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Introduction-Laboratory Quality Management

Jing Wang

- When you receive a new lamp for testing

- What should you do? Why?




Learning Objectives

At the end, 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

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What is Quality?

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What is Quality?

Quality is defined as
conformance to requirements,
not as "goodness" or "elegance"

Philip Crosby

What is Quality?

- Quality & Technology
  - Certification and Accreditation are both based on the quality management system

- Quality & Business

- Quality & Standard

What is Quality Management?

Quality management is not to prove anything wrong, but is the management expectations.

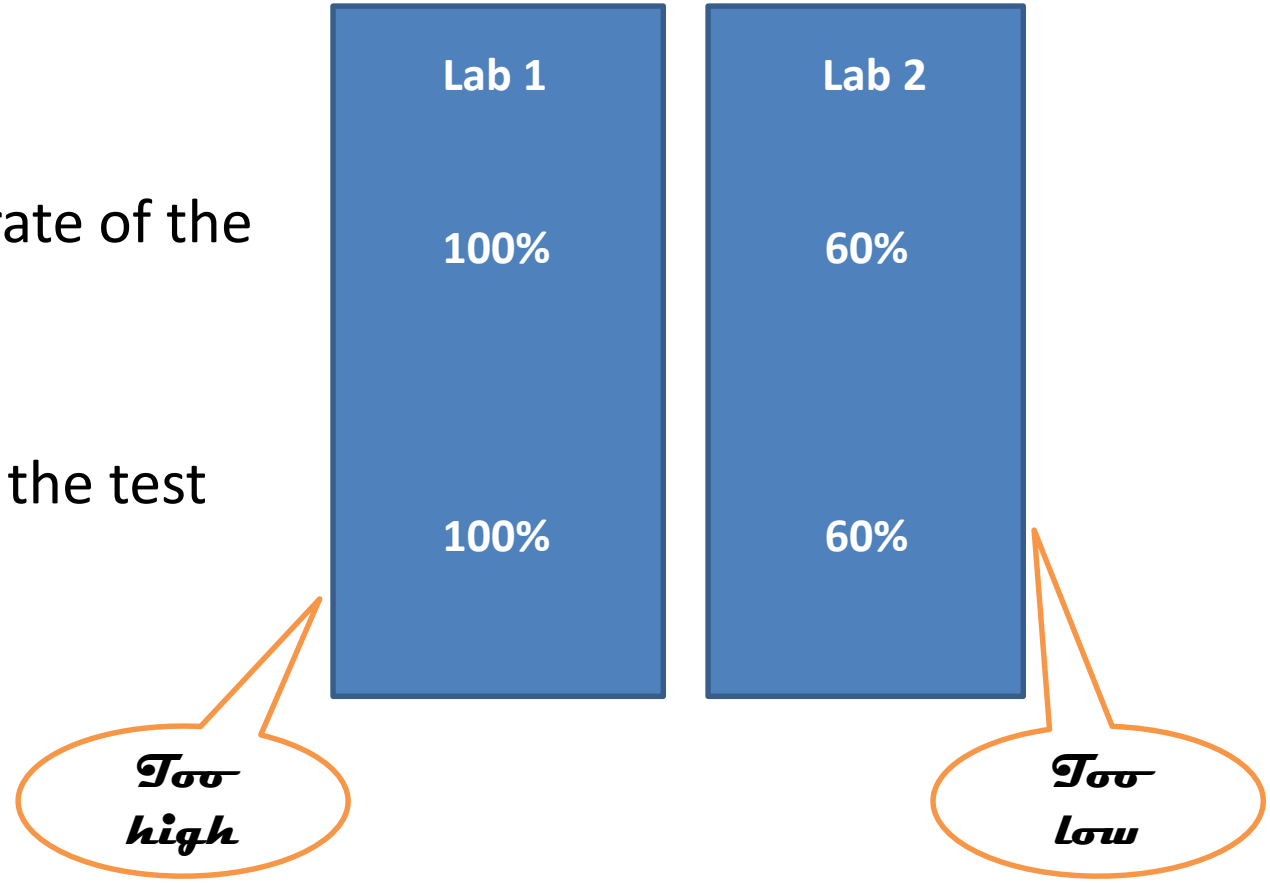
- On the basis of technology
- In accordance to standards management organization
- Requirements to technology, administration and quality

