



Laboratory Quality Management System

Module 3: Organization

Venue:

Presenter:

Date:

Introduction

The term **organization** in the context of QMS is management and the supporting organizational structure of the laboratory.



Learning Objectives

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

- describe organizational elements needed for a quality management system;
- discuss management roles and responsibilities in a quality system;
- explain the process for designing, implementing, maintaining, and improving the laboratory quality system;
- explain the purpose of a quality manual.



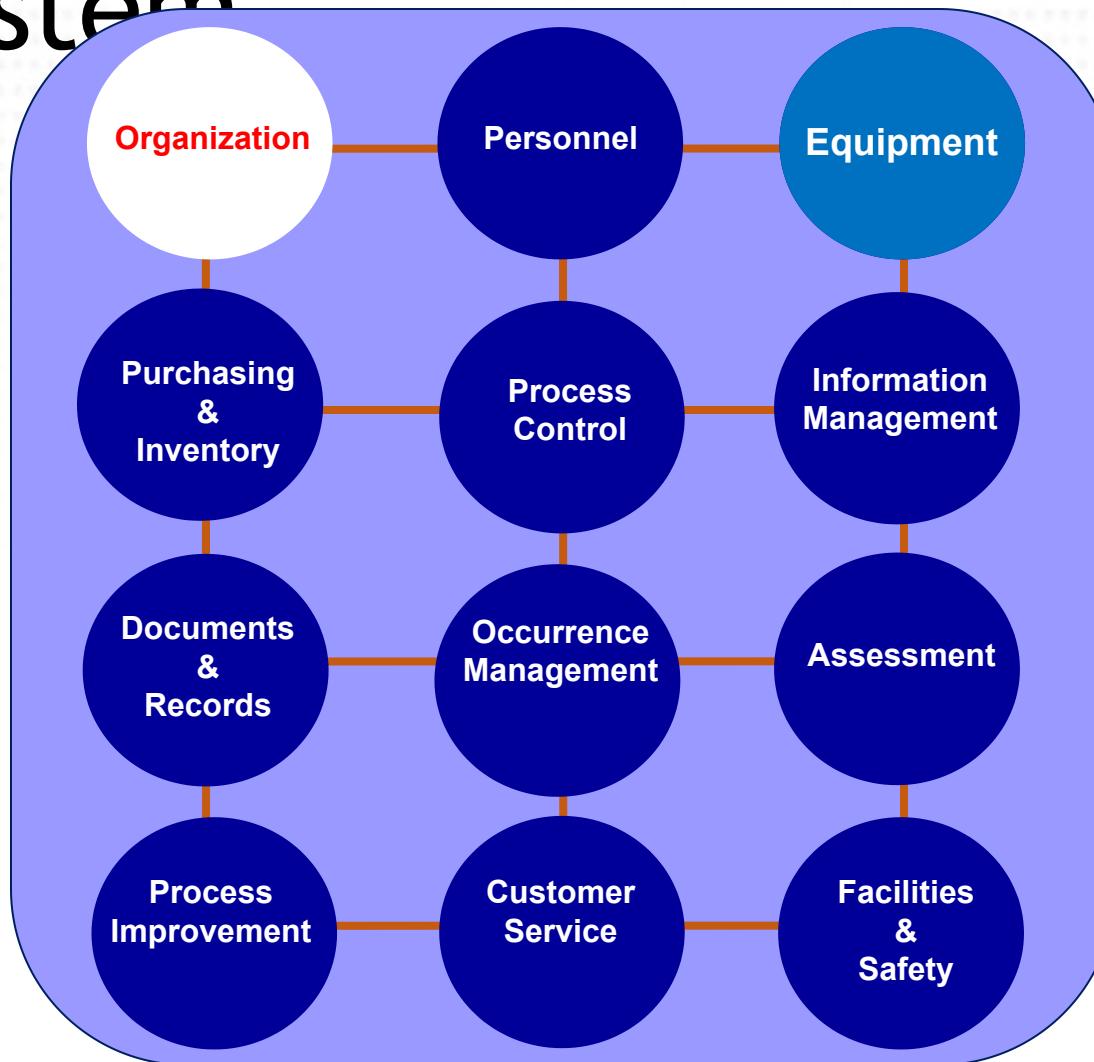
Module Outline



- Organizational requirements for Q...
- Management Role
- Organizational structure
- Organizational functions - Planning
- Organizational functions - Implementation
- Organizational functions - Monitoring
- Quality Manual



