

INTRODUCTION TO MS ISO/IEC 17025:2005

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COURSE CONTENTS:

Understanding ...

1. Importance of quality management in the laboratory
2. Importance and benefits of Accreditation
3. ISO/IEC 17025:2005 - Management Requirements
4. ISO/IEC 17025:2005 - Technical Requirements



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IMPORTANCE OF QUALITY MANAGEMENT SYSTEM IN THE LABORATORY



QUALITY



✓ Degree to which a set of inherent characteristics fulfills requirements.

ISO 9000:2005

(ISO 9000:2005 - covers the basic concepts and language)



WHO IS A CUSTOMER?



- A customer is anyone who receives or is affected by the product or process.
- Include both internal and external customer.

“Understanding customer needs and wants will help you provide good quality service”



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QUALITY MANAGEMENT SYSTEMS

A management system to **direct and control** an organization with regard to **quality**



ISO 9000:2005



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Eight Quality Management Principles

- ✓ **Customers focused organization**
- ✓ **Leadership**
- ✓ **Involvement of people**
- ✓ **Process approach**
- ✓ **System approach to management**
- ✓ **Continual improvement**
- ✓ **Factual approach to decision making**
- ✓ **Mutually beneficial supplier relationship**



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8 Quality Management Principles

1. CUSTOMER FOCUS

Organizations depend on their customers and therefore should understand current and future customer's needs, meet customer requirements and strive to exceed customer expectation.

WE  OUR
CUSTOMER



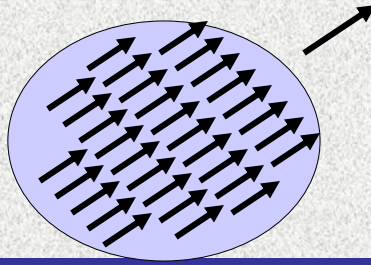
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2. LEADERSHIP

Leaders establish unity of purpose and direction of the organization. They should create and maintain the internal environment in which people can become fully involved in achieving the organization's objectives.



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8 Quality Management Principles

3. INVOLVEMENT OF PEOPLE

People at all levels are the essence of an organization and their full involvement enables their abilities to be used for the organization's benefits.



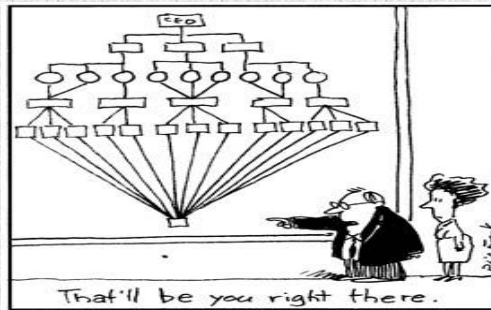
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4. PROCESS APPROACH

A desired result is achieved more efficiently when related resources and activities are managed as a process.



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5. SYSTEM APPROACH TO MANAGEMENT

Identifying, understanding and managing a system of interrelated processes for a given objective improves the organization's effectiveness and efficiency.



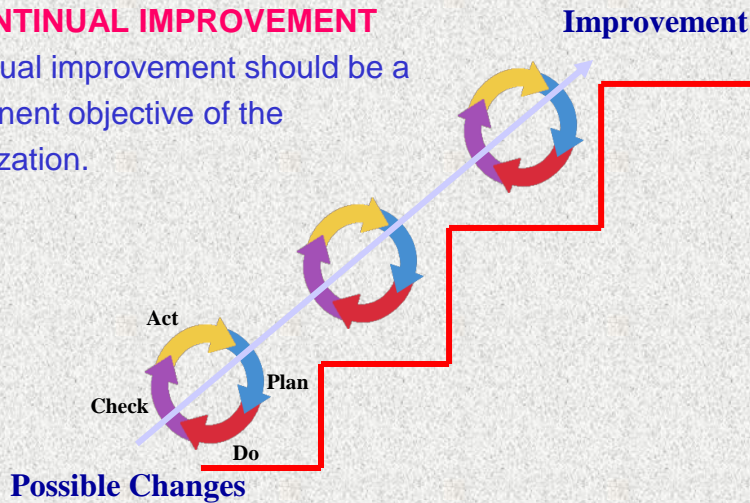
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6. CONTINUAL IMPROVEMENT

Continual improvement should be a permanent objective of the organization.



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8 Quality Management Principles

7. FACTUAL APPROACH TO DECISION MAKING

Effective decisions are based on the analysis of data/information.