Appropriate objectives

For example

The qualification rate of the test report

The timely rate of the test report



There is no best, only the most appropriate

Quality Management is everywhere in the laboratory

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Quality control

- Quality control is a process / system to monitor the testing quality and to correct and accurate of the testing results

- Quality control makes sure the instant implementation of the corrective actions

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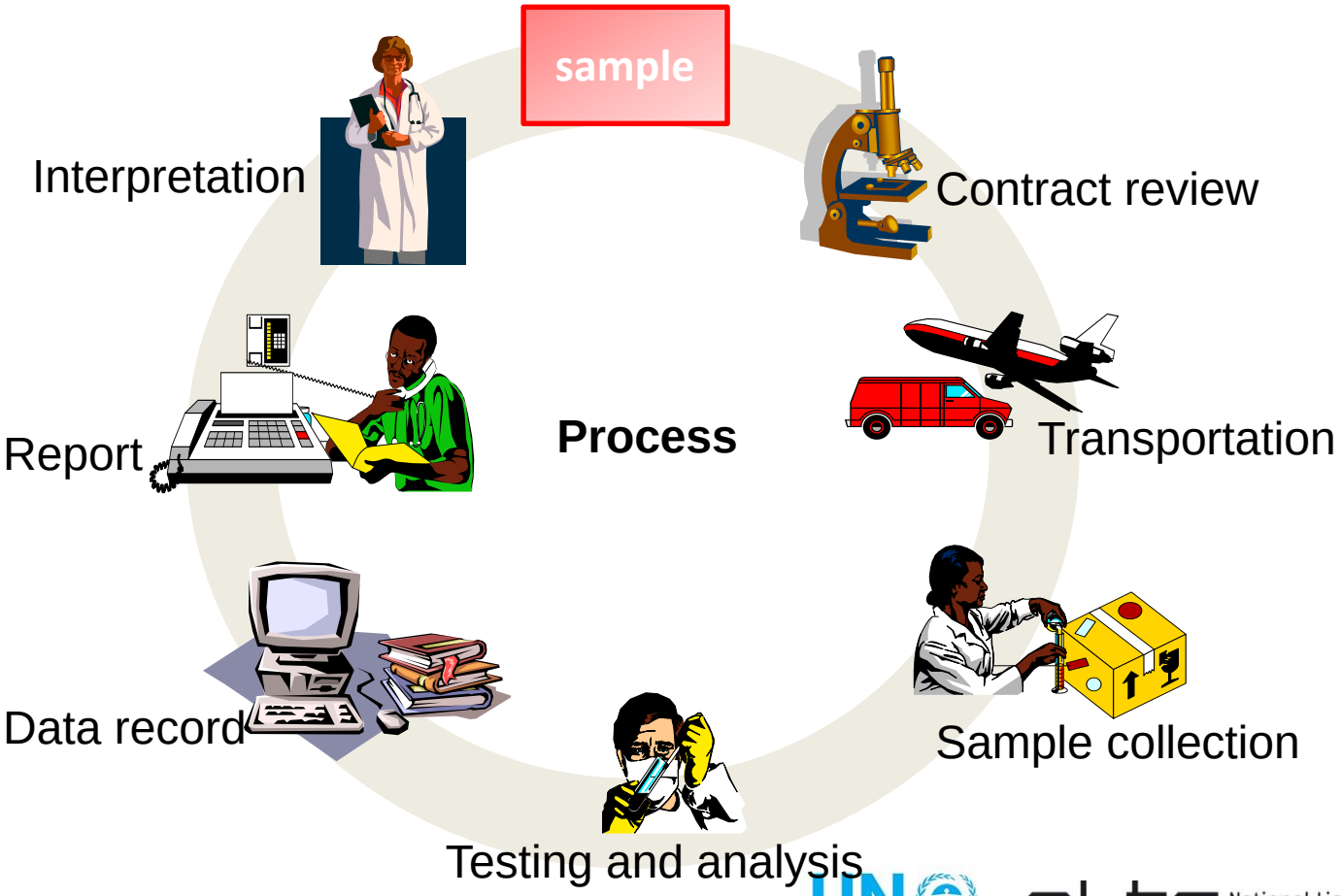
Process

