Introduction– Laboratory Quality Management System

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Learning Objectives

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

- Explain the importance of a quality management system
- List the quality system essential elements
- Describe the history of development of quality principles
- Discuss relationship of this quality model to ISO and CLSI standards

http://www.who.int/ihr/training/laboratory_quality/en/

The Quality Management System

What is Quality?

What is 'quality'?

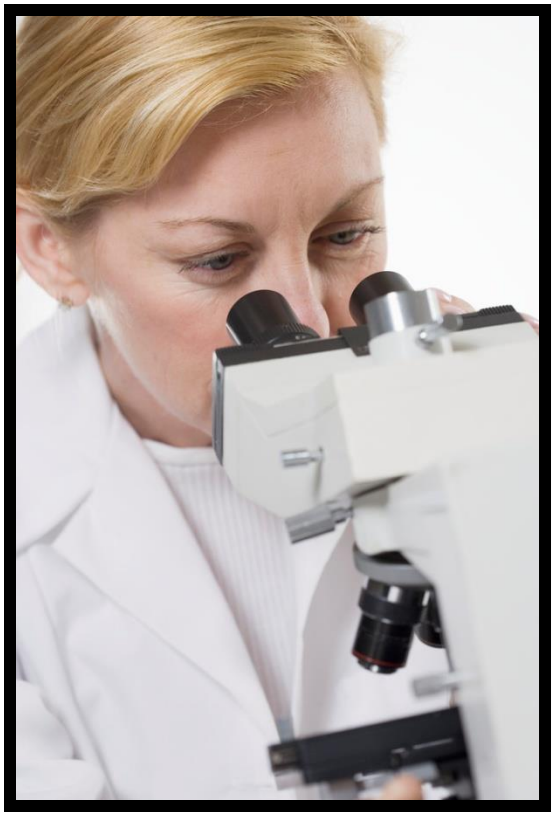
- Good or Excellence
- Retaining standard
- Satisfaction
- Acceptable
- Accuracy
- Reliable
- On time

What is 'quality'?

- Degree to which a set of inherent characteristics fulfils requirements
- The standard of something as measured against other things of a similar kind
- The ability of a product or service to satisfy stated or implied needs of a specific customer

Essential to all aspects of health care are **laboratory results** that are:

- **accurate**,
- **reliable**, and
- **timely**



A laboratory error and its consequences

An 83 year old male was admitted to hospital with fever, weight loss, and cough, and was being investigated for possible tumor. Sputum was reported to be positive for tuberculosis, but on later review, found to be false positive culture due to in-laboratory contamination. Further investigation found 14 additional patients with false positive TB culture.

What problems are created by this error?

