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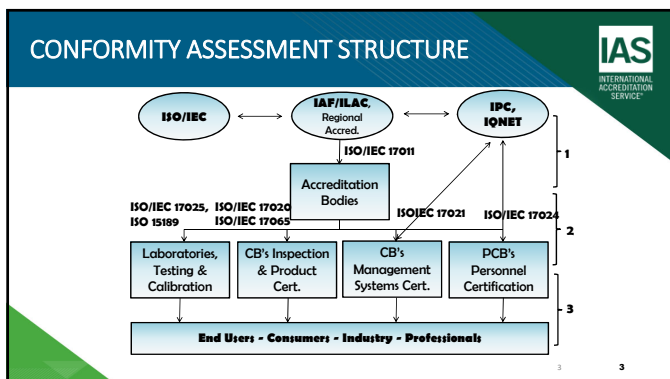
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## Quality Management Systems



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## What is Quality?



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Achieving a **99%** level of quality  
means  
accepting **1%** error rate

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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



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Result of **1%** failure



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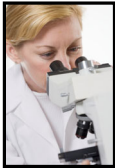
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Essential to all aspects of industry are **laboratory results** that are:

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



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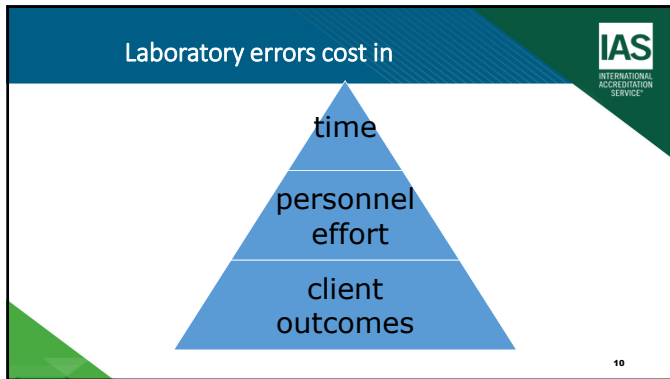
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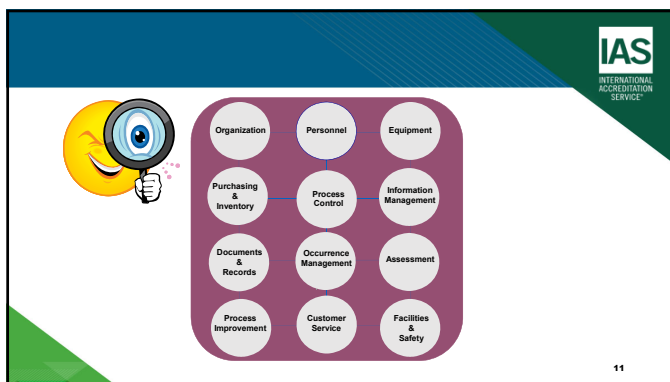
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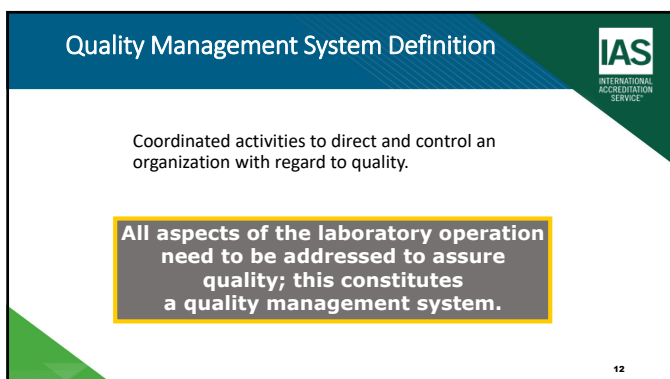
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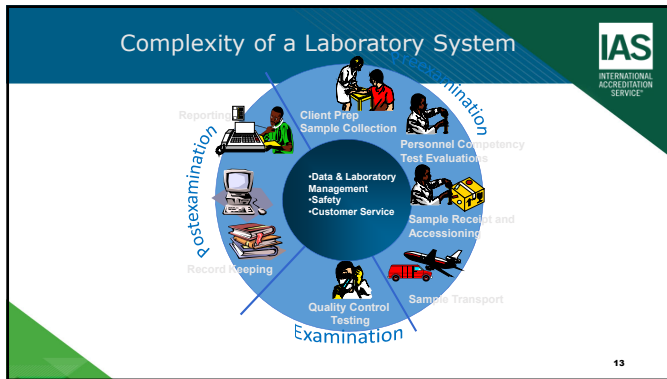
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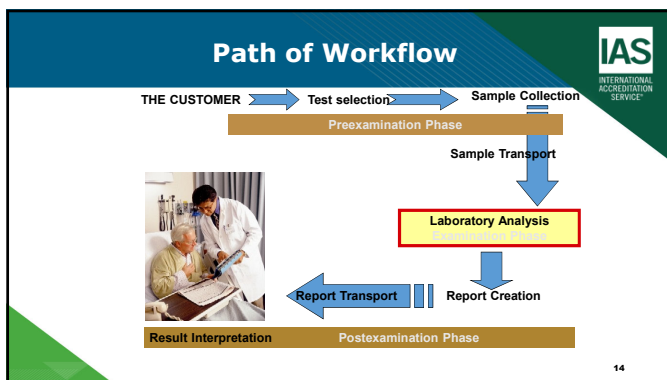
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### WHY is the Path of Workflow essential to consider in laboratories?