The Quality Management System



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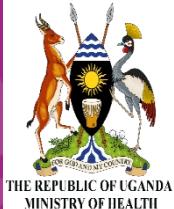
Characteristics Essential to QMS success

1. Management committed to a quality management system.
2. An organizational structure designed to assure quality goals.

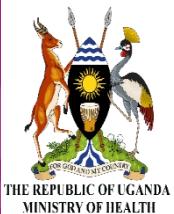
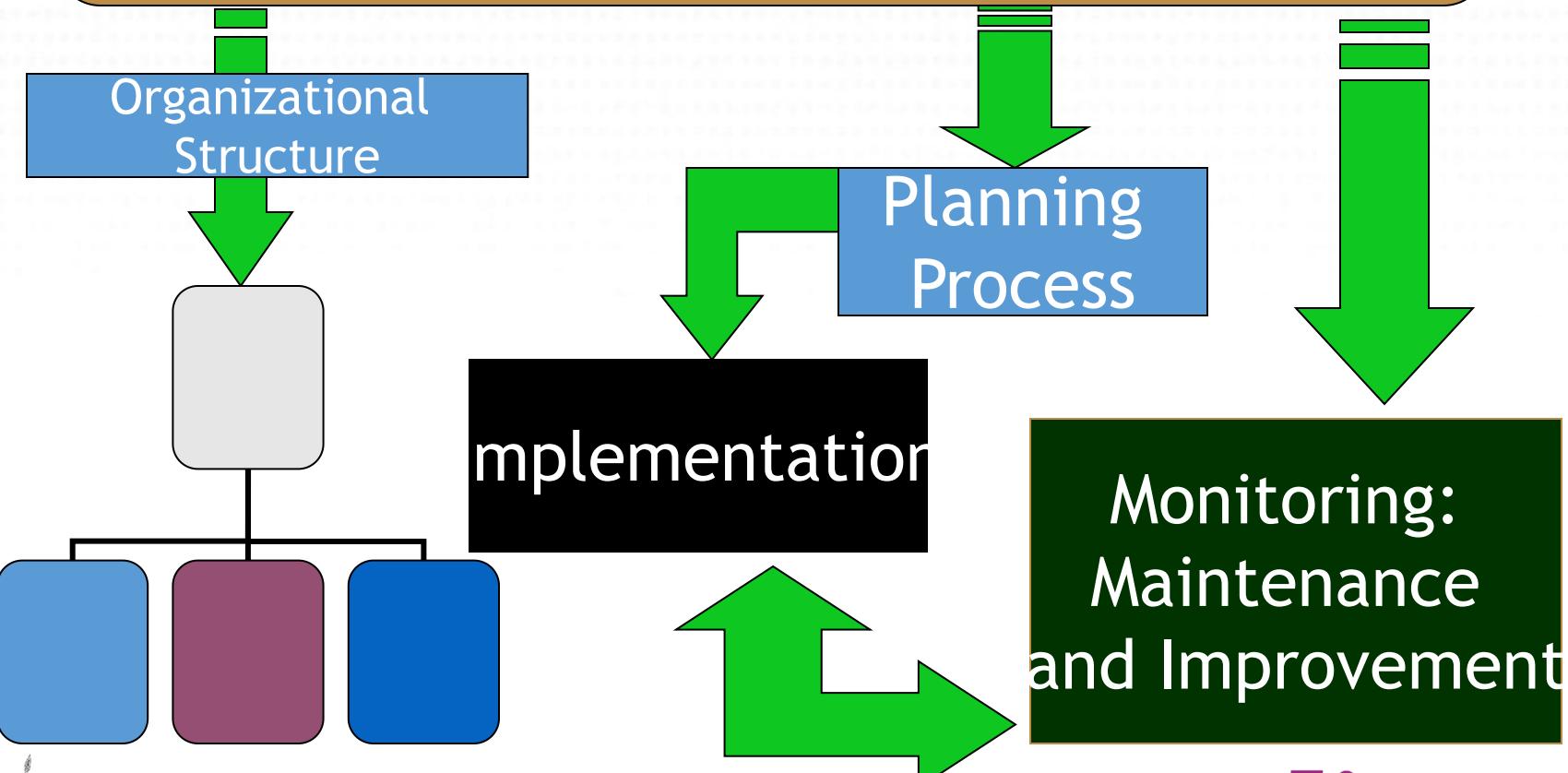


