Lab Quality Managers Roundtable

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Learning Objectives

By the end of this Special Session, you will be able to:

- learn from peers what is working and not working in their laboratories.
- discuss with peers various techniques, approaches, and methods for leading change, creating a goal-oriented culture in the laboratory, implementing a quality management system, how to sustain the continuous improvement mindset, and much more!
- develop immediate strategies to address quality issues within the participant's organization.

How the Session Will Work

- Session is being recorded, so everyone must speak into a microphone
  - Please wait for a facilitator to provide a microphone before speaking
- Discuss “Hot” Topics In Quality
  - Provided by facilitators
  - Provided by participants
- First topic
  - Where is your laboratory in its evolution of quality?

Where is your laboratory in its evolution of Quality?

Elements	Quality Control	Quality Assurance	Quality Management
Focus	Method control	Process control	Organization-wide systems
Scope	Verified examination method controlled by the: • Instrument's internal controls • Manufacturer's control materials • Purchased external control materials	Accuracy and efficiency of: • Preexamination processes • Examination processes • Postexamination processes	System effectiveness and sustainability of the management and technical processes that support and move work through the laboratory
Limitations	Does not prevent preexamination or postexamination errors	Does not prevent errors that occur outside the path of workflow processes listed above	No limitations when all aspects of laboratory management and technical operations are included
Evolution of levels	QC was the beginning of quality measures in the medical laboratory	QA ≠ QC QA's process focus is broader than QC's method focus	QC ≠ QA ≠ QMS A QMS's system-wide focus is broader than QC's method focus and QA's process focus together

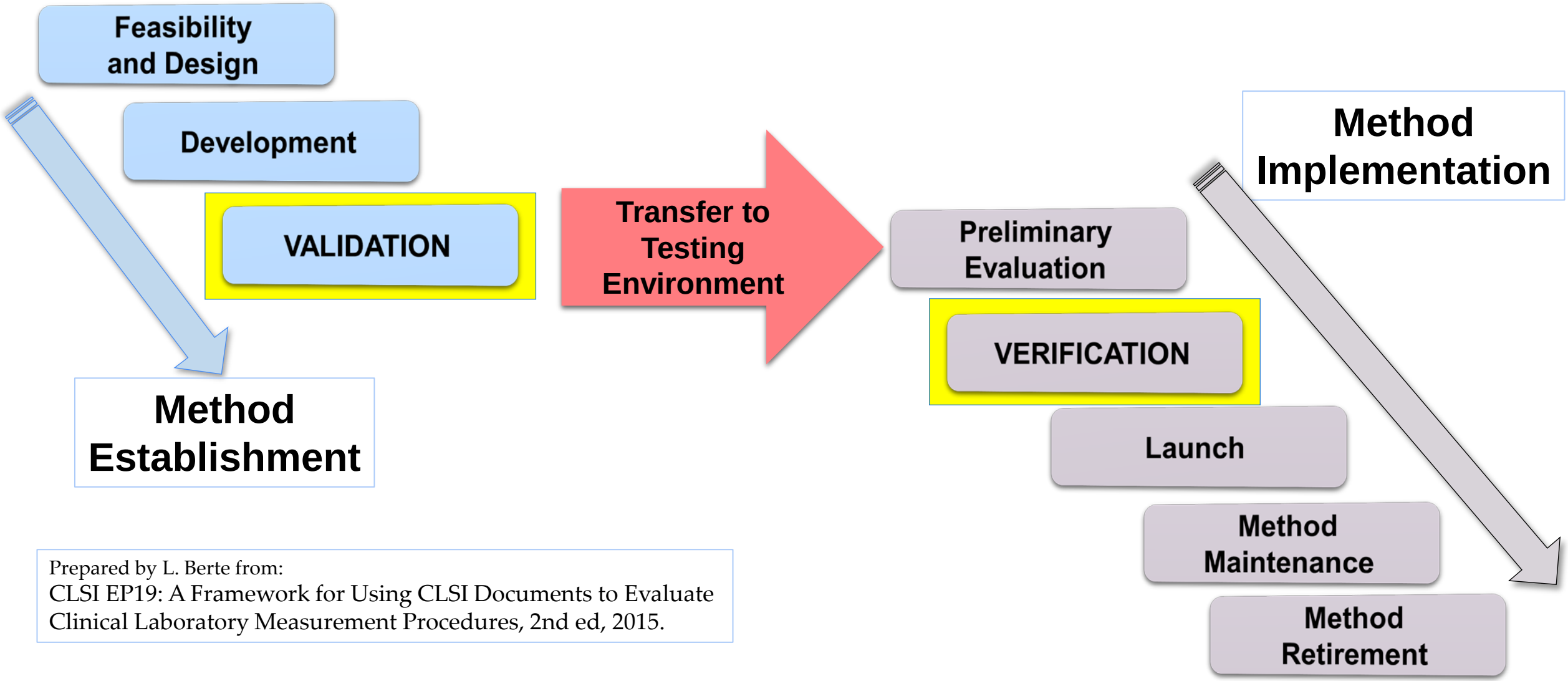
Source: CLSI QMS01 *Quality Management System: A Model for Laboratory Services*