A laboratory error and its consequences

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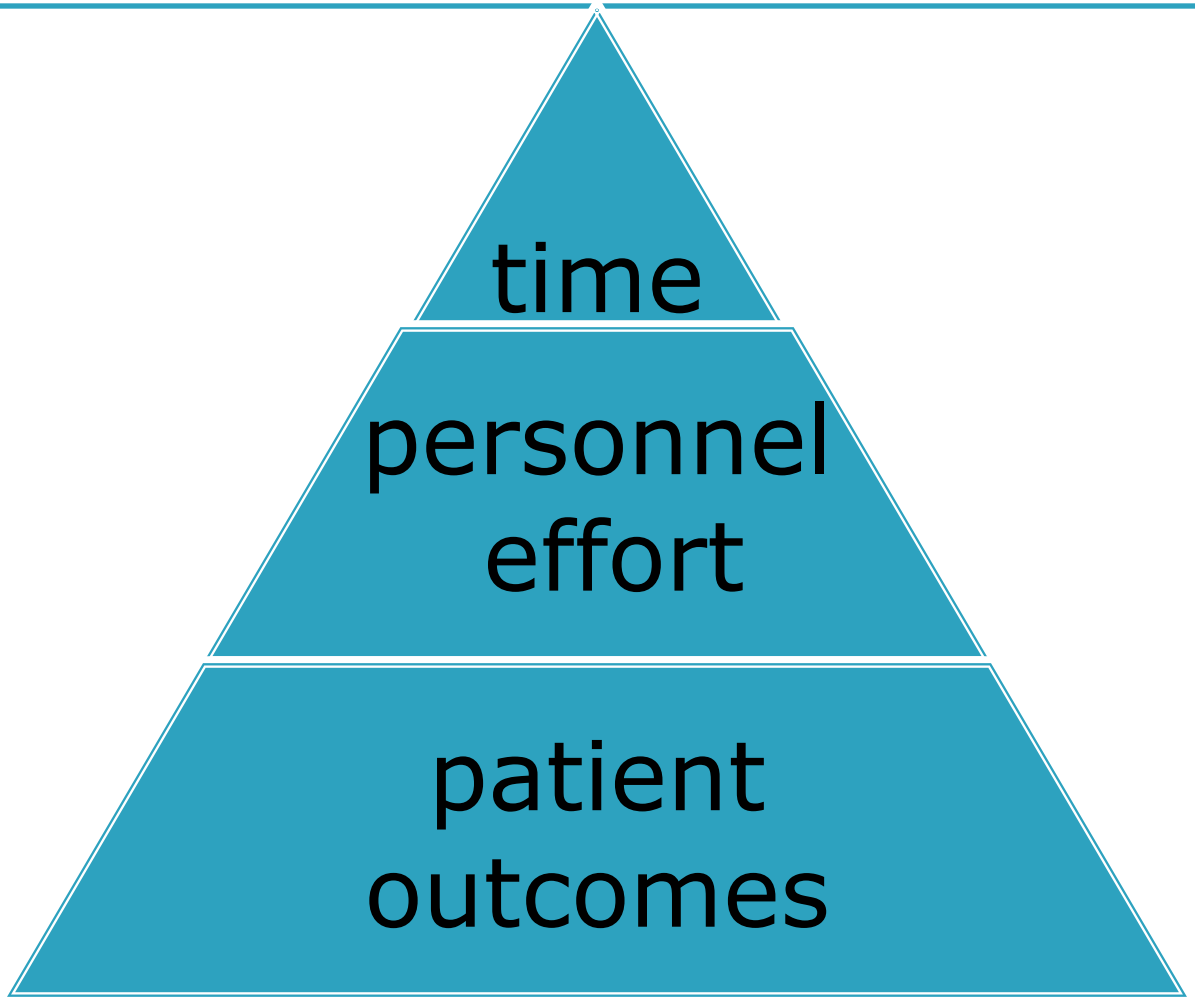
Consequences included:

- ***Delay in correct diagnosis***
- ***Unnecessary treatment***
- ***Treatment complications***
- ***Pattern of other contaminations discovered***
- ***Problem resolution required 6 months of investigation, contacting of more than 200 patients, many requiring culture and X-Ray re-examination.***
- ***Revision of laboratory procedures eradicated the problem.***

Laboratory errors cost in time, energy, personnel, and patient outcomes

Laboratory errors cost in



How do we achieve excellent performance in the laboratory?

Quality Management System Definition

Coordinated activities to 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 a quality management system.

Path of Workflow

THE PATIENT → Test selection → Sample Collection

Preexamination Phase

Sample Transport

Laboratory Analysis
Examination Phase

Report Creation

Report Transport

Result Interpretation

Postexamination Phase

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.

