



Laboratory Quality Management System

Module 1: Introduction to Laboratory
Quality Management System

Venue: SRL Uganda

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Introduction

The laboratory results must be as accurate as possible, all aspects of the laboratory operations must be reliable, and reporting must be timely in order to be useful in a clinical or public health setting.



Learning Objectives

At the end of this module, participants will be able to:

- explain the importance of a quality management system;
- list the quality management system **essential elements**;
- describe the history of development of quality principles;
- Discuss relationship of this quality model to ISO and CLSI standards.

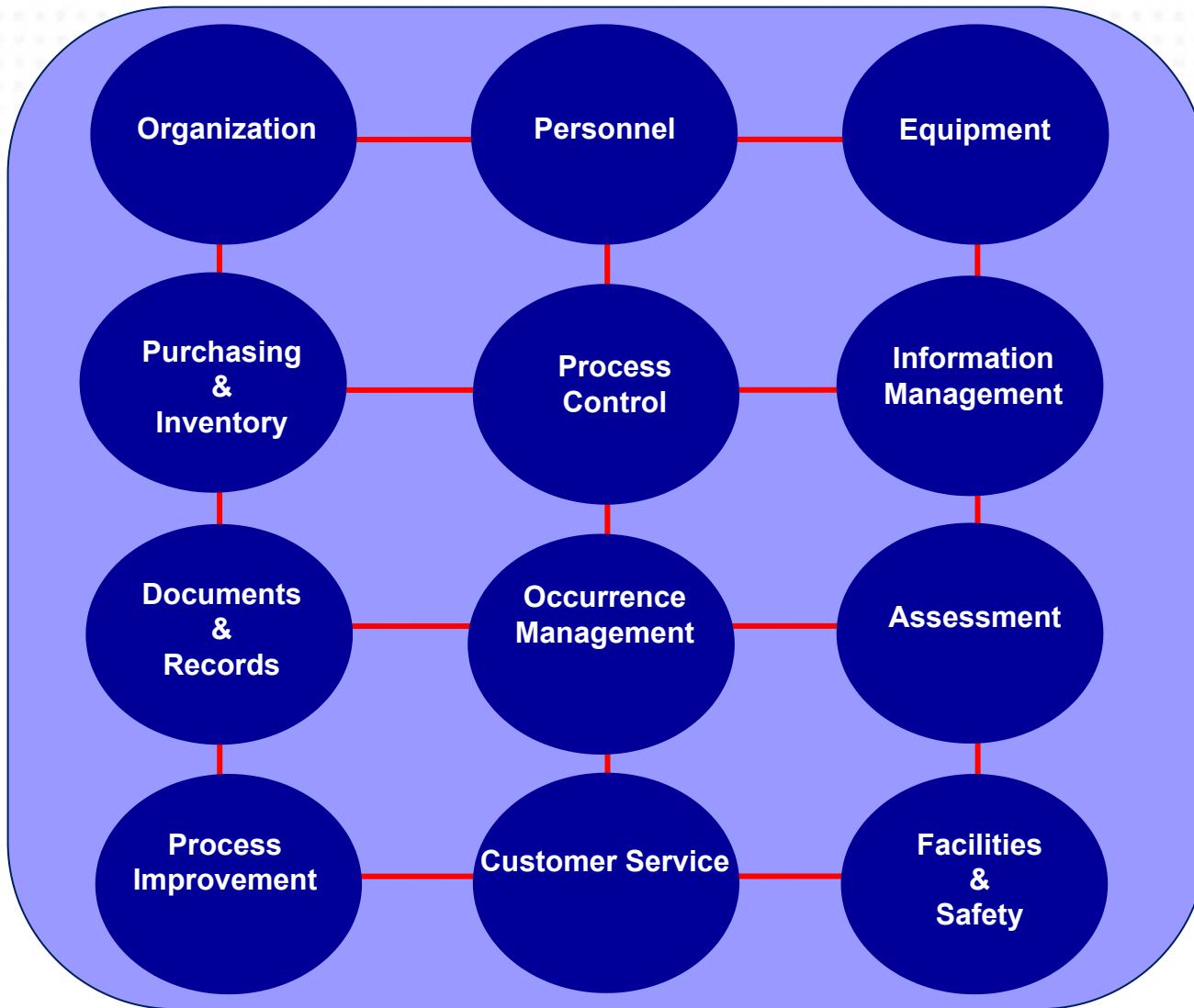


Module Outline

- Definitions
- Complexity of a Quality Management System
- Path of Workflow
- The quality management system essential elements
- The relationship of this quality model to ISO and CLSI standards



