Introduction- Laboratory Quality Management System

Standards Organizations

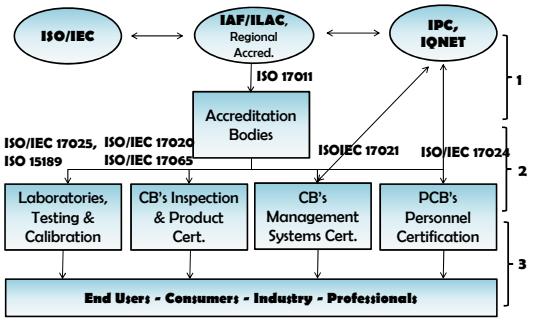
ISO
International Organization for Standardization

Guidance for quality in manufacturing and service industries

Broad applicability; used by many kinds of organizations

Uses consensus process in developing standards

CONFORMITY ASSESSMENT STRUCTURE



The Quality Management System

What is Quality?

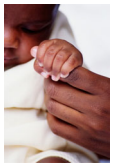
Achieving a **99%** level of quality

means

accepting a **1%** error rate

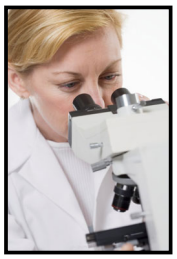
In France a **1% error rate** would mean **everyday**

- 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

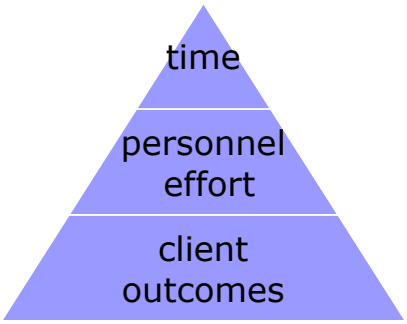


Essential to all aspects of industry are **laboratory results** that are

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



Laboratory errors cost in



How do we achieve excellent performance in the laboratory?

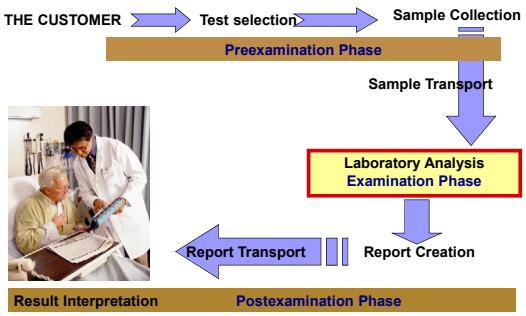
Quality Management System Definition

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

All aspects of the laboratory operation need to be addressed to assure quality; this constitutes a quality management system.

Complexity of a Laboratory System

Path of Workflow



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

The **entire process** of managing a sample must be considered:

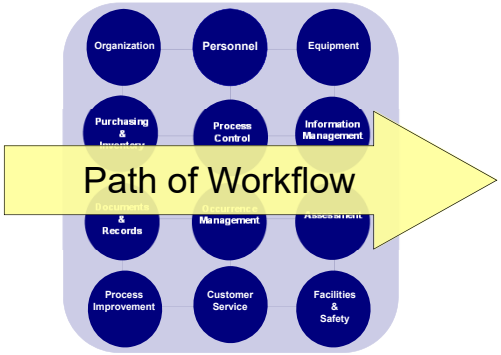
- the beginning: sample collection
- the end: reporting and saving of results
- all processes in between.

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



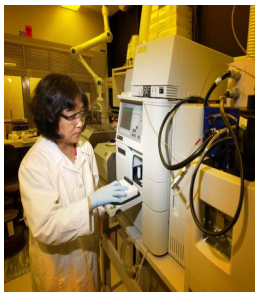
Organization

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

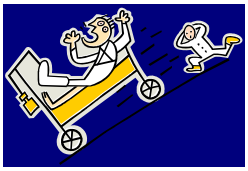
Information Management

- 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

Proficiency testing (EQA)

Inspections

Accreditations

Process Improvement

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

Customer Service

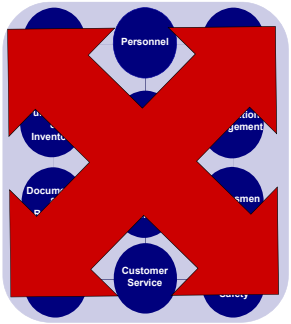
- customer group identification
- customer needs
- customer feedback

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



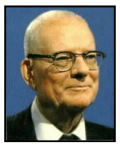
*Laboratories **not*** implementing a quality management system guarantees UNDETECTED ERRORS

Laboratory Quality Management System

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

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

ISO Documents - Laboratory

ISO/IEC 15189:2012 General requirements for the competence of medical 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.

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?