CLSI EP23-A
Laboratory Quality Control Based on Risk Management; Approved Guideline

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CLINICAL AND LABORATORY STANDARDS INSTITUTE®

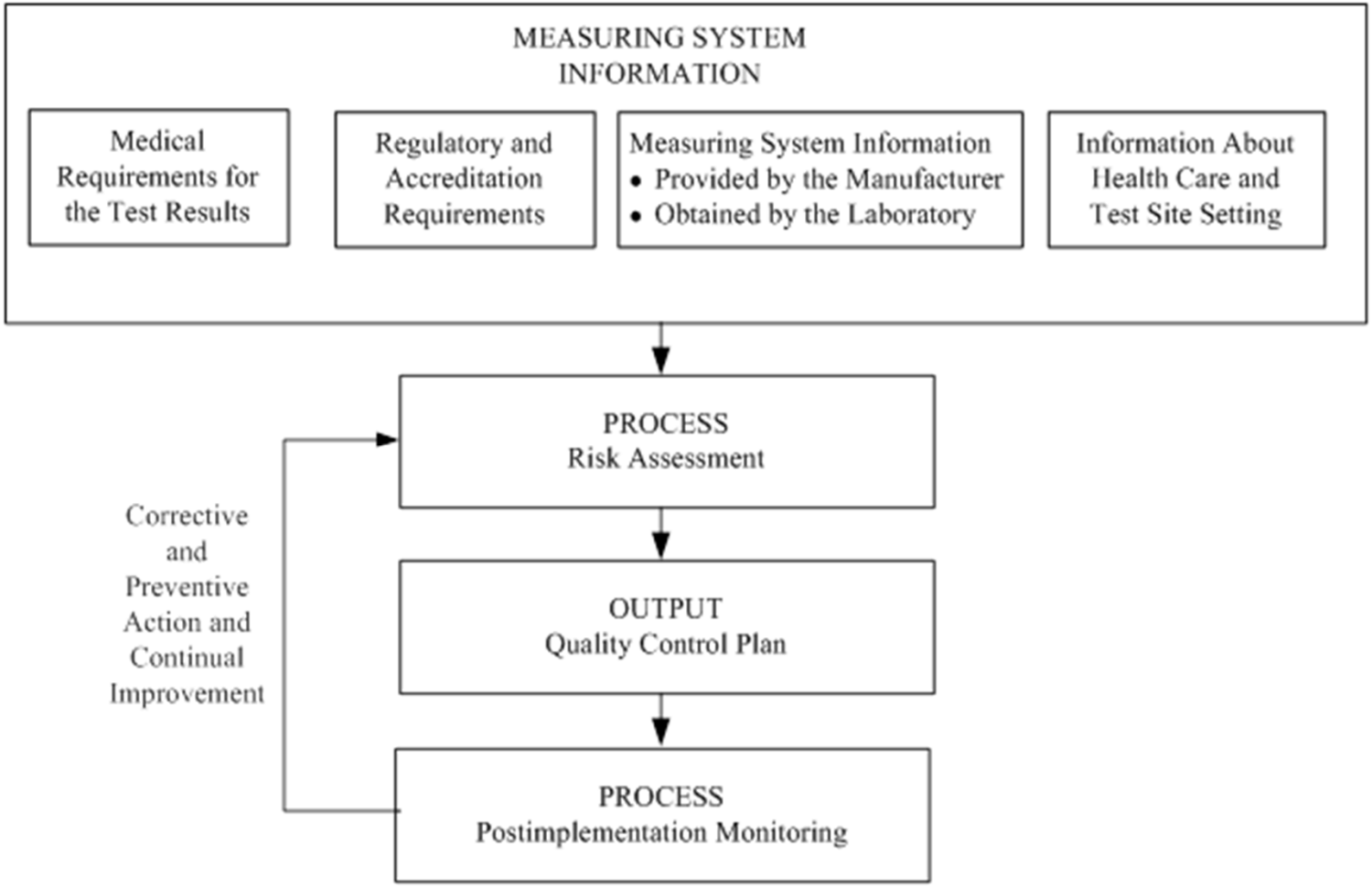
EP23 – “The Right QC”