Key organizational components

- Leadership
- Organizational structure
- Planning
- Implementation
- Monitoring and Improvement



Leadership, Managerial Roles



Activity 3-1- Understanding planning, implementation and monitoring



Microsoft Word
7 - 2003 Document



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1. Management Role



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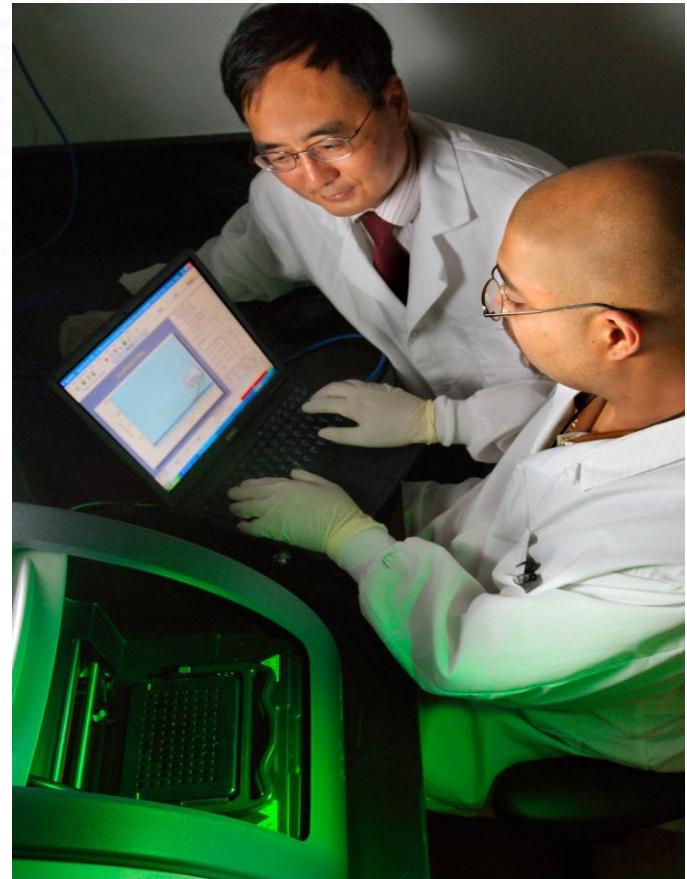
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Providing Leadership

- exercising responsible authority, while providing motivation and vision
- influencing and encouraging staff to good performance



Management Responsibilities in the QMS

- Implement and continuously improve the quality management system
- Document and communicate to all personnel
- Provide a quality manual



Management commitment

- Evidence of management commitment to the development , implementation and continual improvement of the QMS is through