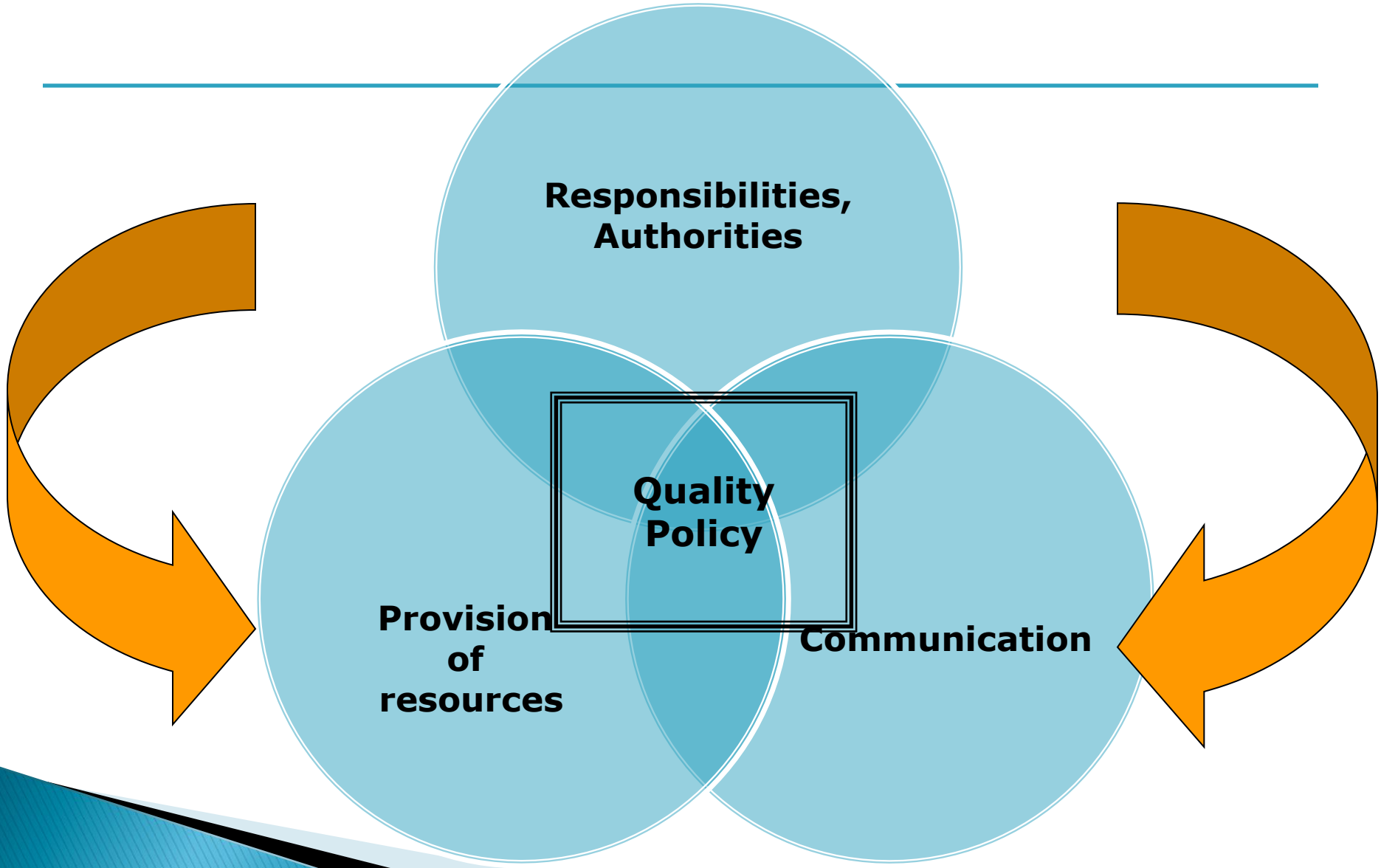
Laboratory tests are influenced by

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

Twelve Quality System Essentials

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

Organization

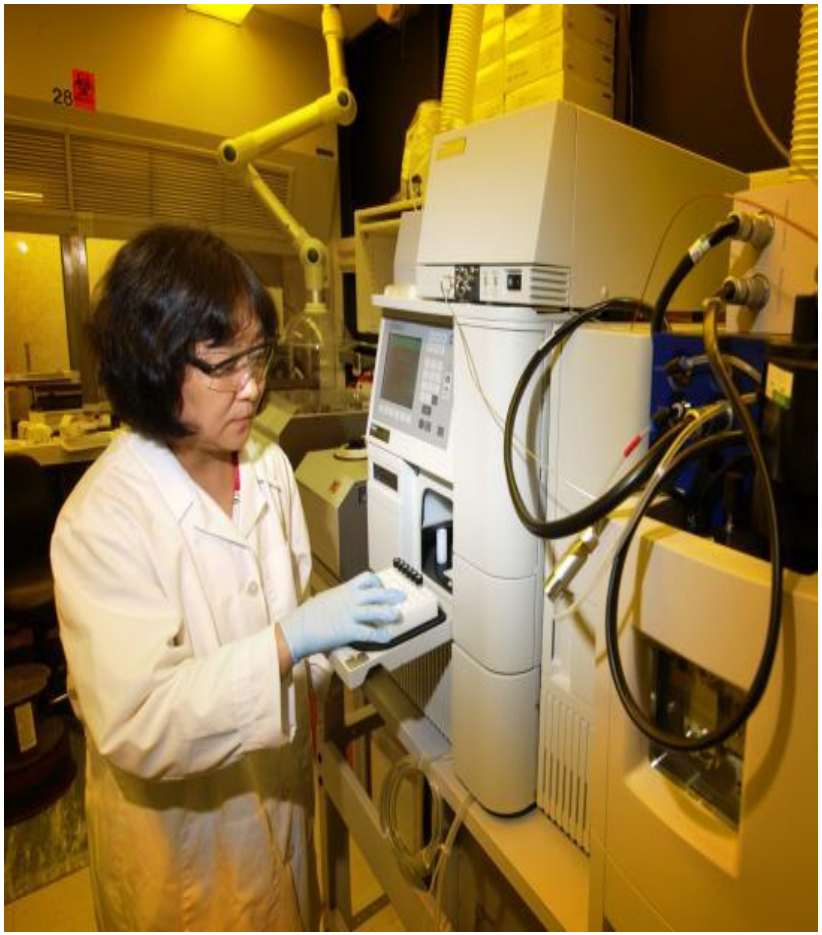


Personnel

- 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



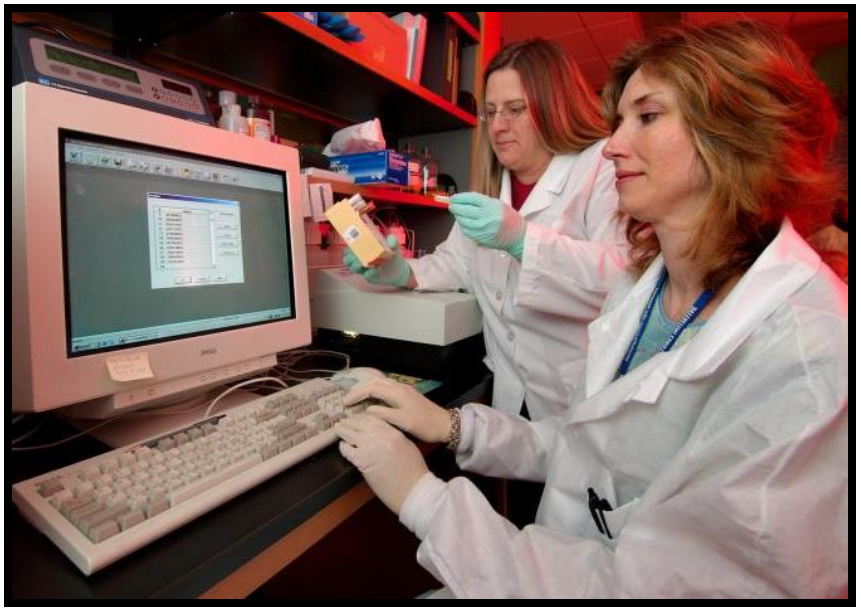