- A process is a set of resources or activities associated with each other that transforms an input into an output
  a) Any process includes both input and output
  b) The process must be done by resources and activities
  c) The inspection, evaluation, measurement shall be conducted in all sessions, in order to control the quality of the process

- All work is done through the process

Process

- Process 1 The management of samples



Sample

The basic principle

The laboratory should develop sample management procedure and the work instruction.

In the delivery and processing, it shall ensure the original nature of the sample, protecting the interests of the laboratory and the customers

Sample

Reception of the sample

ISO/IEC 17025:2005 4.6, 5.7, 5.8.

The receiver should check the package and status of the samples carefully.
If the customer has any special requests to the test, it should provide detailed written instructions/info.
The quantity of the samples cannot be less than the requested number, otherwise, it should be noted in the agreement.

Sample

Flow of the sample

The samples shall be marked with the unique identifications, and design and usage of the marking should be such as ensure that there is no confusion in the samples or in the records involved.

The identification system ensures that the sample is not confused during the delivery process; should contain the breakdown of the item and the control method that is passed inside and out of the laboratory

The environmental conditions for sample preservation should be controlled, monitored and recorded

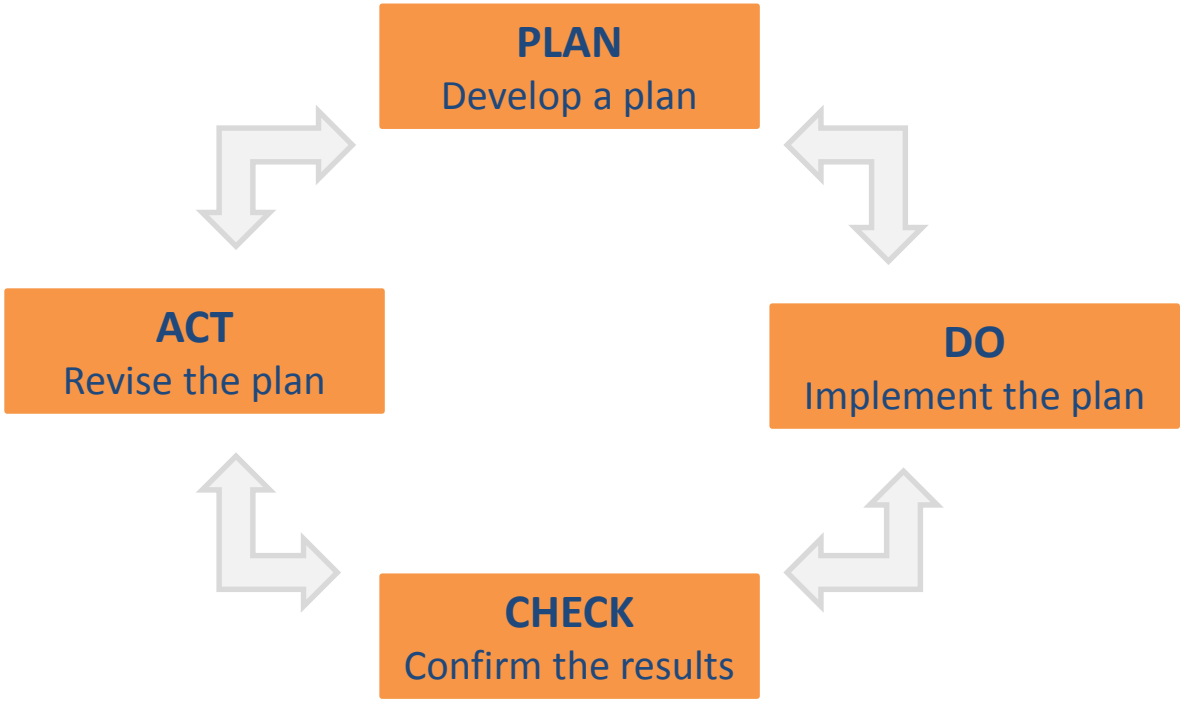
WHAT to be considered in the laboratories?