Ensuring requirements and needs of users are met

Establishing the quality policy and objectives

establishing communication processes and interrelationships

appointing a quality manager,

conducting management reviews

ensuring persons are competent

Ensuring resources are availed for lab processes



Management Commitment

Ministry of Health



Finance Manager



Staff
Meeting

S

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2. Organizational Structure

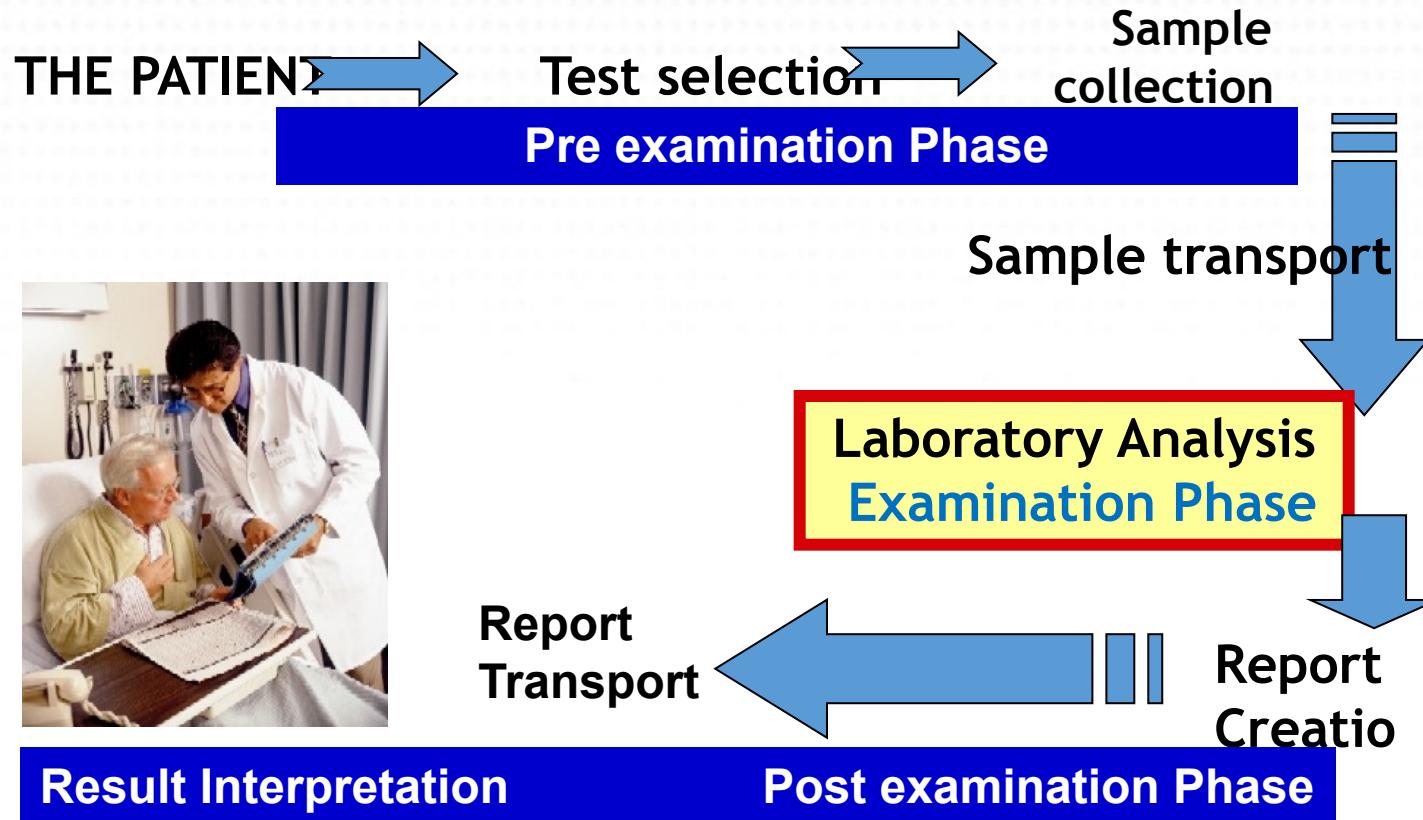


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Establish a working structure that ensures sufficiency at all parts in the laboratory work flow

Path of Workflow



④ Designate Responsibility, authority and interrelationships



Laboratory Management shall ensure all responsibilities, authority and interrelationships are defined, documented & communicated to staff

