



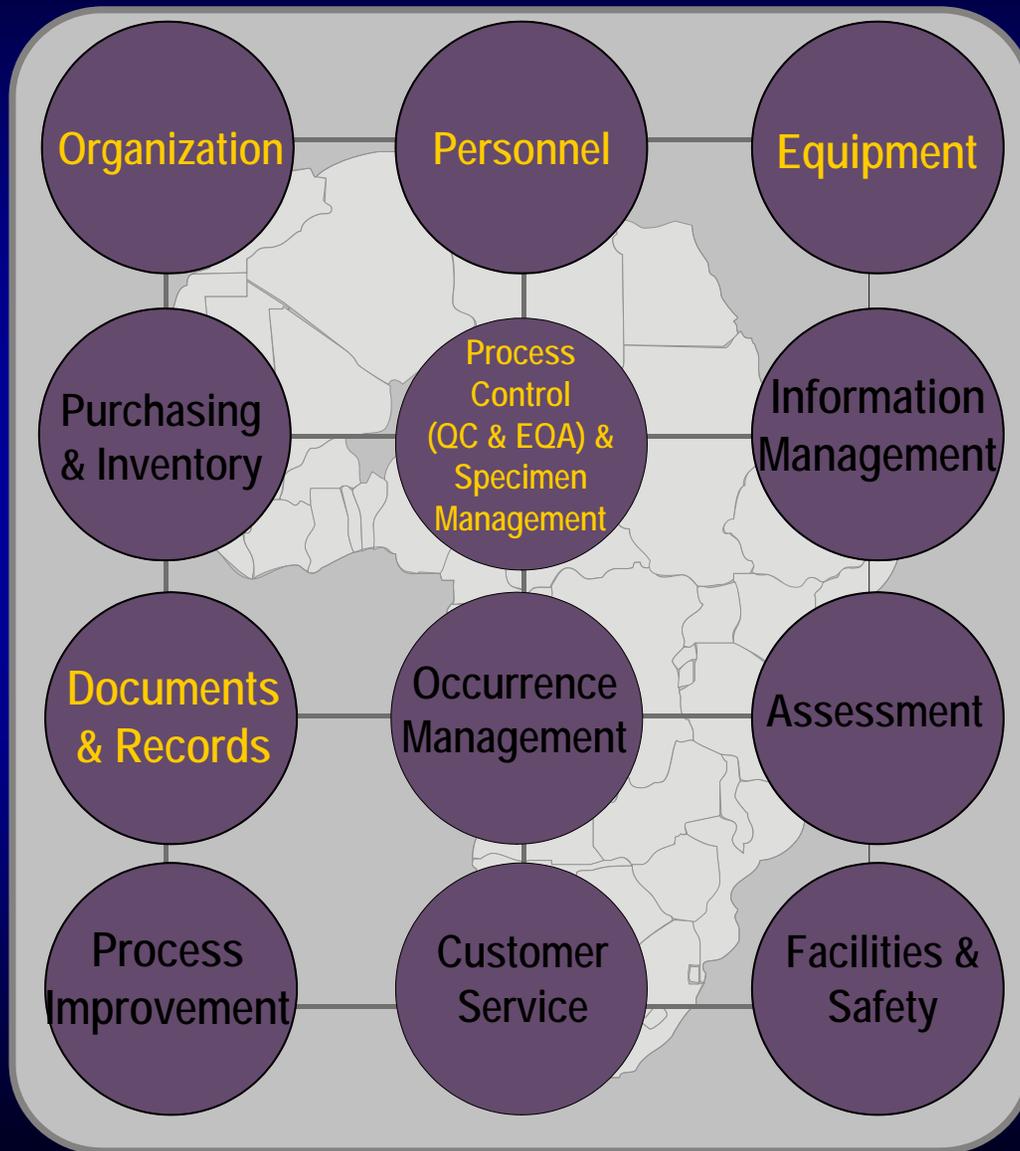
DEPARTMENT OF HEALTH AND HUMAN SERVICES

ORGANIZATION

SAFER • HEALTHIER • PEOPLE™



The Quality System



Key Components

- Leadership
- Organizational structure
- Planning
- Implementation
- Monitoring

From Intent to Action

- Assure commitment from top management
- Develop quality system plan
- Assign responsibility for implementation
- Allocate resources
- Develop and distribute a quality manual
- Implement quality system
- Monitor compliance with quality system requirements

Who is responsible for Quality?