The Quality Management System



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1. What is Quality

Quality Definition:

The degree to which a set of inherent characteristics fulfils requirements



- Essential to all aspects of health care are **laboratory quality results** that are
 - **accurate**,
 - **reliable**, and
 - **timely**



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Achieving a **99%** level of quality

means

accepting a **1%** error rate

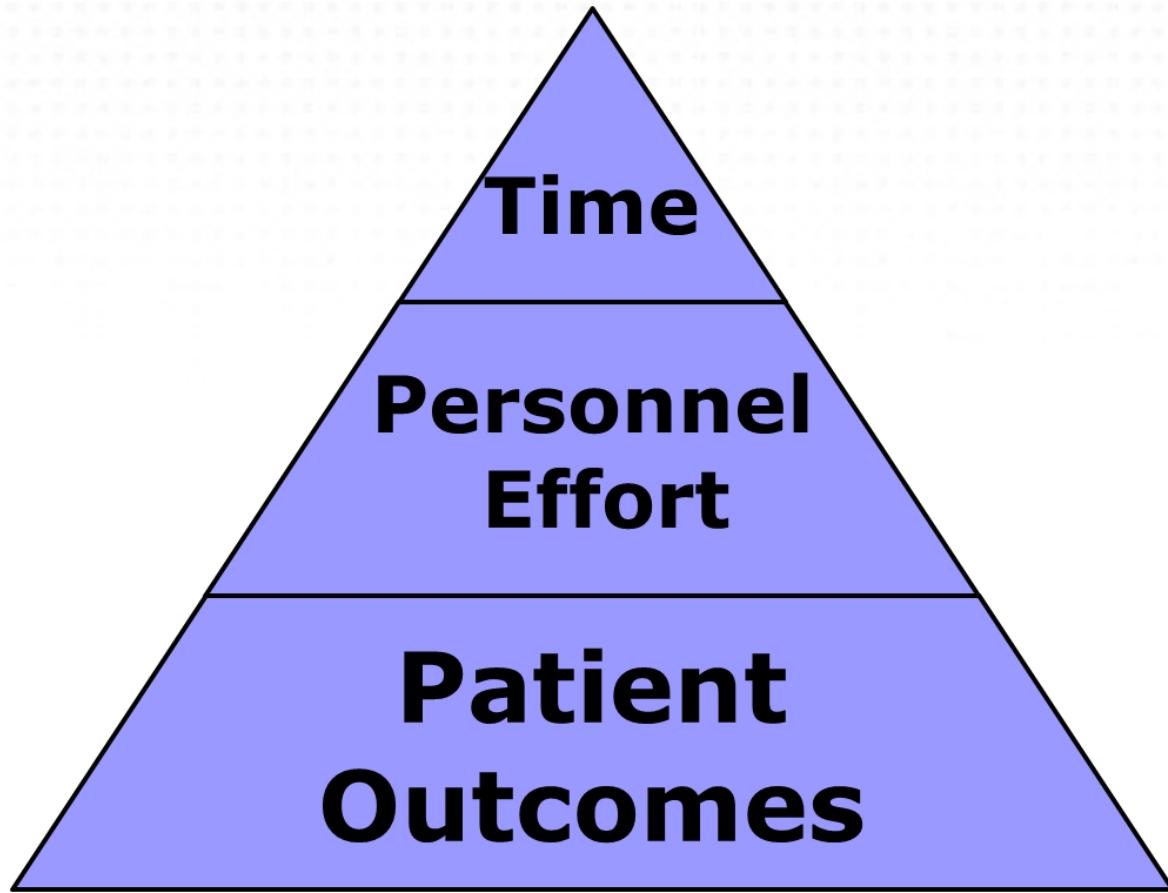


In France a **1% error rate** would mean **everyday**

- 14 minutes without water or electricity
- 50,000 parcels lost by postal services
- 22 newborns falling from midwives' hands
- 600,000 lunches contaminated by bacteria
- 3 bad landings at Orly Paris airport