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.

Deming Cycle

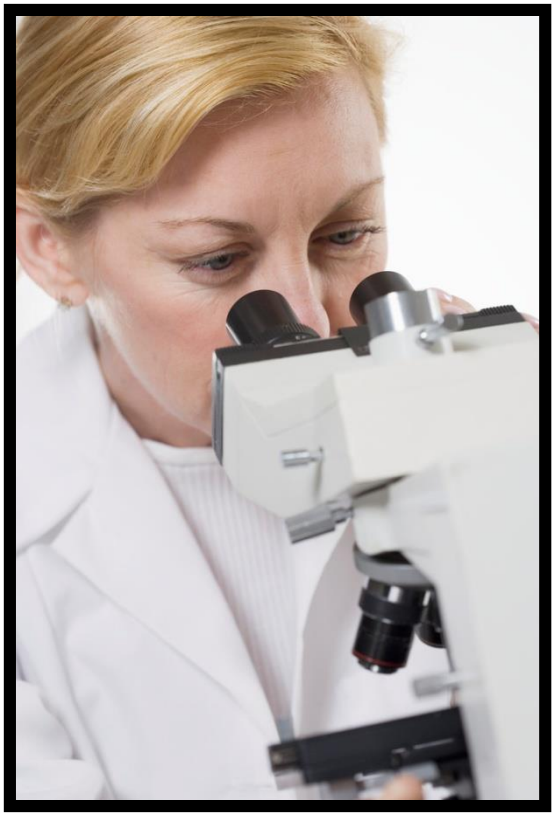
The Deming Cycle



Continuous improvement is the eternal theme

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

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



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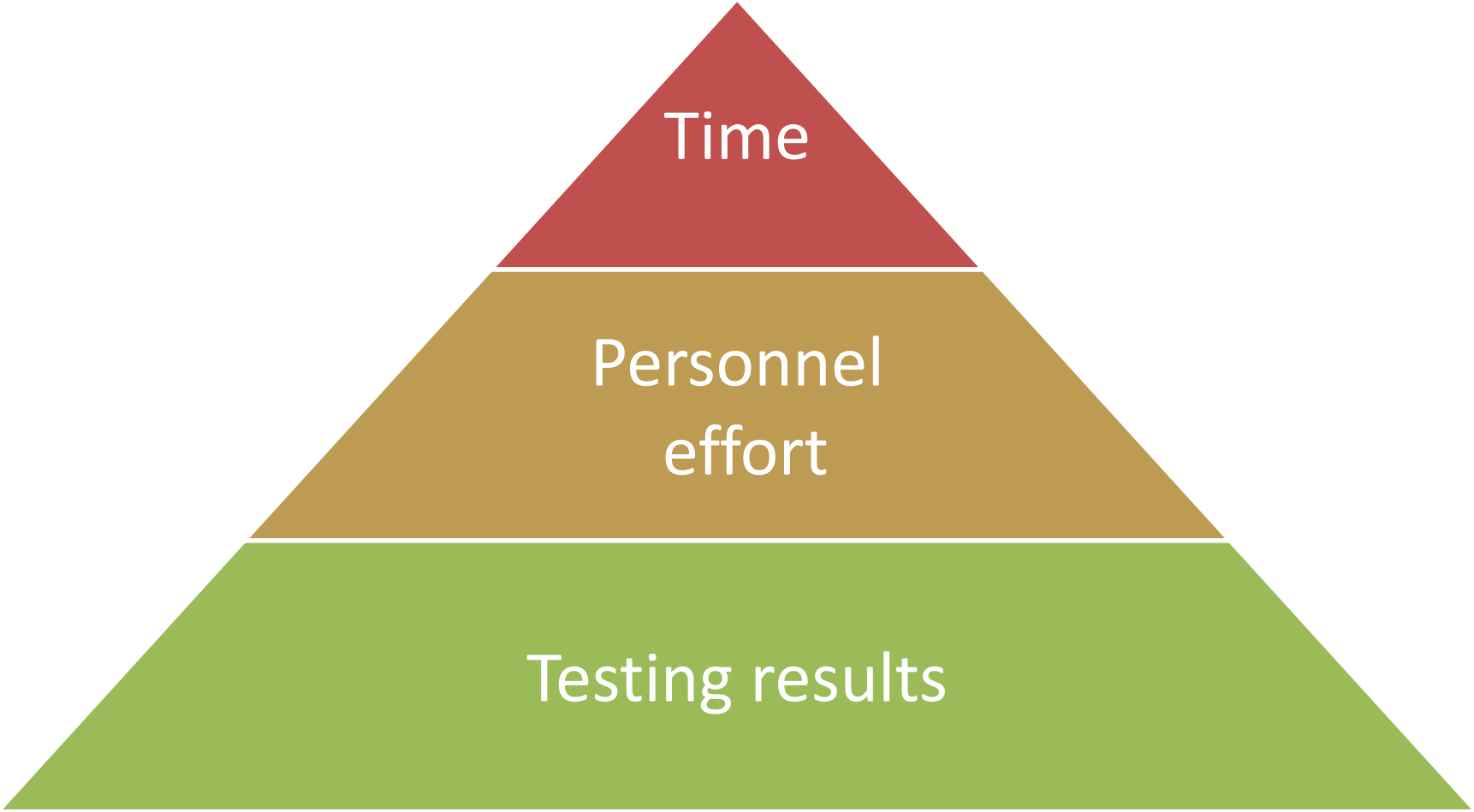
Laboratory errors cost in



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How do we achieve excellent performance in the laboratory?

- Organization
- Personnel
- Equipment
- Purchasing & Inventory
- Process Control
- Information Management
- Documents & Records
- Occurrence Management
- Assessment
- Process Improvement
- Customer Service
- Facilities & Safety

Quality Management System

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

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

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Laboratory tests are influenced by