What is the role of a Quality Manager or Quality Support Service in a Laboratory?

Thoughts…

- Owns the process
- Participates in the process
- Audits the process

Test Life Cycle: Validation vs Verification



Prepared by L. Berte from:
CLSI EP19: A Framework for Using CLSI Documents to Evaluate Clinical Laboratory Measurement Procedures, 2nd ed, 2015.

Risk Management Case Study

What are the primary factors that need to be considered?

Thoughts…

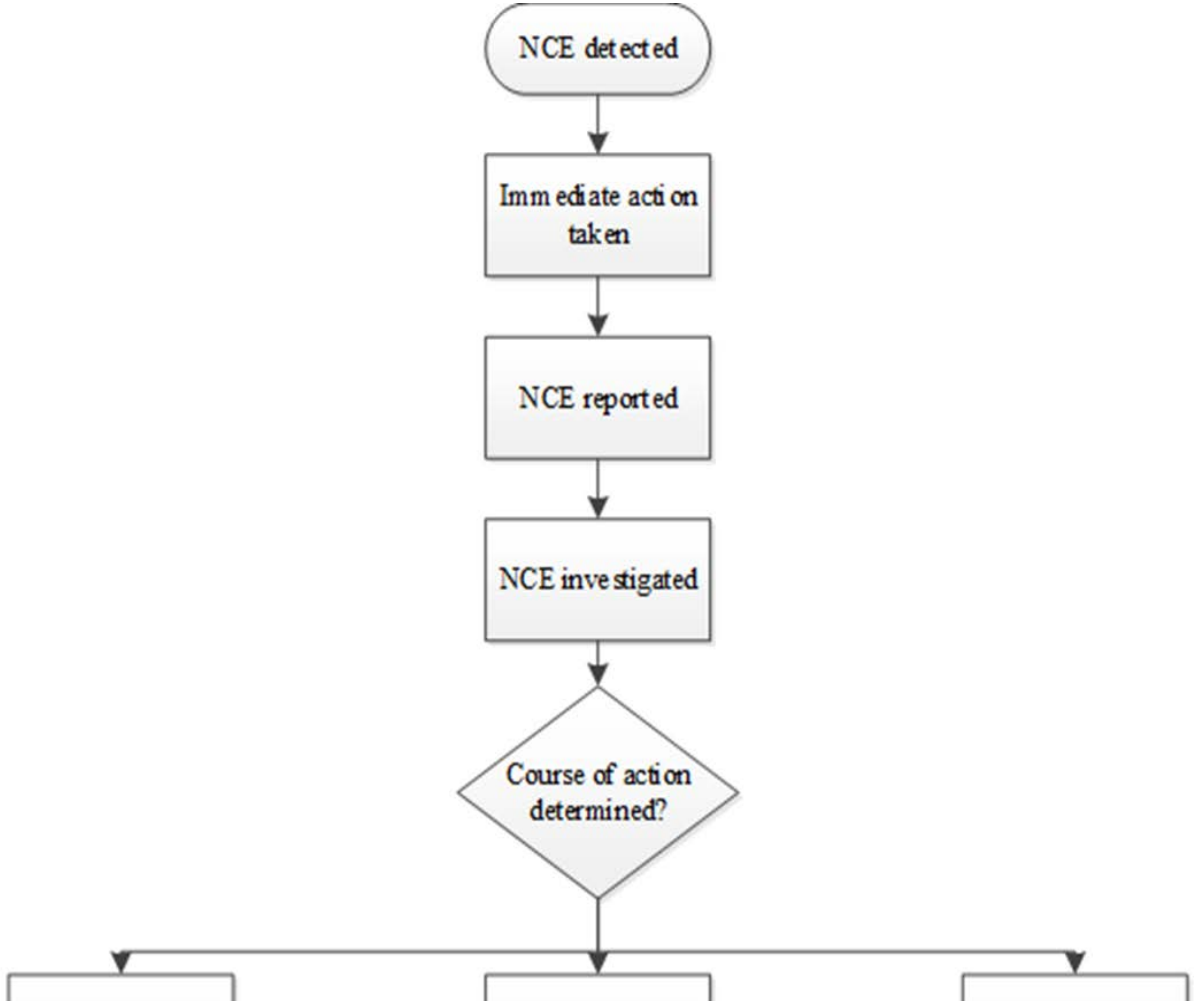
- Who needs to be involved
- Patient safety
- Regulatory requirements
- Patient / clinician confusion
- Financial impact