Laboratory errors cost in



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How do we achieve
excellent
performance in the
laboratory?



LQMS Formula

- Familiarize and grasp the 12 quality Essentials using the formula

4P 2O DI-FACE



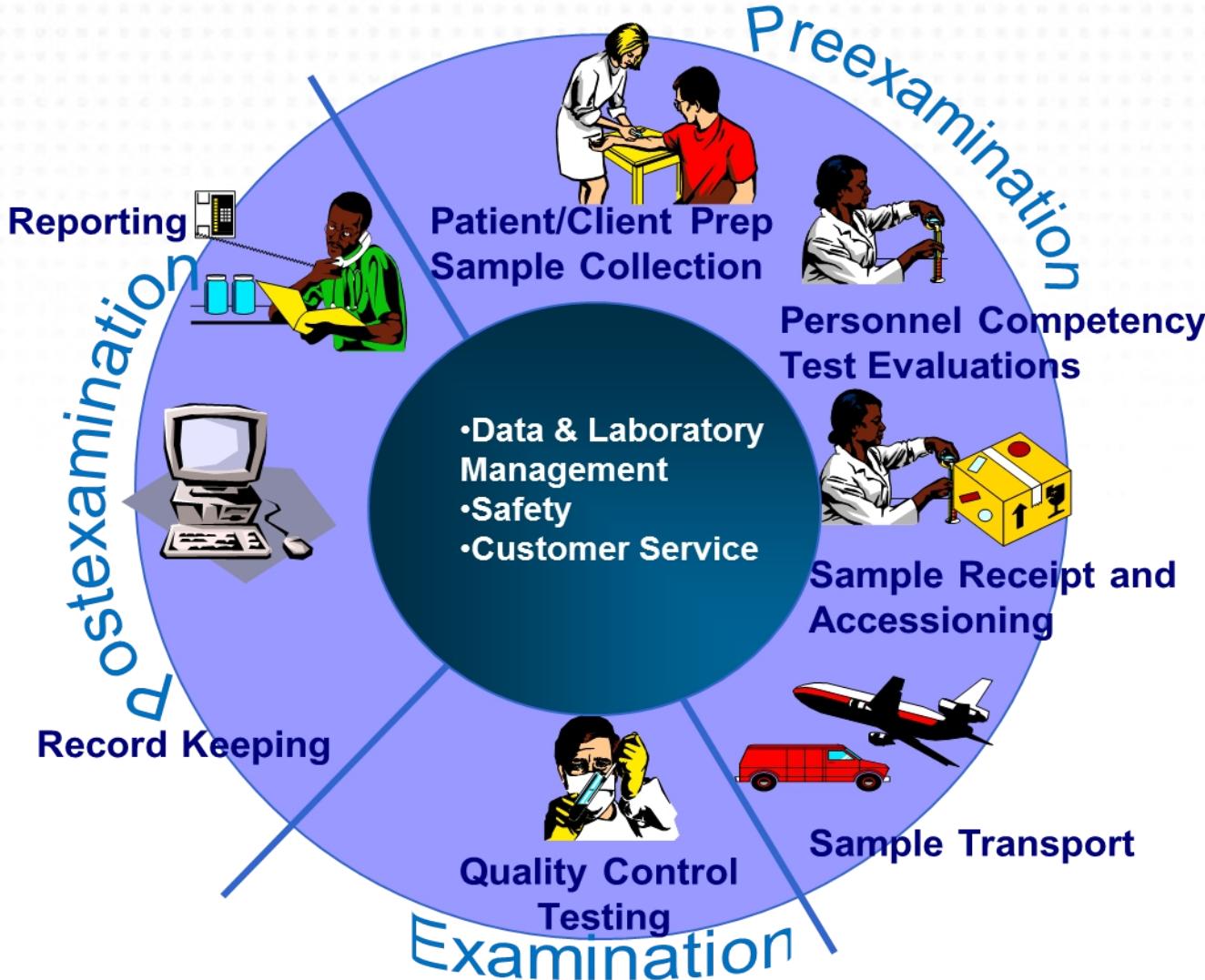
Quality Management System Definition

Coordinated activities to plan, direct, and control an organization with regard to quality (ISO, CLSI).

All aspects of the laboratory operation need to be addressed to assure quality; this constitutes

