' Requirements

What happens to EQC and why?

- The laboratory may continue to use EQC policies and procedures until that option is replaced with IQCP at the end of the education and transition period.

- IQCP is a total quality assurance process that represents an innovative QC approach, considers the entire testing process, and provides flexibility.

CMS' Requirements

Does IQCP apply to laboratory-developed tests (LDTs) and molecular assays?

- Yes, IQCP may be used for LDTs and molecular tests, except those in the specialty of pathology.
  - Exception: Under CLIA, certain tests may be assigned to one of several specialties/subspecialties.

CMS' Requirements

Must the laboratory have data to support its decisions for the IQCP, and must the decisions be documented?

- Yes, the laboratory must have sufficient data to support their decisions, and all IQCP activities must be documented.

CMS' Requirements

Who is responsible for the laboratory's IQCP?

- The laboratory director is responsible for the laboratory's IQCP.
- The director may assign, in writing, specific duties for the IQCP to qualified individuals in the laboratory but is still responsible overall for the entire testing process.

CMS' Requirements

Will laboratories need to perform new studies to gather data/information for the IQCP development for existing tests?

- Most of the data is already being accumulated in the process of routinely operating the laboratory, meeting CLIA regulations, and implementing quality systems.
- Example: Verification of manufacturer's performance specifications, QC records, PT, corrective actions, etc.
  - There must be documented data that demonstrate the stability of the test system and support the QC type and frequency in the IQCP.

CMS' Requirements

What happens when multiple identical devices are used by the laboratory (eg, identical devices at different locations)?

- For multiple identical devices, the IQCP may be developed for the test system, taking into consideration the unique environment, testing personnel, etc.
- If those devices are dispersed throughout a health care facility, the IQCP must be developed for the devices at the different locations.

CMS' Requirements

How will the laboratory know that its IQCP is working?

- Monitors are put into place to help identify problems in a process. Continuous monitoring, investigation, and problem solving will allow the laboratory to determine if the IQCP is working and to make adjustments to the IQCP as the data warrant.

CMS' Requirements

Must an IQCP be performed if the laboratory chooses the default regulation?

- No, IQCP is not necessary if the laboratory chooses to meet the default regulation.
- However, after the IQCP education and transition period, the current EQC option will no longer be acceptable, and any laboratory that chooses to do QC less frequently than the default regulatory requirements will be out of compliance.

Resources for Related Information

- www.cms.gov/.../Individualized_Quality_Control_Plan_**IQCP**.html
- www.cms.gov/Medicare/...and.../Survey-and-Cert-Letter-13-54.pdf
- www.cms.gov/Regulations-and-Guidance/ .../**IQCP**benefits.pdf
- www.cms.gov/Regulations-and-Guidance/ .../CLIAbrochure11.pdf

CMS' Requirements

Easiest way:

- www.cms.gov
- Type **IQCP** in the search field.

CLSI Resources

- EP23-A, *Laboratory Quality Control Based on Risk Management; Approved Guideline*
- EP23-A, Implementation Workbook
- EP23-A, Worksheet
- Laboratory Quality Management System Certificate Program
- The Key to Quality™
- QMS01-A4, *Quality Management System: A Model for Laboratory Services: Approved Guideline fourth edition*
- www.clsi.org

Let’s Chat