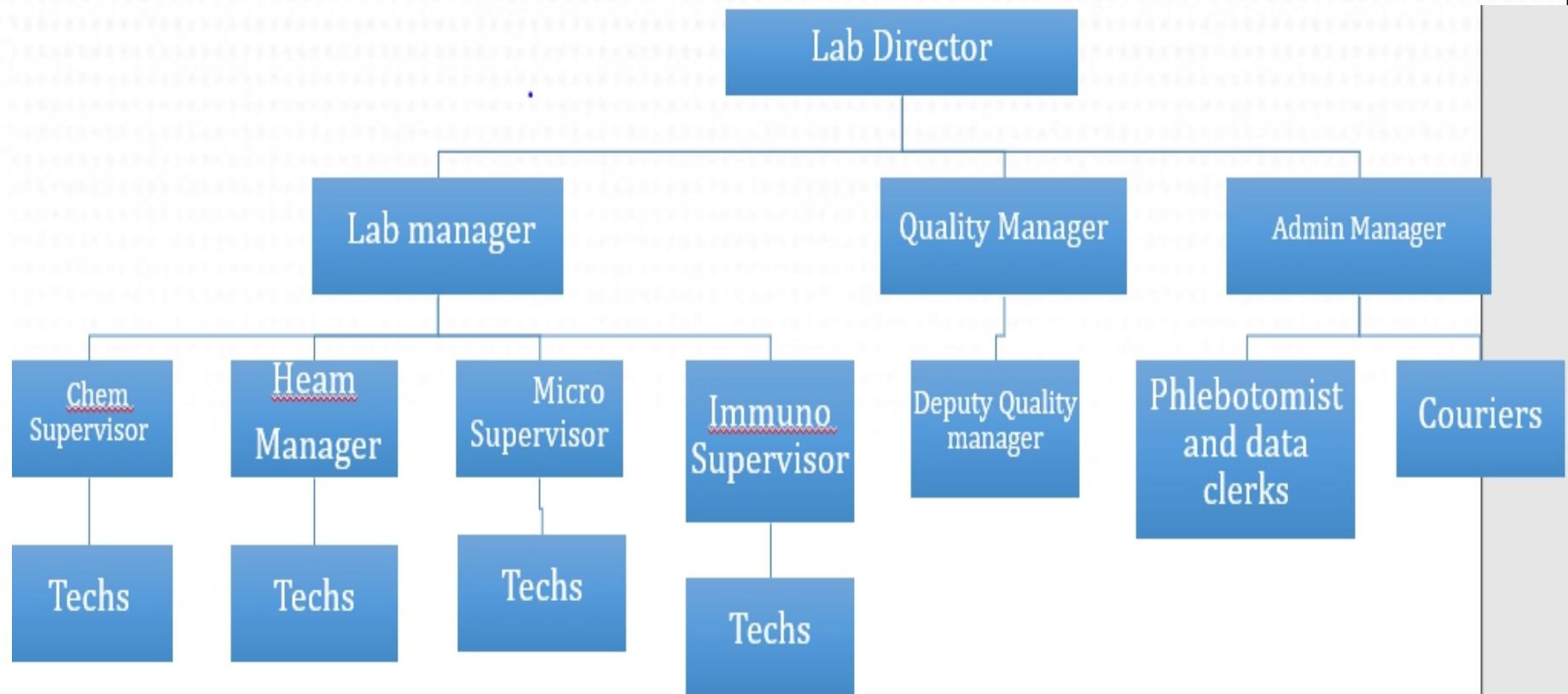
All staff should have an appointment letter that clearly outlines their respective functions and job descriptions

All key managerial and technical positions should have a deputy

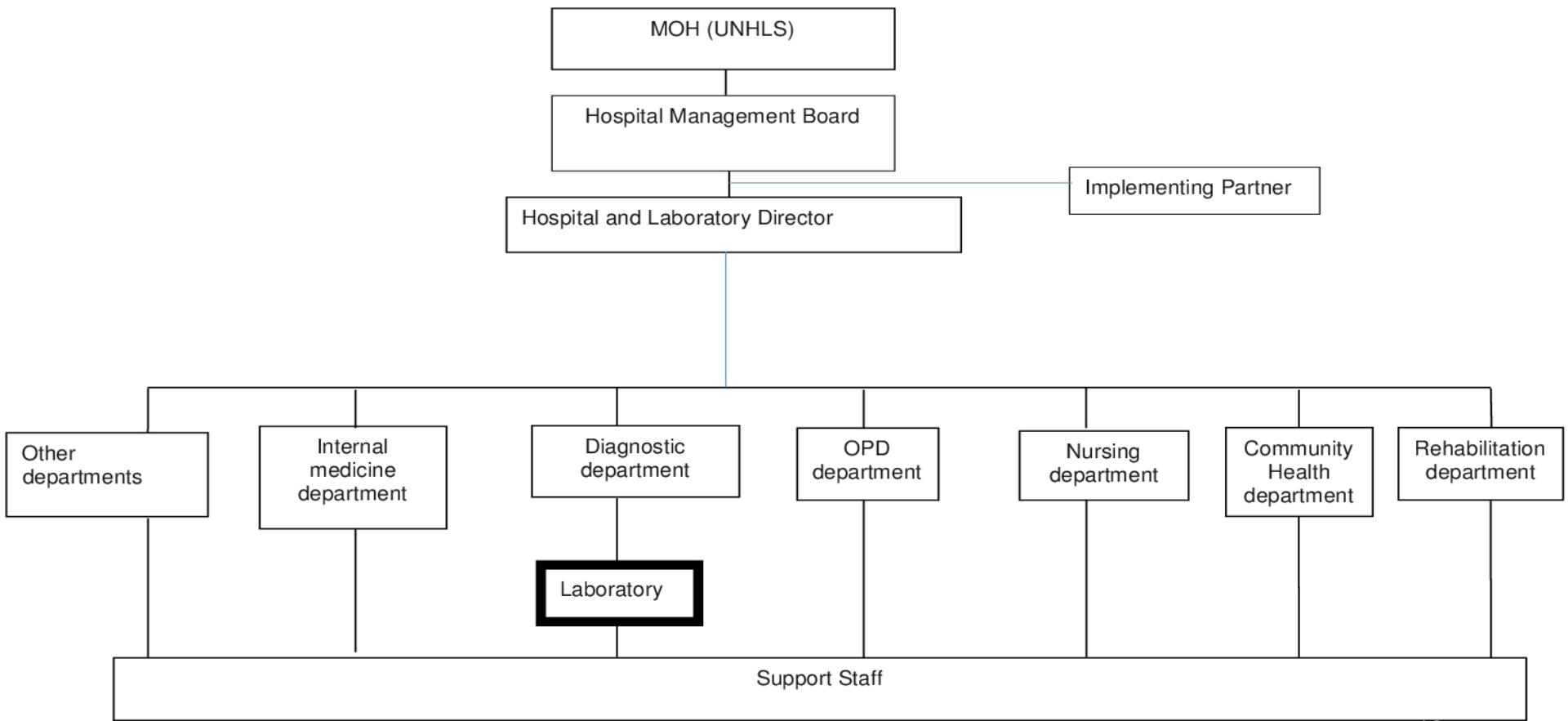
All appointment letters should be signed as proof of acceptance.