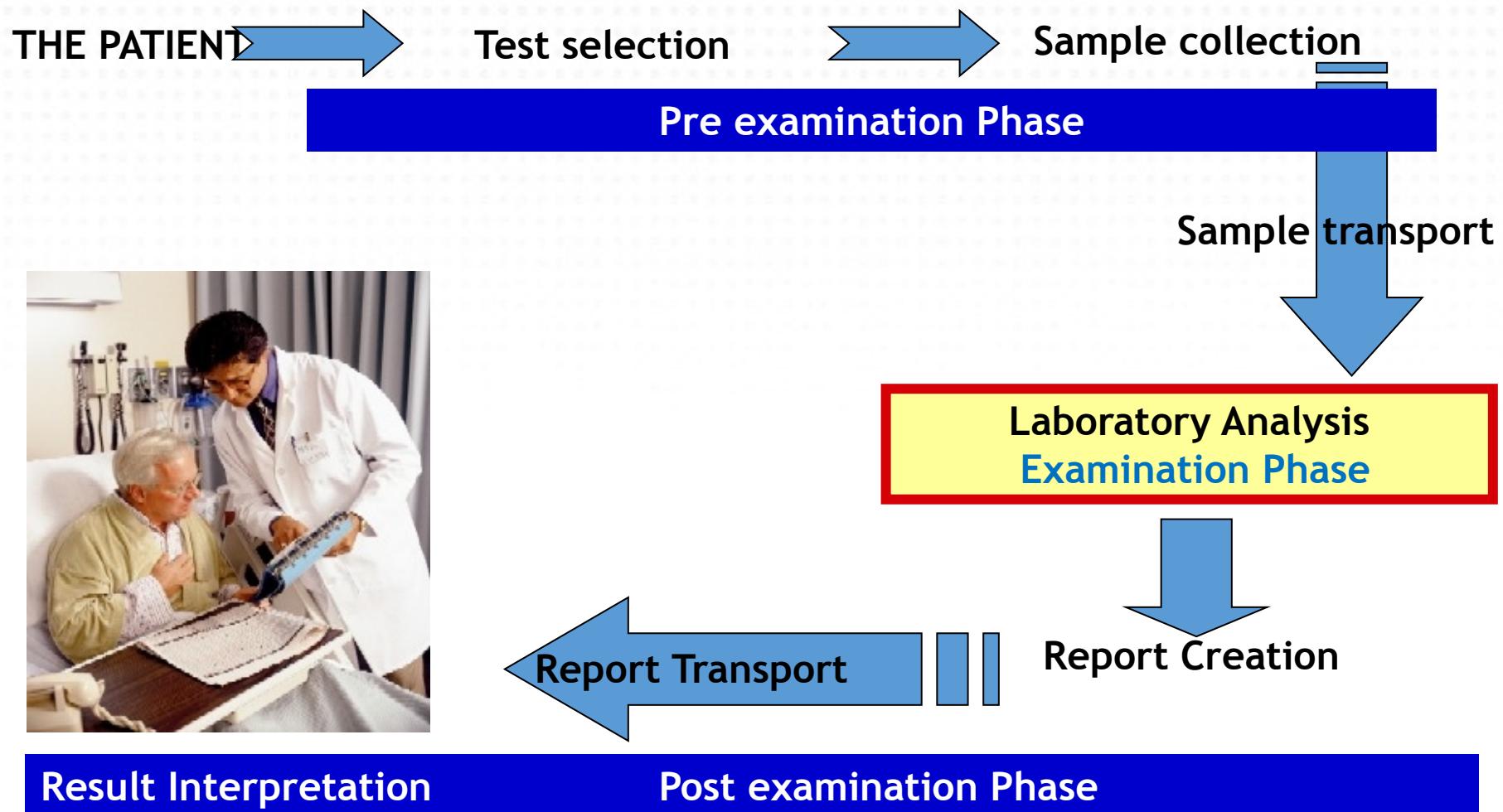


2. Complexity of a Laboratory System



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3. Path of Workflow



WHY is the Path of Workflow essential to consider in health laboratories?

The entire process of managing a sample must be considered:

- ─ the beginning: sample collection
- ─ the end: reporting and saving of results
- ─ all processes in between.