Purchasing and Inventory

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

Process Control

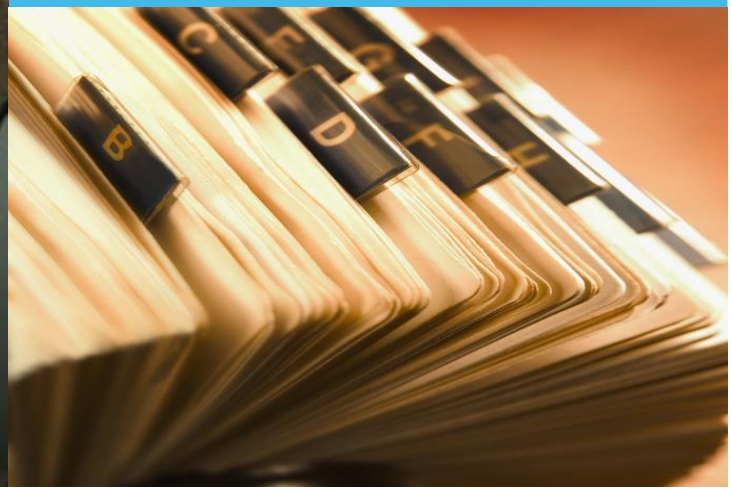
- quality control
- sample management
- method validation
- method verification

Information Management



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

Documents	Records
creation	collection
revisions and review	review
control and distribution	storage
	retention