Interrelationships can be illustrated on an organogram

Q Develop an Organizational chart



Organogram: Parent organisation



Designate a Quality manager



Reporting to lab management (Decision makers) on lab policy, objectives, and availability of resources, QMS performance & improvement requirements



Process needed for QMS establishment, implementation & maintenance



Promotion of users needs and needs of the laboratory

Quality Manager other Responsibilities

- Monitor quality management system
- Assure compliance
- Review all records
- Conduct, coordinate audits
- Investigate deficiencies
- Inform decision makers



① Allocate sufficient Resources

① Financial requirements/budget

① Personnel needs

- additional staff
- skills, training needed

① Facilities, equipment, supplies, computers



3. Organizational functions

1. Planning QMS
2. Implementation
3. Monitoring



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3-1:Organizational functions - Planning

- () Approaches vary with local situation
- () Many factors influence starting point
- () Include all quality elements in plan



May implement in stepwise

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Organizational functions - Planning

Keep in mind

- Communicate, be transparent
- Set feasible timelines
- Develop realistic, measurable objectives



Set priorities, proceed stepwise

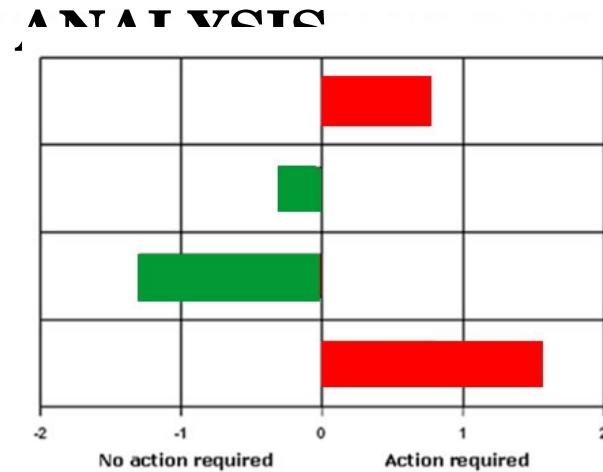
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Organizational functions - Planning

Conduct Gap Analysis

- Determine the gaps, using quality management systems checklist **GAP**
- Develop a task list
- Prioritize by:
 - quick fixes first
 - determine what would have the greatest positive impact



Organizational functions - Planning Gap Analysis---

Common problems identified

- ⌚ test ordering
- ⌚ sample management
- ⌚ training level (competence) of technical staff
- ⌚ quality control
- ⌚ analytical process
- ⌚ recording and reporting results
- ⌚ reagent and equipment management