Managing Laboratory (Test) Utilization

- Who is responsible for this?
- How do you approach it?
- What are some lessons learned?

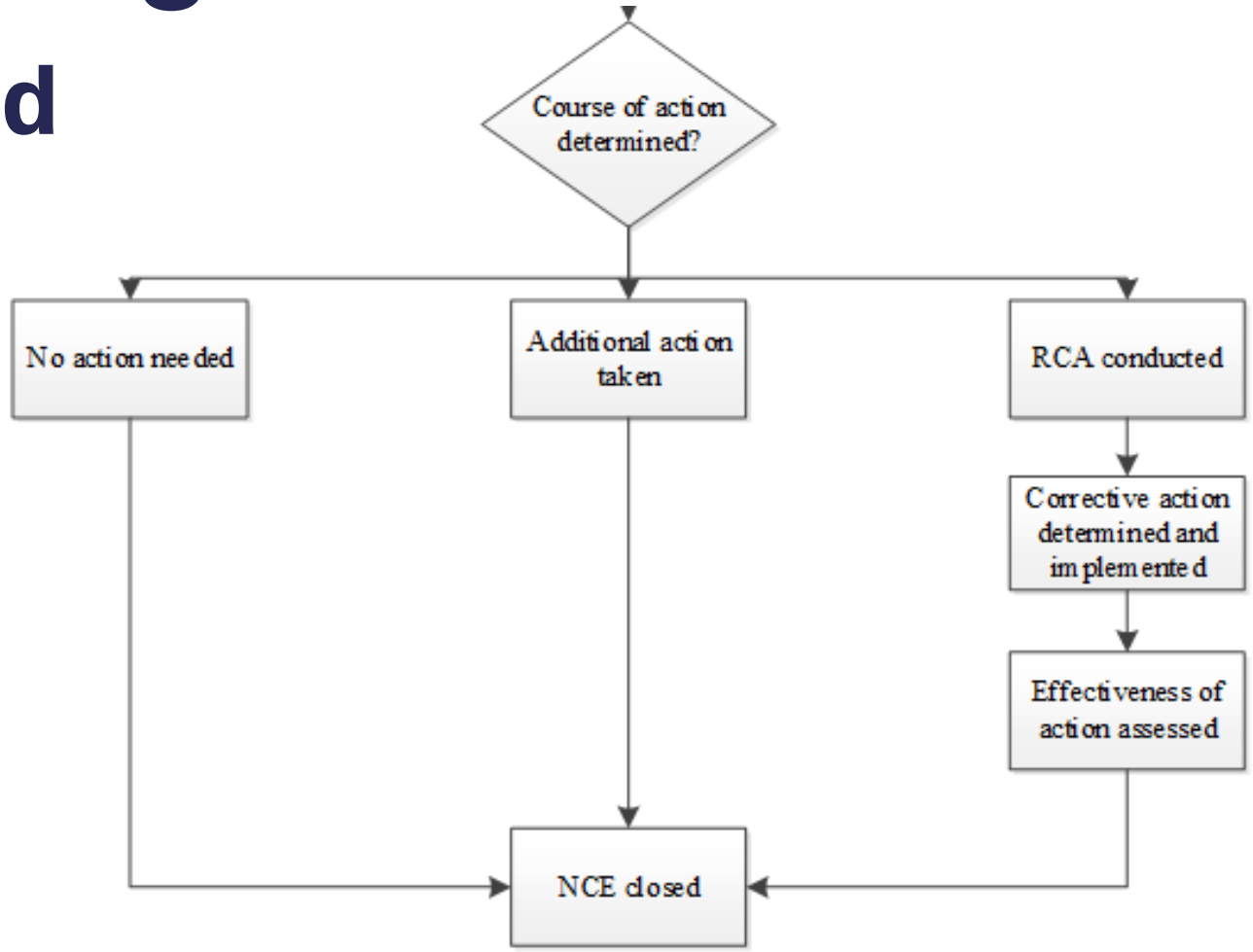
New Resource: CLSI's *Developing and Implementing a Laboratory (Test) Utilization Program,* Published 2017