Occurrence Management

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

Laboratory Assessment

External

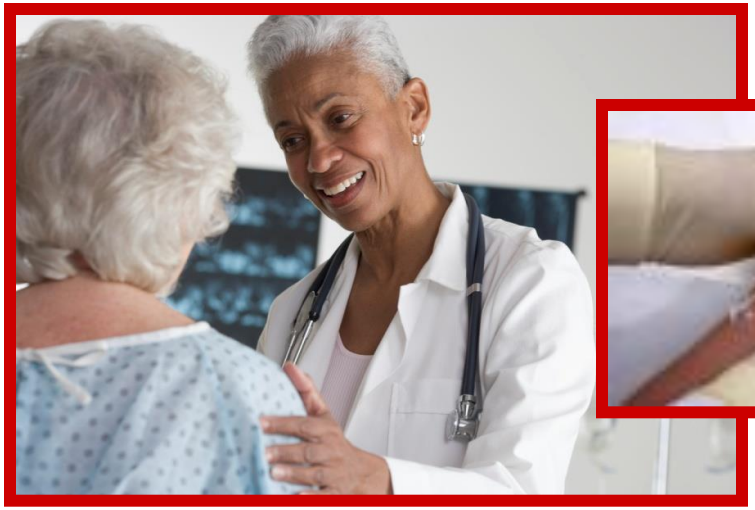
- **EQA**
  - Proficiency testing
- **Accreditations**
  - Inspections