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

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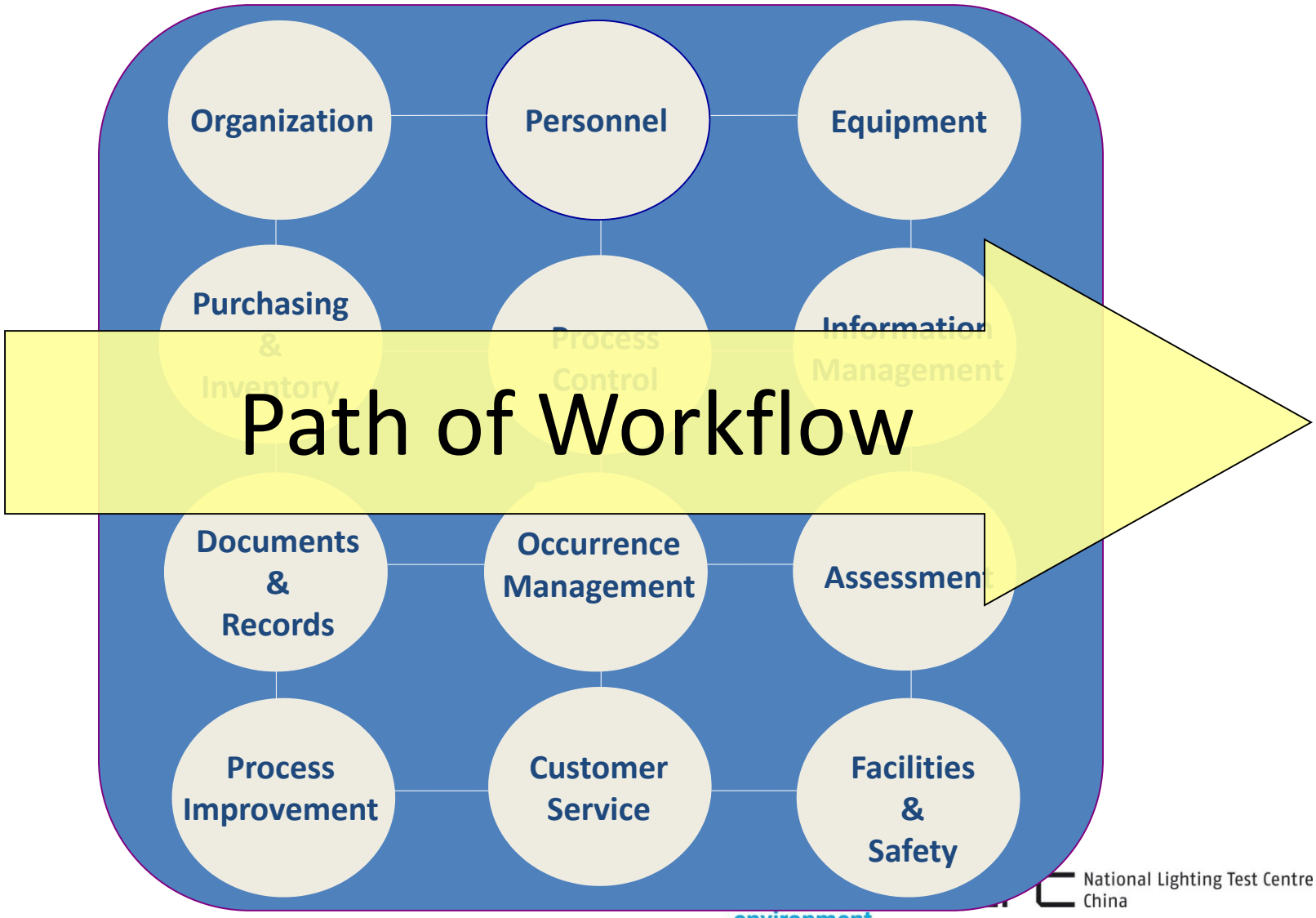
Quality System Essentials

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


Organization
Personnel
Equipment
Purchasing & Inventory
Process Control
Information Management
Documents & Records
Occurrence Management