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.

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Laboratory tests are influenced by

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



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### Twelve Quality System Essentials

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



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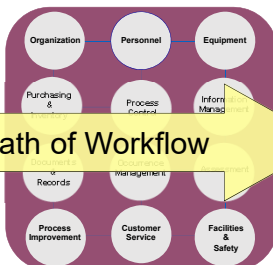
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### Path of Workflow



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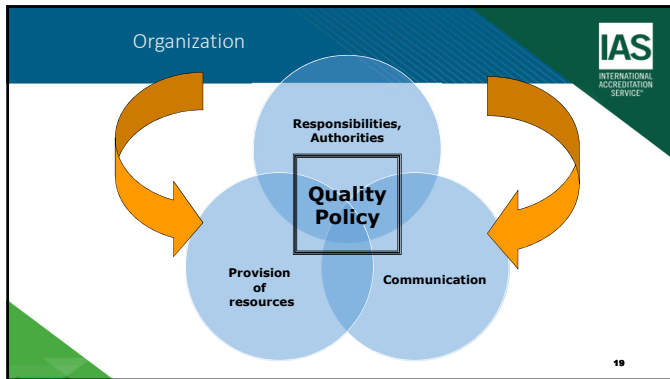
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Personnel

- 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 and reagents
- 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



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### Occurrence Management

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





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### Laboratory Assessment

**Internal**

Quality indicators

Audit program

Audit review




**External**

Proficiency testing (EQA)

Inspections

Accreditations



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### Process Improvement

- opportunities for improvement (OFIs)
- 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
- containment
- waste management
- laboratory safety
- ergonomics



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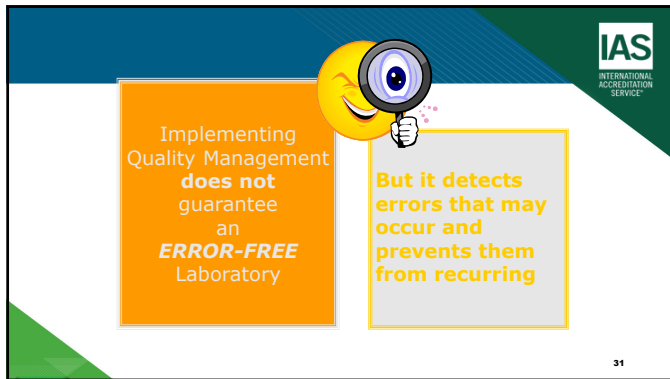
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Implementing Quality Management **does not** guarantee an **ERROR-FREE** Laboratory

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

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

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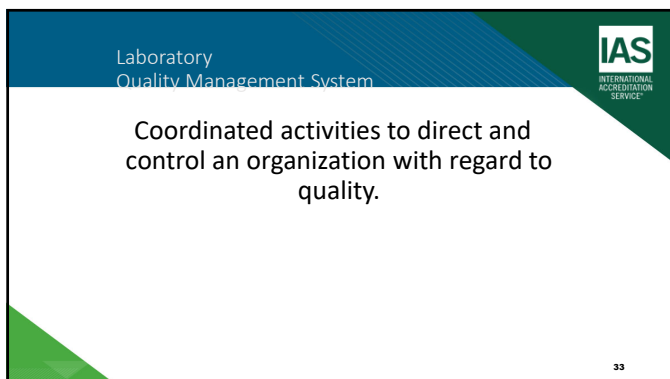
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Laboratory Quality Management System

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	<b>1920s</b>	Statistical Process Control
W. Edwards Deming	<b>1940s</b>	Continual Improvement
Joseph M. Juran	<b>1950s</b>	Quality Toolbox
Philip B. Crosby	<b>1970s</b>	Quality by Requirement
Robert W. Galvin	<b>1980s</b>	Micro Scale Error Reduction

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### ISO Documents - Laboratory

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

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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 medical 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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Questions?

Comments?

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**Thank you!**



### Contact information