- EP23 IS NOT about reducing quality control
- EP23 IS about understanding where errors can occur, and putting the right “controls” in place to reduce the risk of errors occurring

EP23 – “The Right QC”

- EP23 helps the lab director and the lab staff better understand their entire testing process, from collecting the sample to reporting the result
- EP23 stresses the importance of, identifies, and formalizes all of the other activities that labs do to ensure quality results
- EP23 expands the concept of what constitutes “quality control”

Overview of the EP23 Process



How does this work?

- The lab director creates a Quality Control Plan (QCP) based upon their testing processes
  - Includes sample acquisition through result reporting
  - Includes analyzing of all process steps to see where errors could occur, and what actions could prevent or reduce the risk of that error occurring
  - Results in a plan that encompasses all of the identified activities
  - Customized for each specific test, instrument, facility

The Benefits

- CLSI document EP23 provides instruction on developing an appropriate QCP that will:
  - Improve lab efficiency and quality- save time and money through reducing errors
  - Appropriately use electronic and/or integrated QC features
  - Incorporate all actions that ensure quality
  - Be truly customized for the specific laboratory and facility situation

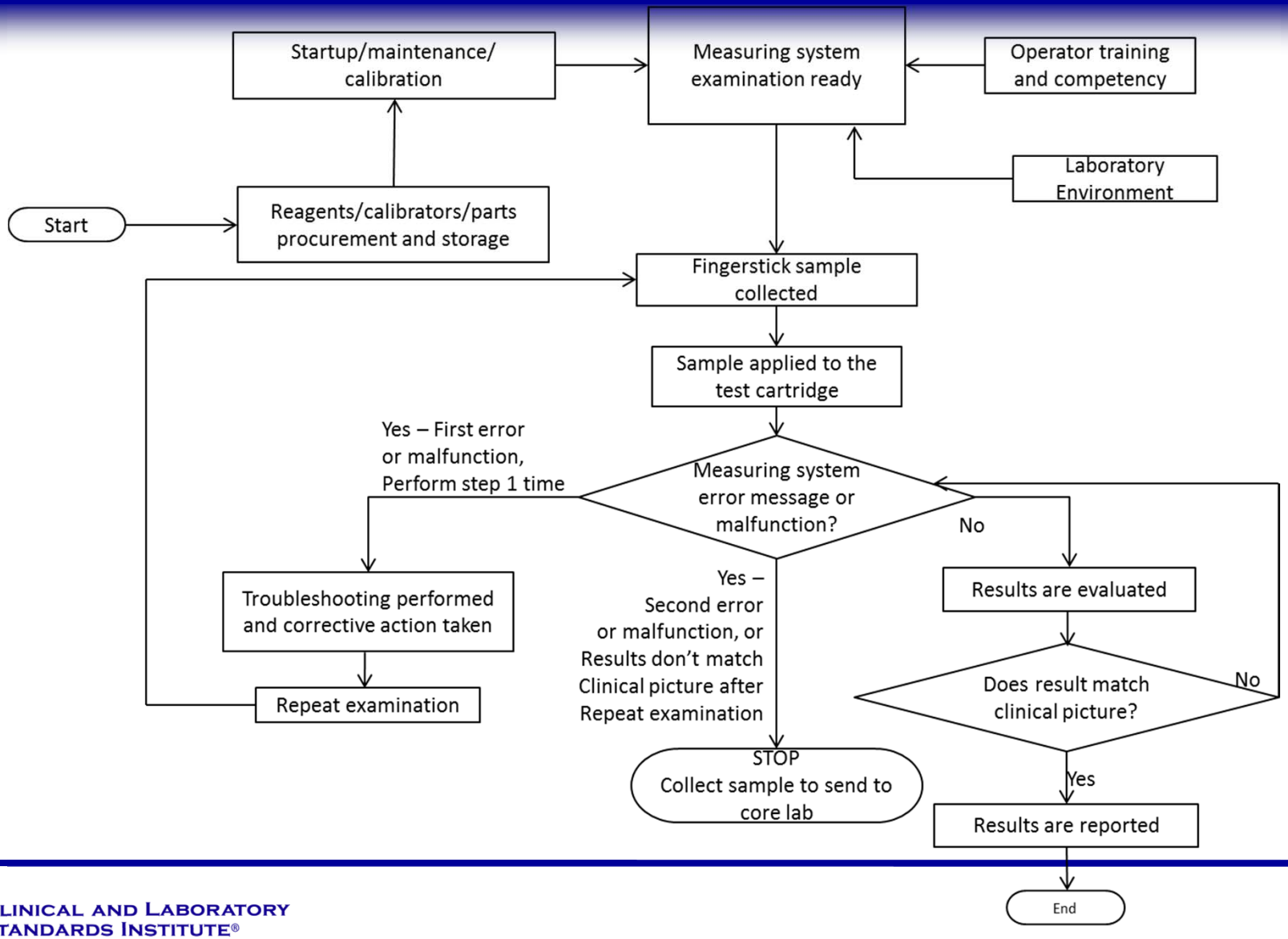
EP23 and The Quality Control Toolbox

- Understand that each QC tool has its strengths and weaknesses (there is no perfect QC tool)
- Implement a combination of tools in order to properly control the test
- EP23 explains the strengths and weaknesses of the different types of QC

Introduces the Concept of Risk Assessment

- Gather information from several sources:
  - Regulatory and accreditation requirements
  - Measuring system information
  - Health care and testing site settings
  - Medical requirements for the test results
- Compile this information together by creating a process map and a fishbone diagram