Assessment
Process Improvement
Customer Service
Facilities & Safety
Path of Workflow

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Organization

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Personnel

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

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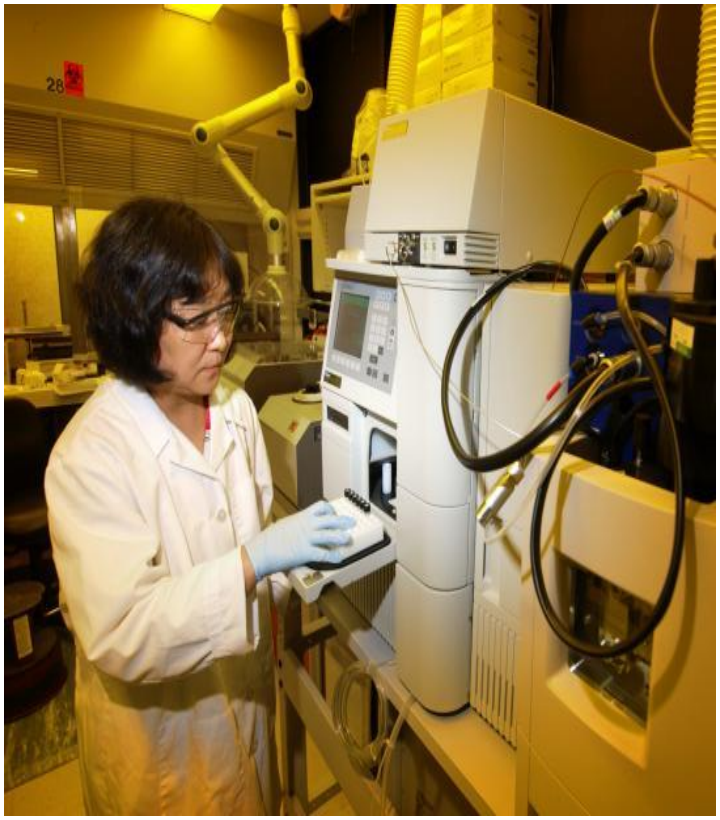
Equipment