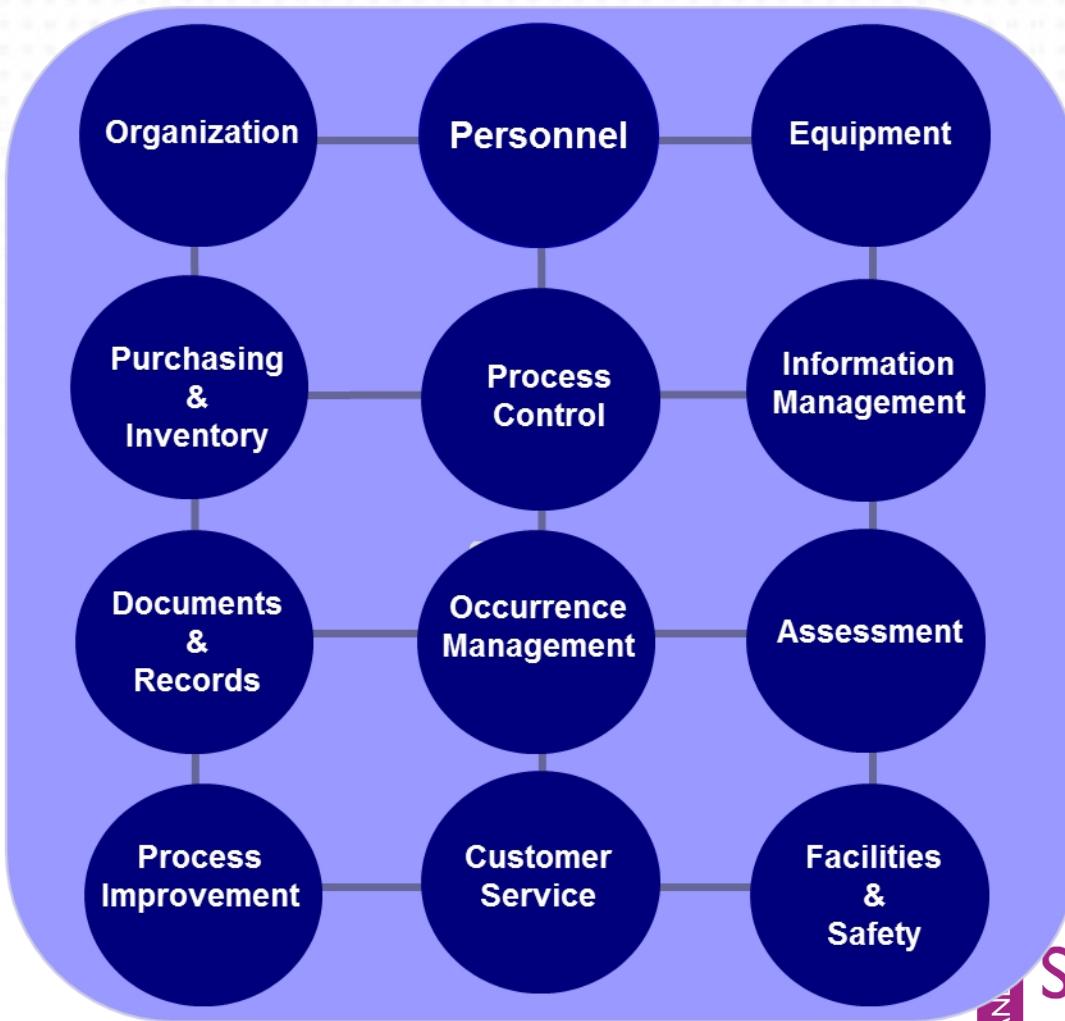
Laboratory tests are influenced by

- laboratory environment
- knowledgeable staff
- competent staff
- reagents and equipment
- quality control
- communications
- process management
- occurrence management
- record keeping



4. Twelve Quality System Essentials

Set of coordinated activities that function as building blocks for quality management





Organization



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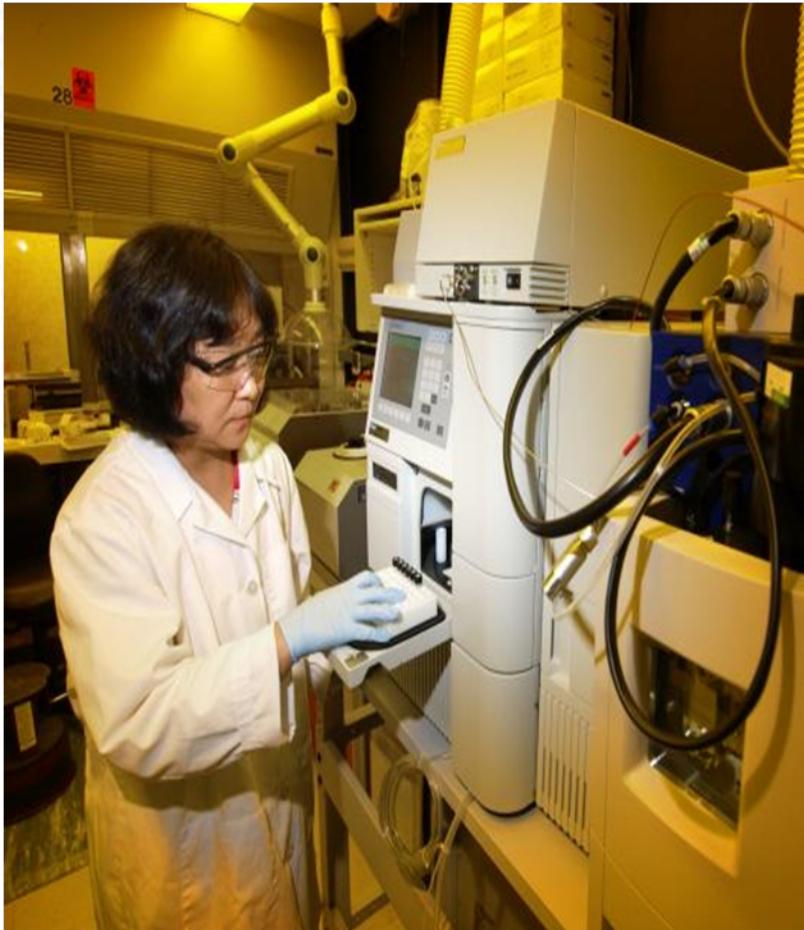
Personnel

- human resources
- job qualifications
- job descriptions
- orientation
- training
- competency assessment
- professional development
- continuing education



Equipment

- acquisition
- installation
- validation
- maintenance
- calibration
- troubleshooting
- service and repair
- records



Purchasing and Inventory

- vendor qualifications
- supplies and reagents
- critical services
- contract review
- inventory management