- EVERYONE IN THE LABORATORY!
- Laboratory management must commit to meeting quality needs
- Laboratory personnel must carry out quality assurance procedures

Management Commitment

- Seek support from upper management
 - Identify appropriate management level
- Must involve those making financial decisions
- Communicate commitment of laboratory managers to staff

Quality System Planning

- Approaches to developing a quality system vary with local situation
- Many factors influence starting point
- Plan should include all quality elements
- May implement in stepwise process

Conduct Gap Analysis

- Determine the gaps in your QA program
 - Use Quality Systems Checklist
- Develop a task list using identified gaps
- Prioritize filling these gaps by –
 - Considering the quick fixes first
 - Determining what would have the greatest positive impact

Quality System Plan

- Plan should be written, available to all staff
 - include training needed, assignment of responsibility
- Develop timeline
- Sources of information and assistance

Assign Responsibility

- Prepare laboratory organizational chart
- Appoint Quality Manager
- Designate Quality Committee
- Define responsibility for all staff
- Prepare an organizational chart describing the laboratory as part of the health organization

Quality Manager / Committee Responsibilities

- Monitor and maintain records of data in support of QA program
- Conduct audits to assess compliance with QA policies and procedures
- Investigate deficiencies
- Coordinate on-site inspections of monitoring or accrediting agencies

Implementing a Quality System – Resource Requirements

- Financial requirements / budget
- Personnel needs
 - Additional staff
 - Skills, training needed
- Facilities, equipment, supplies, computers

Documenting the Quality System

WHAT IS A QUALITY MANUAL?

A document stating the quality policy, quality system and quality practices of an organization

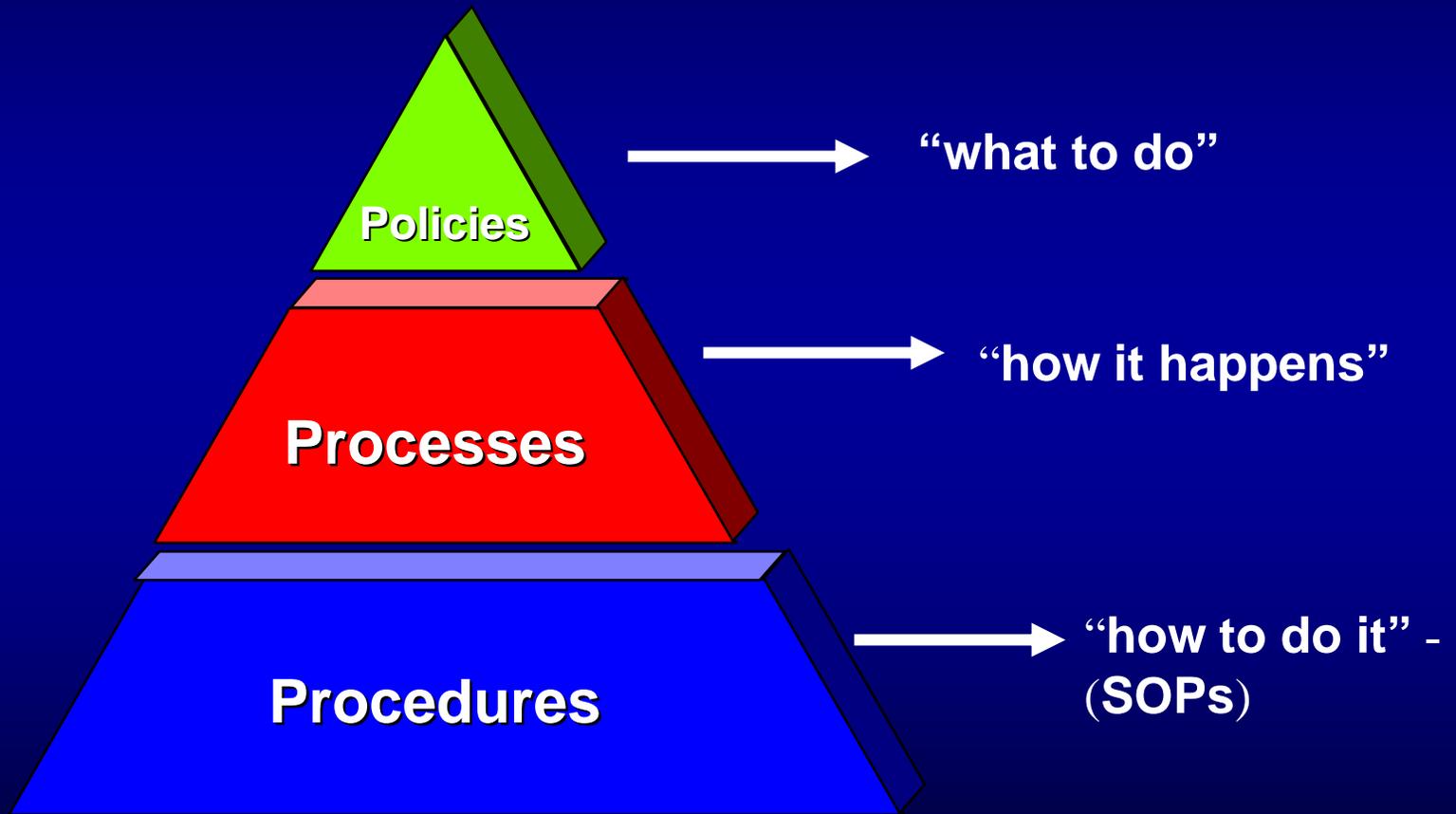
(ISO/IEC Guide 25)

Quality Manual

WHAT IS IT'S PURPOSE ?