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



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Purchasing and Inventory

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

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Process Control

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

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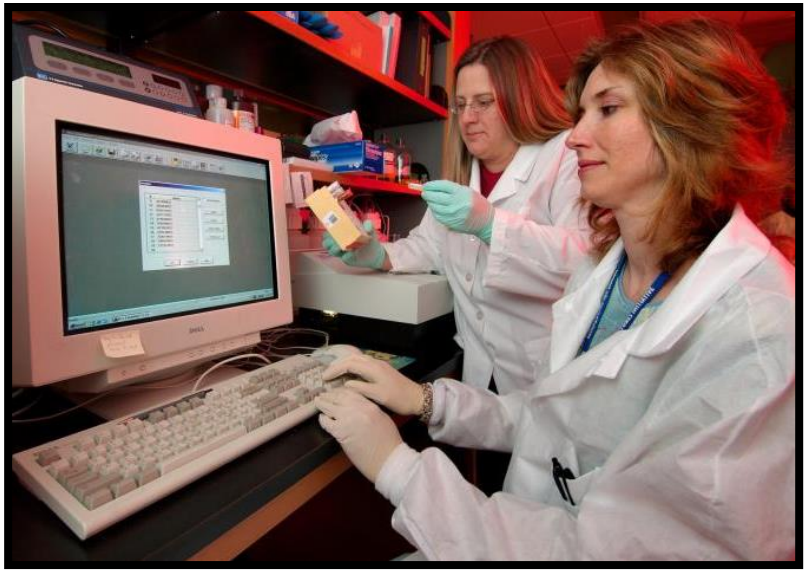
Information Management

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



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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

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Laboratory Assessment

External

Proficiency testing

Inspections

Accreditations

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Process Improvement

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

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Customer Service

- customer group identification
- customer needs
- customer feedback

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Facilities and Safety

- safe working environment
- transport management
- Security
- waste management
- laboratory safety

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Implementing Quality Management **does not** guarantee an ***ERROR-FREE*** Laboratory