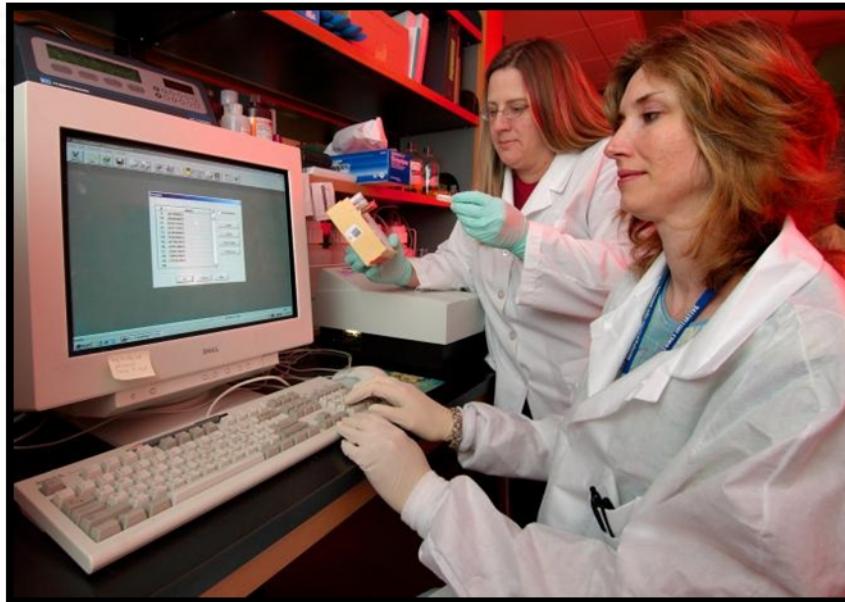
Process Control

- quality control
- sample management
- method validation
- method verification



Information Management

- confidentiality
- requisitions
- logs and records
- reports
- computerized laboratory information systems (LIS)



Documents

creation
revisions and review
control and distribution

Records

collection
review
storage
retention



Occurrence Management

- complaints
- mistakes and problems
- documentation
- root cause analysis
- immediate actions
- corrective actions
- preventive actions



Laboratory Assessment



Laboratory Assessment

- Proficiency Testing (EQA)
- Inspections
- Accreditations

Process Improvement

- opportunities for improvement (OFIs)
- stakeholder feedback
- problem resolution
- risk assessment
- preventive actions
- corrective actions



Customer Service

- customer group identification
- customer needs
- customer feedback



Facility and Safety

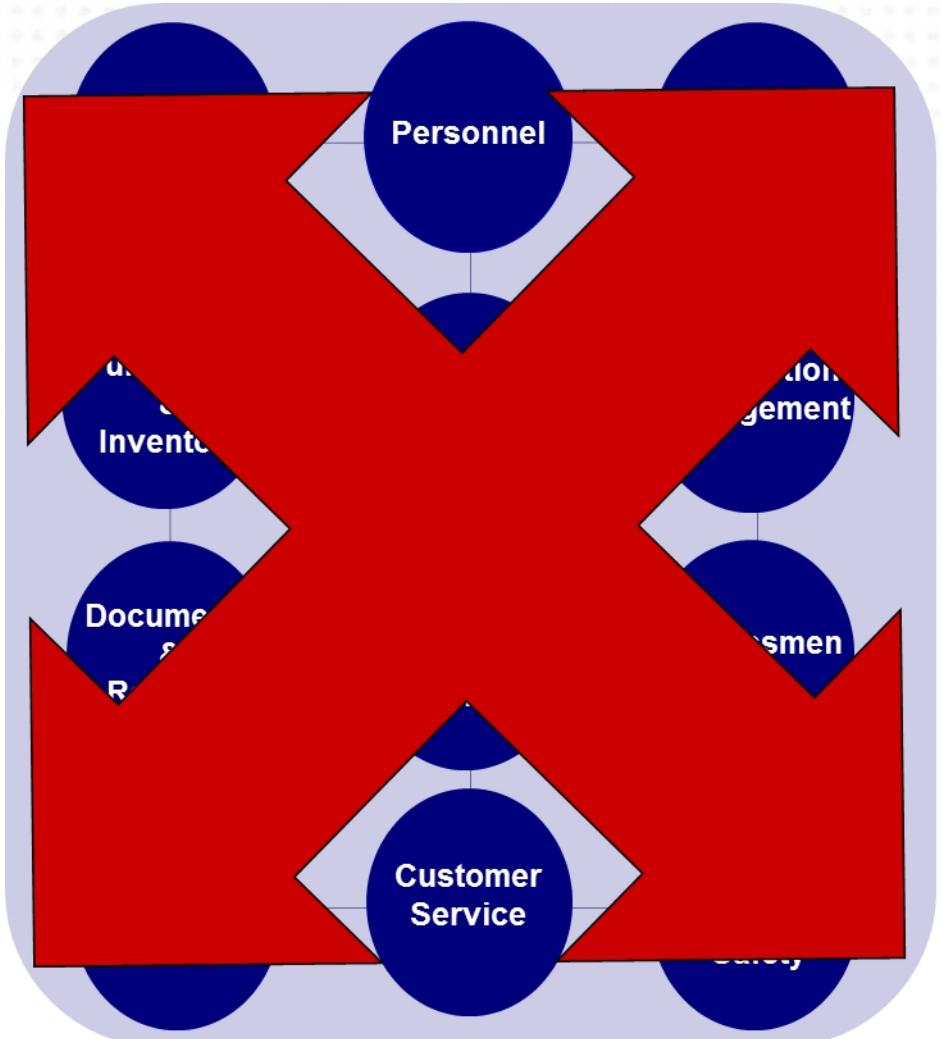
- safe working environment
- transport management
- security
- containment
- waste management
- laboratory safety
- ergonomics