Organizational functions -

Planning Quality Management System Plan should include

- what should be done
- who will be responsible
- when (timeline)
- how many resources are needed

Must be available to all staff



3-2: Organizational function - Implementation

- Commit to completion
- Prepare for implementation in stages
- Assure resources are available
- Use a Gantt chart
- Be sure everyone knows their responsibility



then



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Successful implementation requires

- ❑ having management commitment
- ❑ understanding the benefits of a quality management system
- ❑ engaging staff at all levels
- ❑ striving to continually improve
- ❑ having realistic expectations



Intent to Action



Intent to Action

- assign responsibility for implementation
- allocate resources
- develop and distribute a quality manual
- implement quality system
- monitor compliance with quality management system requirements



3-3: Organizational function - Monitoring Compliance

- Assign responsibility
- Develop indicators
- Establish monitoring system
- Conduct audits
- Management review



4. QUALITY MANUAL

What is a Quality Manual?

- A document describing the quality management system of an organization.
- essential organizational step
- management responsibility



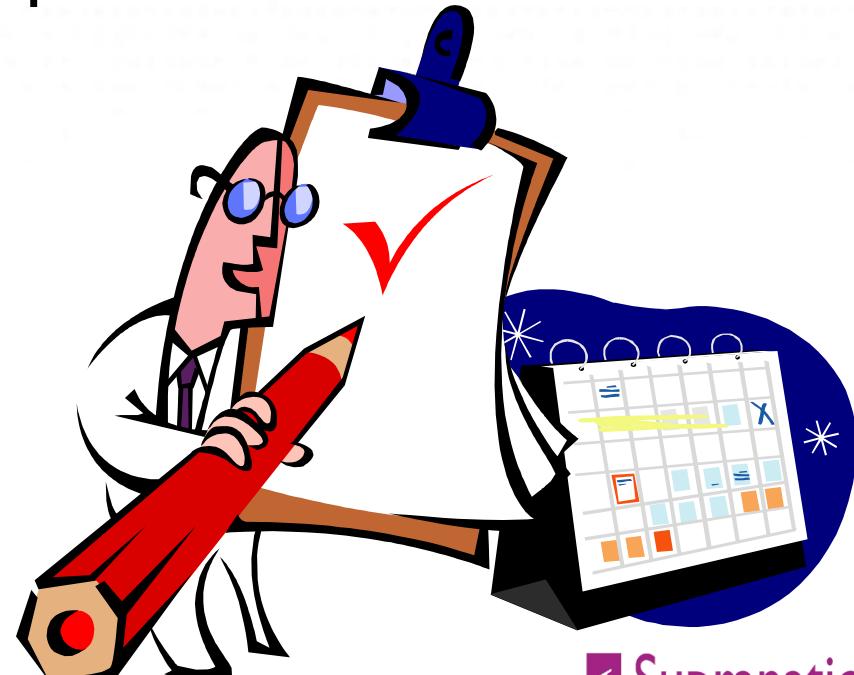
Quality Manual

- communicates information
- serves as a framework for meeting quality system requirements
- demonstrates management's commitment to quality



Maintaining the Quality Manual

- ❑ communicates quality policy
- ❑ needs management approval
- ❑ requires updating



Activity 4-1- Understanding managerial and staff responsibilities



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Remember

- Quality is not a science,
it's a way of thinking.
- Spend time today to
gain rewards tomorrow:
 - quality results
 - efficiency
 - professional, personal satisfaction
 - peer recognition



Assessment

- What are the organizational elements needed for a quality management system.
- List the management roles and responsibilities in a quality system.
- Explain the purpose of a quality manual



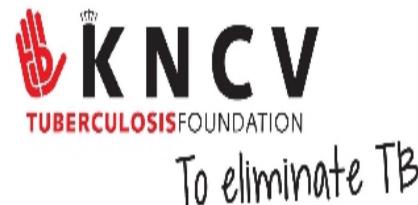
Who is Responsible for Quality?



Reference

- ◆ ISO 15189:2012 Medical Laboratories - Requirements for Quality and Competence
 - « Clause 4.1.1.2, 4.1.1.3, 4.1.1.4, 4.1.2, 4.2,
 - »
- ◆ CLSI
- ◆ ASLM

Acknowledgement



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