Responding to a Nonconforming Event



Responding to a Nonconforming Event

- Continued



Source: CLSI QMS11-A2, *Nonconforming Event Management,* Section 2.2, Figure 3

Leadership QMS Responsibilities

Dimension	QMS Expectation	Fundamental Responsibility
Cultural	Vision for quality Making the case for a QMS	Formulating and articulating a vision for quality
	Committing to quality and good professional practice	• Maintaining a quality policy as a formal statement of commitment • Conducting business ethically and professionally • Fostering a culture that supports the vision for quality
Structural	Committing to quality and good professional practice	Maintaining an appropriate scope of services
	Creating and maintaining an organizational structure to ensure quality	• Maintaining the legal identity of the laboratory • Maintaining an appropriate organization structure with defined roles and responsibilities
	Effectively implementing the QMS	Designing and implementing a QMS
Functional	Managing resources	Managing and allocating resources sufficient for scope of services and quality goals
	Planning for quality	Planning for quality
	Management review	Assessing the effectiveness of the QMS
	Communicating quality-related information	Communicating quality-related information

Source: CLSI QMS14 Quality Management System: Leadership and Management Roles and Responsibilities, 2012

Seven basic ISO 9000 generic quality principles

Principle	Description
Customer focus	The primary focus of quality management is to meet customer requirements and strive to exceed customer expectations.
Leadership	Leaders at all levels establish unity of purpose and direction and create conditions in which people are engaged in achieving the organization's quality objectives.
Engagement of people	Competent, empowered, and engaged people at all levels throughout the organization are essential to enhance the organization's capability to create and deliver value.
Process approach	Consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes that function as a coherent system.
Improvement	Successful organizations have an ongoing focus on improvement.
Evidence-based decision making	Decisions based on the analysis and evaluation of data and information are more likely to produce desired results.
Relationship management	For sustained success, organizations manage their relationships with relevant interested parties, such as providers.

Source: ISO 9000:2000 Quality Management systems – Fundamentals and vocabulary