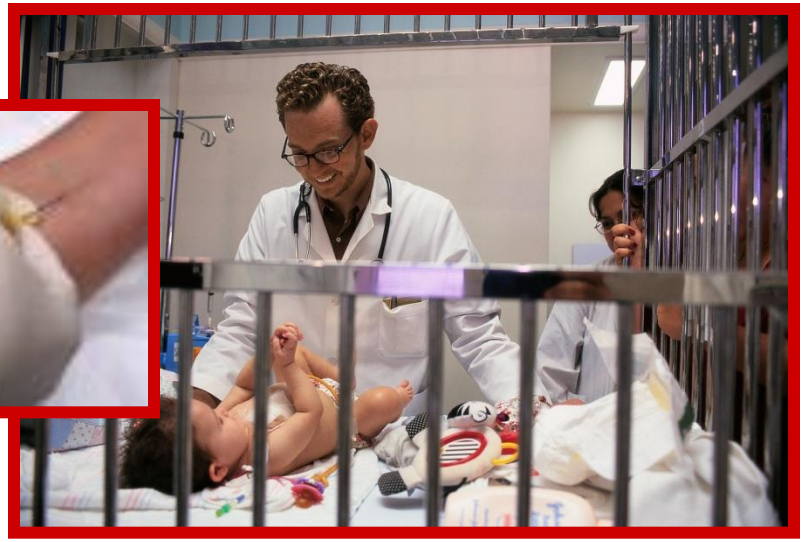
Process Improvement

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

Customer Service

- customer group identification
- customer needs
- customer feedback



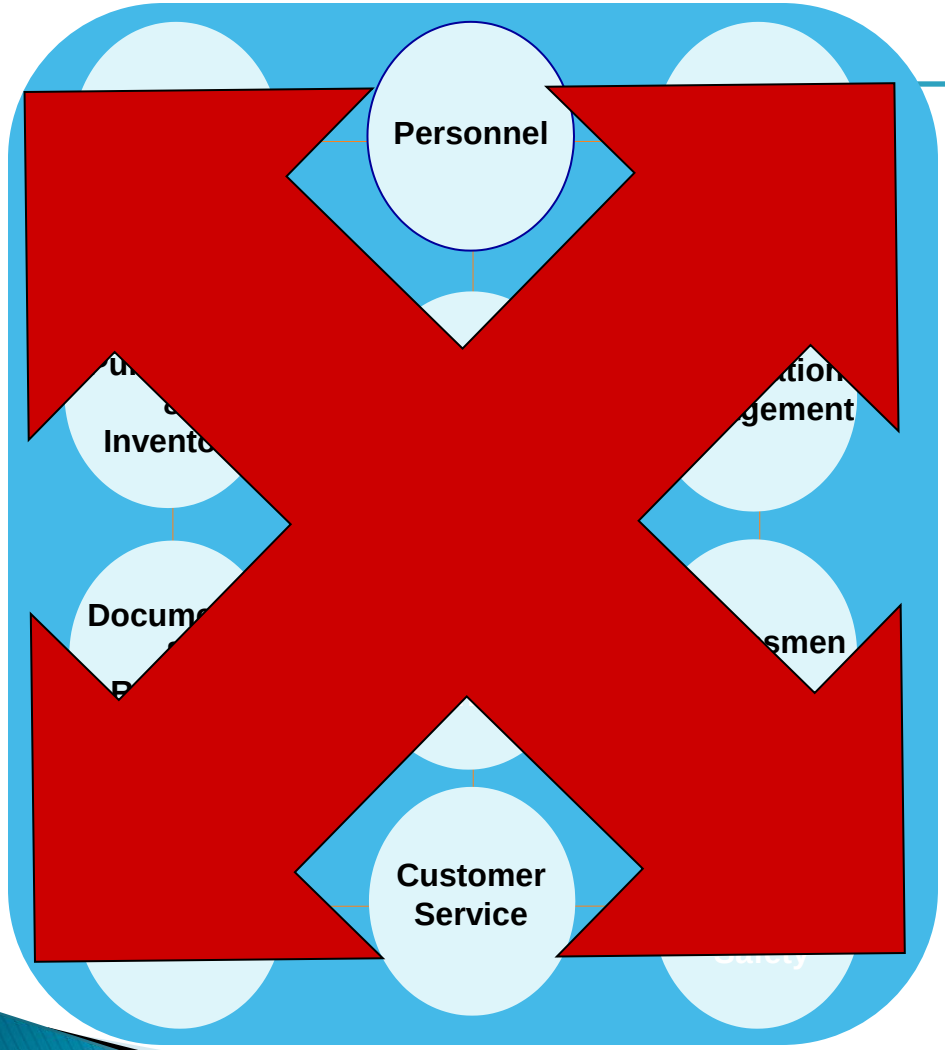


Facilities and Safety

- 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

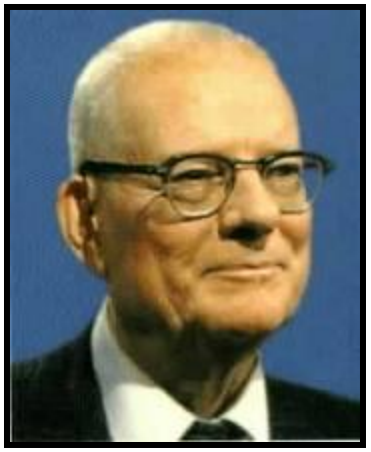
Laboratory Quality Management System

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

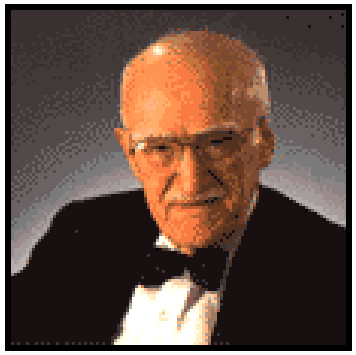
ISO 9000:2000

Innovators of Quality

Walter Shewhart
1891-1967

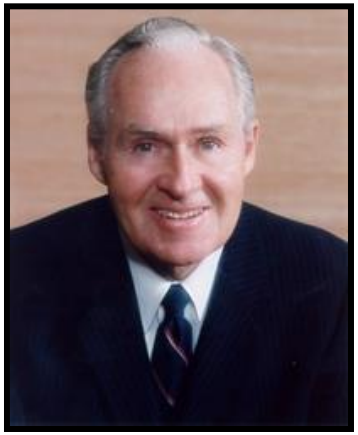


W. Edwards Deming
1900-1993



Joseph Juran
1904-2008 (103 years)

Philip Crosby
1926-2001



Robert Galvin
b. 1922

A Brief History of Quality Management

Quality Management is not new.

Innovator	Date	Cycle
Walter A.Shewhart	**1920s**	Statistical Process Control
W. Edwards Deming	**1940s**	Continual Improvement
Joseph M. Juran	**1950s**	Quality Toolbox
Philip B. Crosby	**1970s**	Quality by Requirement
Robert W. Galvin	**1980s**	Micro Scale Error Reduction

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 9001:2000 Quality Management System Requirements
Model for QA in design, development production, installation, and servicing

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

ISO 15189:2007 Quality management in the clinical laboratory

ISO 15189:2007

International Organization for Standardization

- The foundation of international medical laboratory quality management
- Medical laboratories–Particular requirements for quality and competence

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

GP26-A3 Application of Quality Management System Model for Laboratory Services

- 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

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.

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.

Questions?

Comments?

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