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

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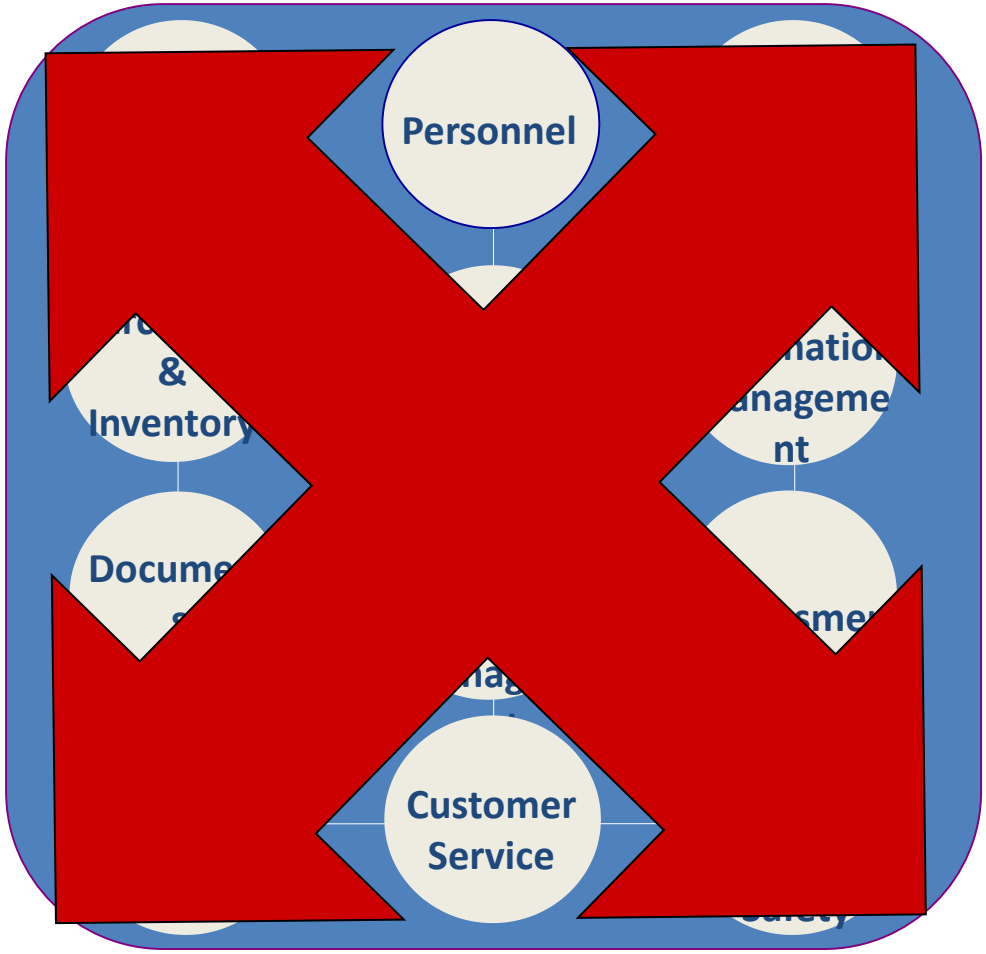

*Laboratories is **not*** implementing a quality management system guarantees UNDETECTED ERRORS

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Laboratory
Quality Management System

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

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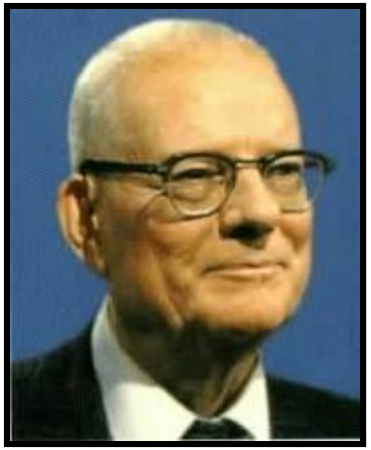
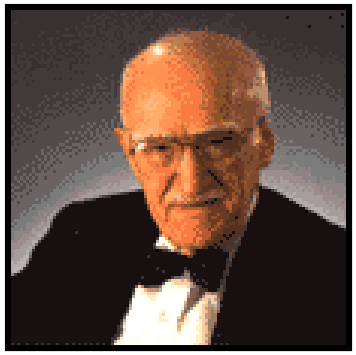
Innovators of Quality

Walter Shewhart
1891-1967

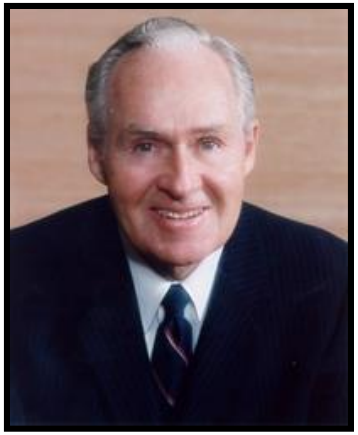


W. Edwards Deming
1900-1993



Joseph Juran
1904-2008 (103 years)

Philip Crosby
1926-2001



Robert Galvin
b. 1922

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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
Guidance for quality in manufacturing and service industries
Broad applicability; used by many kinds of organizations
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

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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 testing laboratory as it is for manufacturing and industry.

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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.

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