Create a Process Map

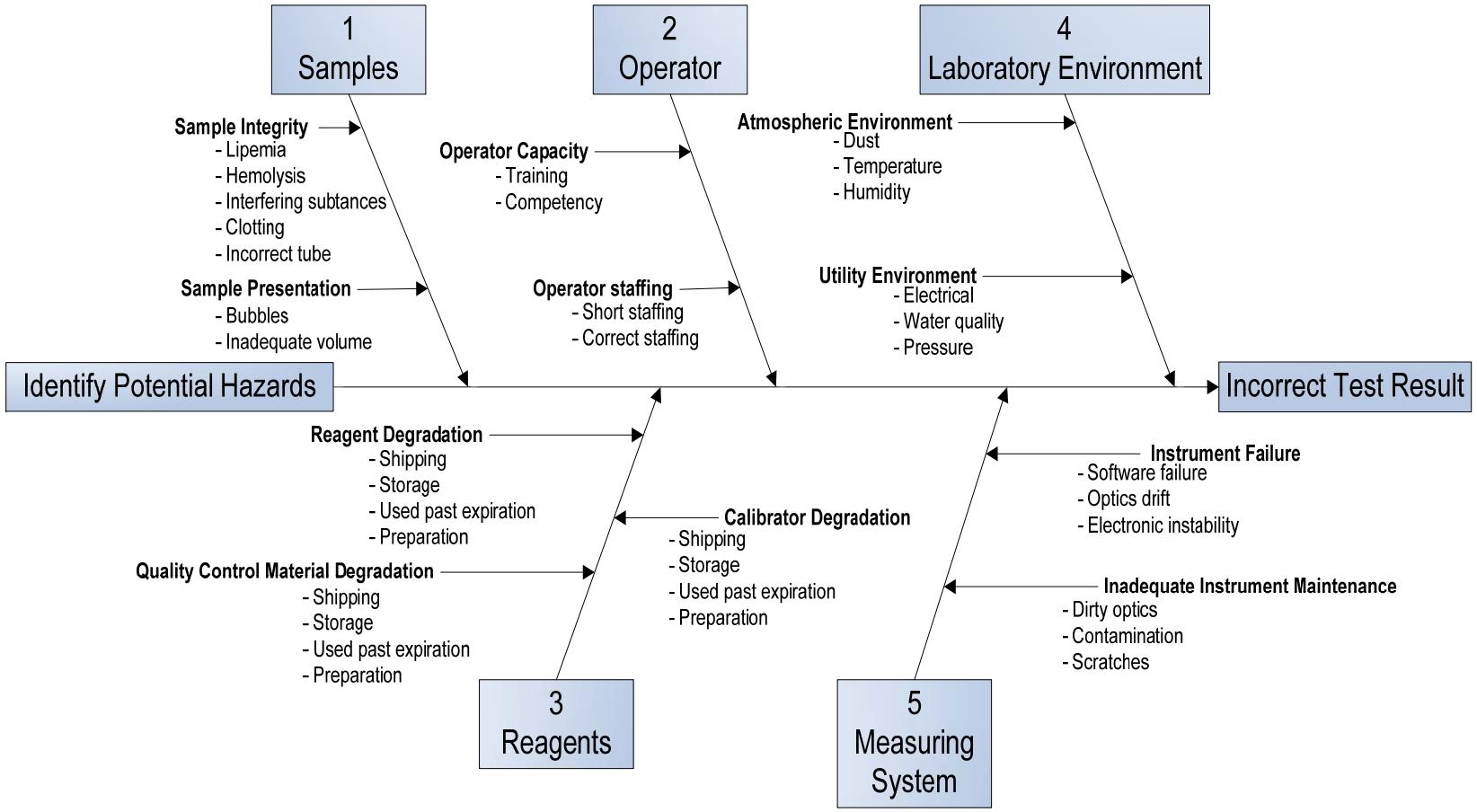


Identify Key Process Steps

- Once the process map is created, examine it for places where errors could occur.

- Five major areas:
  - Samples
  - Operator
  - Reagents
  - Laboratory environment
  - Measuring system

Group into a Fishbone Diagram



Perform the Risk Assessment

- Identify the potential hazards and their causes.
- Assess each potential failure.
- Where harm could occur, add an element in the QCP that will reduce the severity of harm, making residual risk acceptable.
  - For some types of failures, the manufacturer's information may already have a quality check in place.

Perform the Risk Assessment

- Construct a table; see which types of errors are detected and which ones are not.
  - If not detected, it must be included in the QCP.
- For each possible hazard, assess the severity of harm.
  - Do this for each hazard on five-point scales.
  - Use all of the information gathered in order to make these assessments.

Perform the Risk Assessment

	Severity of Harm				
Probability of Harm	**Negligible**	**Minor**	**Serious**	**Critical**	**Catastrophic**
Frequent	Unacceptable	Unacceptable	Unacceptable	Unacceptable	Unacceptable
Probable	Acceptable	Unacceptable	Unacceptable	Unacceptable	Unacceptable
Occasional	Acceptable	Acceptable	Acceptable	Unacceptable	Unacceptable
Remote	Acceptable	Acceptable	Acceptable	Acceptable	Unacceptable
Improbable	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable

Definitions for categories are from ISO 14971

Assemble the Quality Control Plan

- Use the chart developed earlier to add all of the identified risks and their control measures.
- Construct the QCP.
- Include each of the identified QCP Actions in the QCP.