Implementing
Quality Management
does not
guarantee
an
ERROR-FREE
Laboratory



**But it detects
errors that may
occur and
prevents them
from recurring**



Laboratories **not**
implementing a
quality management
system guarantees
**UNDETECTED
ERRORS**



Laboratory Quality Management System

Coordinated activities to direct and control an organization with regard to quality.

ISO 9001:2015



5. Standards Organizations

ISO International Organization for Standardization	CLSI Clinical and Laboratory Standards Institute (formerly known as NCCLS)
Guidance for quality in manufacturing and service industries	Standards, guidelines, and best practices for quality in medical laboratory testing
Broad applicability; used by many kinds of organizations	Detailed; applies specifically to medical laboratories
Uses consensus process in developing standards	Uses consensus process in developing standards



ISO Documents - Laboratory

ISO 9001:2015 Quality Management Systems - Requirements

ISO/IEC 17025:2005 General requirements for competence of testing and calibration laboratory

ISO 15189:2012 Requirement for Quality and competence of Medical Laboratory

ISO 15190:2012 Requirement for Safety of Medical Laboratory



ISO 15189:2012



International
Organization for
Standardization

- Standardizing the laboratory quality management system
- Provides particular requirements for quality and competence
- Checks the quality improvement



CLSI Quality Documents



HS1-A2 A Quality Management System Model for Health Care

- describes quality system model, 12 essentials
- aligns to ISO 15189 and parallels ISO 9000
- applies to all health care systems

QMS01-A4 Quality Management System: A Model for Laboratory Services. Guidelines

- describes laboratory application of quality system model
- relates the path of workflow to the quality system essentials
- assists laboratory in improving processes
- relates to HS1-A2 and ISO 15189

Key Messages

- A laboratory is a complex system and all aspects must function properly to achieve quality.
- Approaches to implementation will vary with local situation.
- Start with the easiest, implement in stepwise process.
- Ultimately, all quality management system elements must be addressed.



Assessment

1. What is Quality
2. Define Quality Management System.
3. What are the Twelve Quality System Essentials
4. What are the three major stages of the Path of workflow
5. Which ISO standard provides requirements for Competence of clinical Laboratories?



In Summary

- Quality management is not new.
- Quality management grew from the good works of innovators who defined quality over a span of 80 years.
- Quality management is as applicable for the medical laboratory as it is for manufacturing and industry.



References

ISO 15189:2012 Requirement for Quality and competence of Medical Laboratory

CLSI

ASLM



Acknowledgement