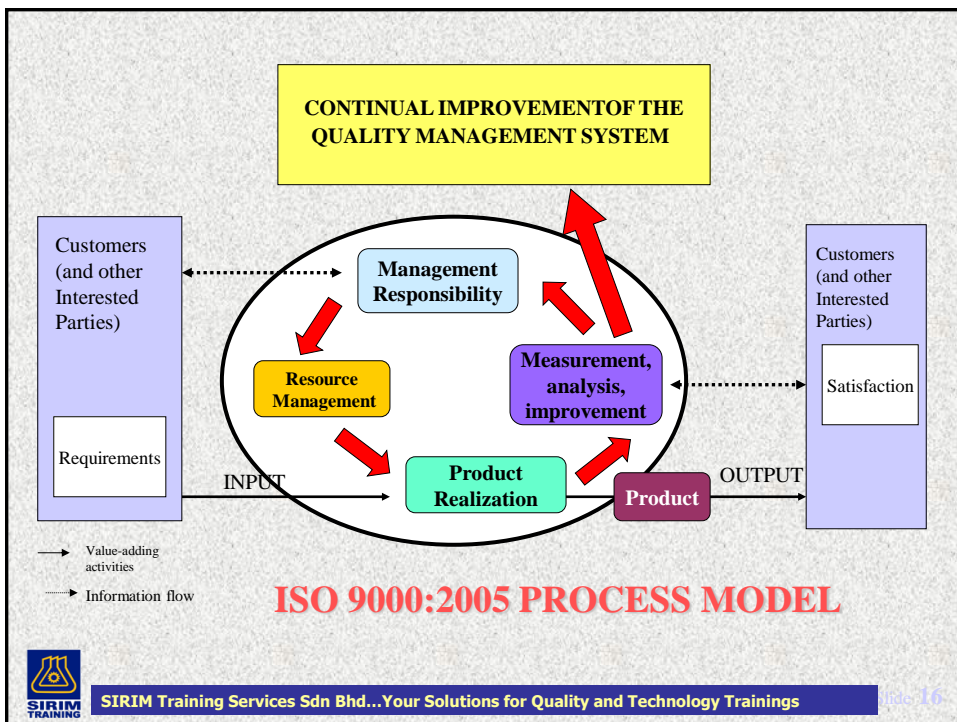
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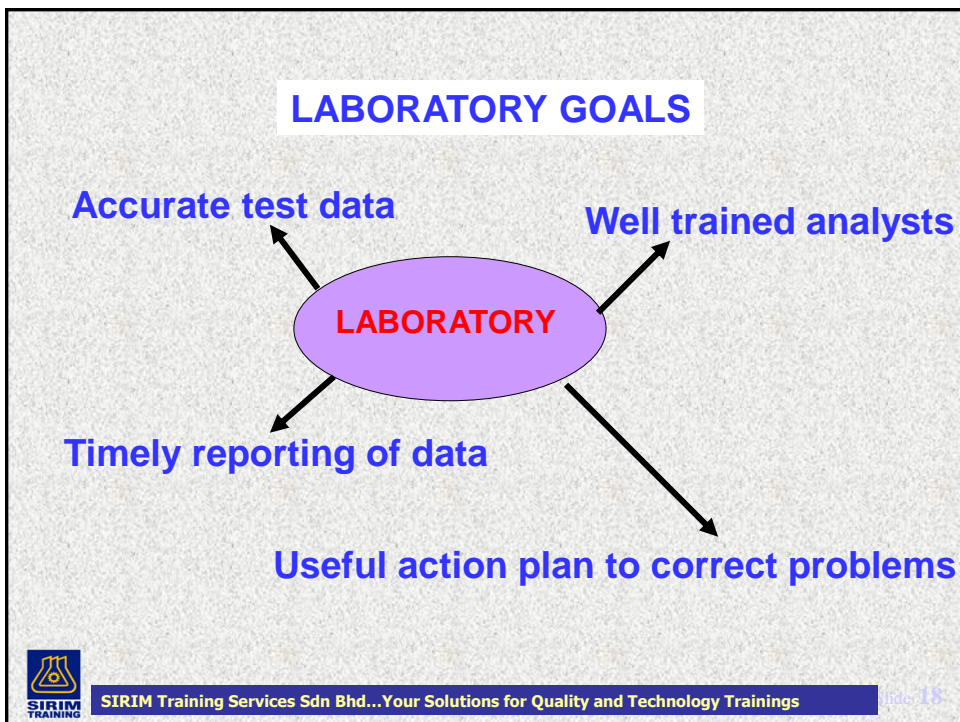
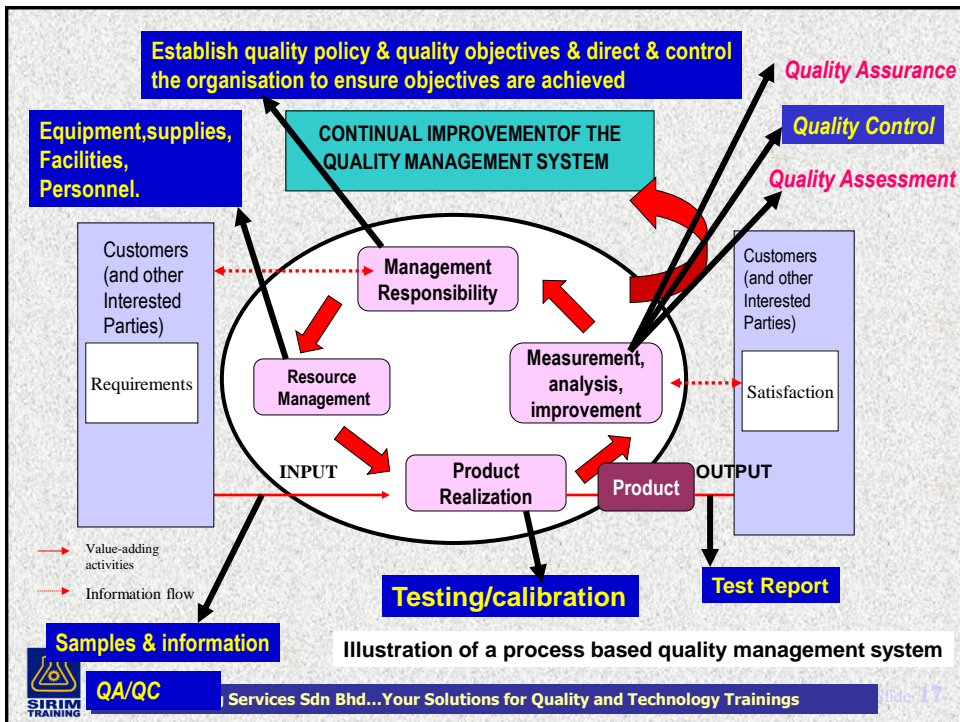
Slide 14