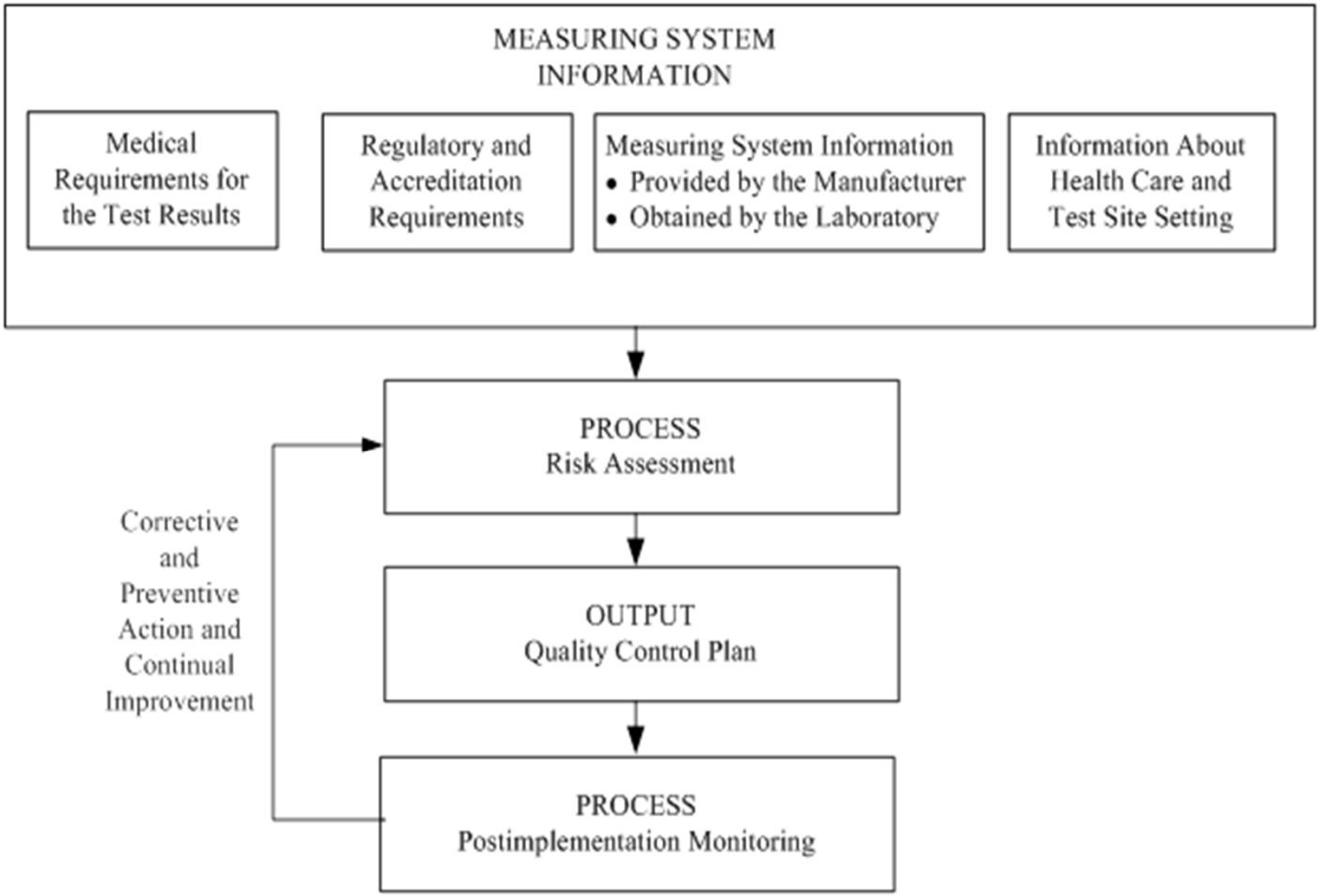
Monitor Quality Control Plan for Effectiveness

- Verify that QCP put in place actually works
- Continue to monitor errors and control failures.
- If an error occurs:
  - Take the appropriate corrective action.
  - Investigate the cause of the error.
  - Once the cause is understood, evaluate whether any changes need to be made in the QCP.

Monitor Quality Control Plan for Effectiveness

- Review any complaints that the laboratory receives from health care providers.
  - These complaints may include pointing out another source of QC “failure” that must be addressed.
- For patient safety, review EP23 on a regular basis to ensure an optimal QCP.

EP23 Summary



EP23 Companion Products

- EP23 Implementation Workbook
- EP23 Risk Assessment Worksheet
  - Template and Example
- QCP Examples
  - Blood Glucose is in the EP23 document
  - PT/INR is in the workbook
  - Molecular test is coming soon
  - Blood gas test is in development
- Webinars
  - For labs and for instrument/test manufacturers

Thank you!