- Communicates information
- Serves as a framework for meeting quality system requirements
- Demonstrates management 's commitment to quality

Quality Manual (Add work instructions)



Quality Manual Basics

- Table of contents, introduction
- Description of the organization, including scope of activities
- Quality policy
- Reference to supporting documents
- Structure of documentation
- Glossary of terms

Structure of Documentation

Quality Manual

Processes

Procedures

Work instructions

Forms

Records

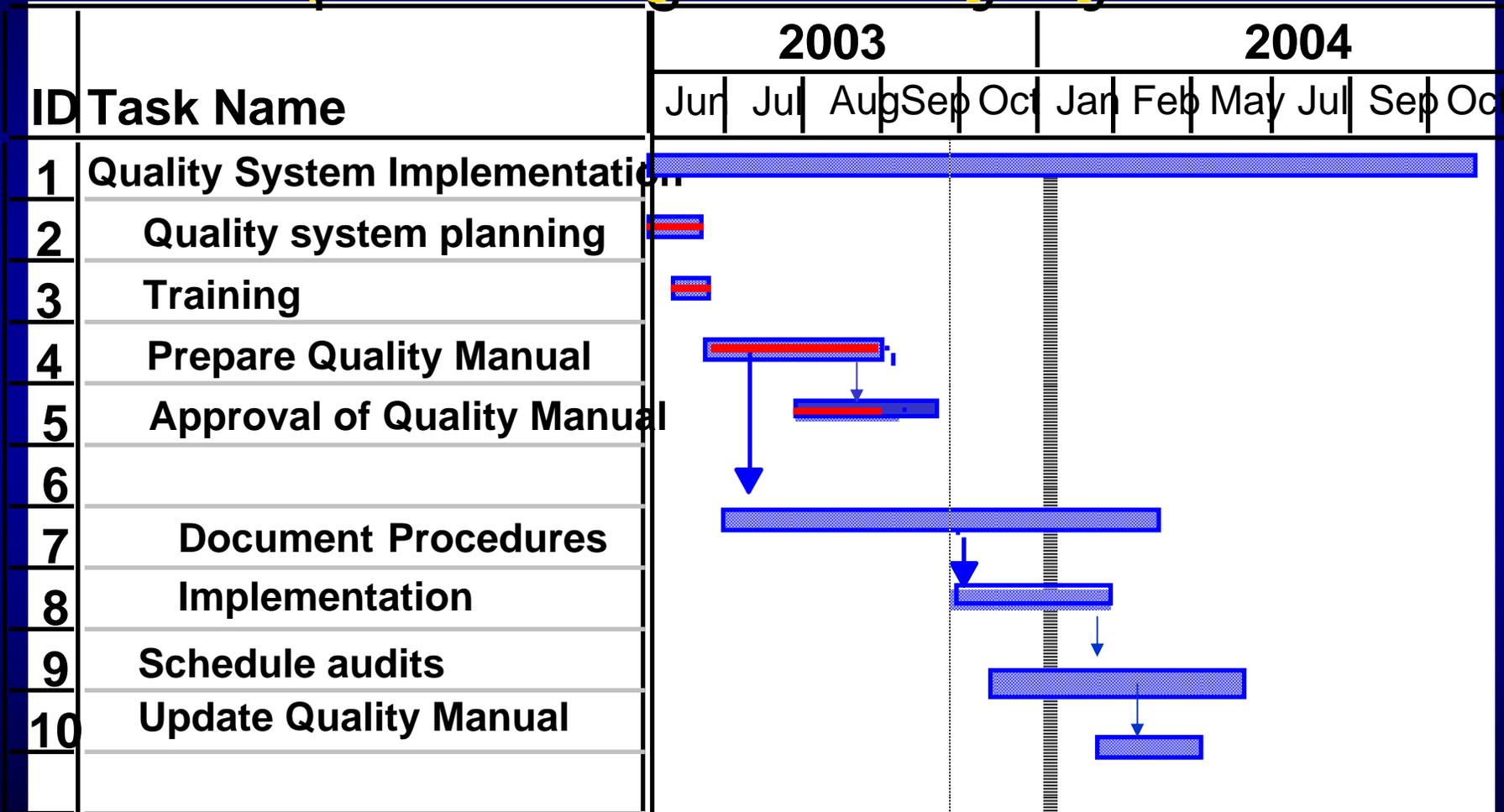
Quality Manual – Implementing and Maintaining

- Approval process
- Method of communication to all employees
- Process for updating
 - frequency
 - responsibility
 - documentation

Implementing a Quality System

- Estimate time needed based upon available resources
- Prepare for implementation in stages
- Stagger start dates
- Determine resource requirements
- Developing a Gantt chart may be useful

Implementing a Quality System



Monitoring Compliance

- Assign responsibility; usually Quality Manager
- Develop indicators using quality policy
- Systems for monitoring
- Conduct audits or periodic reviews
 - Internal and external

Successful implementation requires:

- planning, management commitment
- belief in system
- understanding the "spirit" of the standard
- understanding organization's aims
- having staff involved at all levels
- looking for ways to continually improve
- setting realistic time frames