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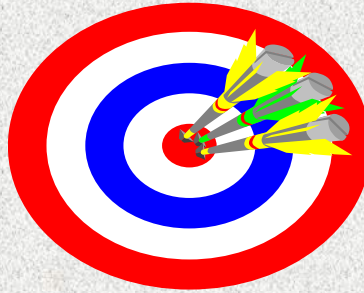
8. MUTUAL BENEFICIAL SUPPLIER RELATIONSHIP

An organization and its suppliers are interdependent and a mutually beneficial relationship enhances the ability of both to create value.





HOW TO MEET THESE GOALS?



HAVE A QUALITY PROGRAM TO MONITOR AND EVALUATE ALL LABORATORY PROCEDURES AS WELL AS THE COMPETENCE OF THE LABORATORY ANALYSTS.



4 KEY QUESTIONS

1. Are we doing it right?
2. Can we keep doing it right?
3. Are we doing it in the best way?
4. Is it the right thing to do?



QUALITY COSTS

- **PREVENTION COSTS**

The cost of trying to do it right the first time.

- Planning the system
- Documenting the plan
- Training staff
- Equipment management
- Reviewing the system



QUALITY COSTS

- **APPRAISAL COSTS**

The cost of checking to confirm it was right the first time.

- Internal and external QC
- Internal and external audits



QUALITY COSTS

• FAILURE COSTS

The cost incurred because it wasn't right the first time.

- ➔ Re-testing
- ➔ Lost productivity
- ➔ Processing complaint
- ➔ Recall of products and client's product
- ➔ Loss of staff morale
- ➔ Lost of business



COST OF POOR QUALITY



HOW DO YOU CONSISTENTLY PROVIDE QUALITY PRODUCT TO YOUR CUSTOMERS AND INTERESTED PARTIES?

- through Quality Assurance
- competent staff
- controlling process
- use technically valid methods
- by implementing an effective Quality Management System



BENEFITS OF QMS STANDARDS

- Improved service performance and customer satisfaction
- Confidence in data and protection against liability claims
- Improved productivity and cost reduction
- Improved market share



The Culture of Quality Management

- Responsibility begins with top management
- Quality concerns everyone
- Quality doesn't occur by accident
- Management of quality reflects quality of management
- Quality management pays

