Laboratory Management of a Quality System

Module 2:
Overview of Quality Systems

ACKNOWLEDGEMENTS

- Ministry of Health and Social Welfare – Tanzania
- Muhimbili University of Health and Allied Science
- World Bank
- ECSA- HC

Learning Objectives

- Describe the importance of quality systems
- List four components of a total quality management system
- Identify twelve quality system essentials
- Describe the laboratory's path of workflow

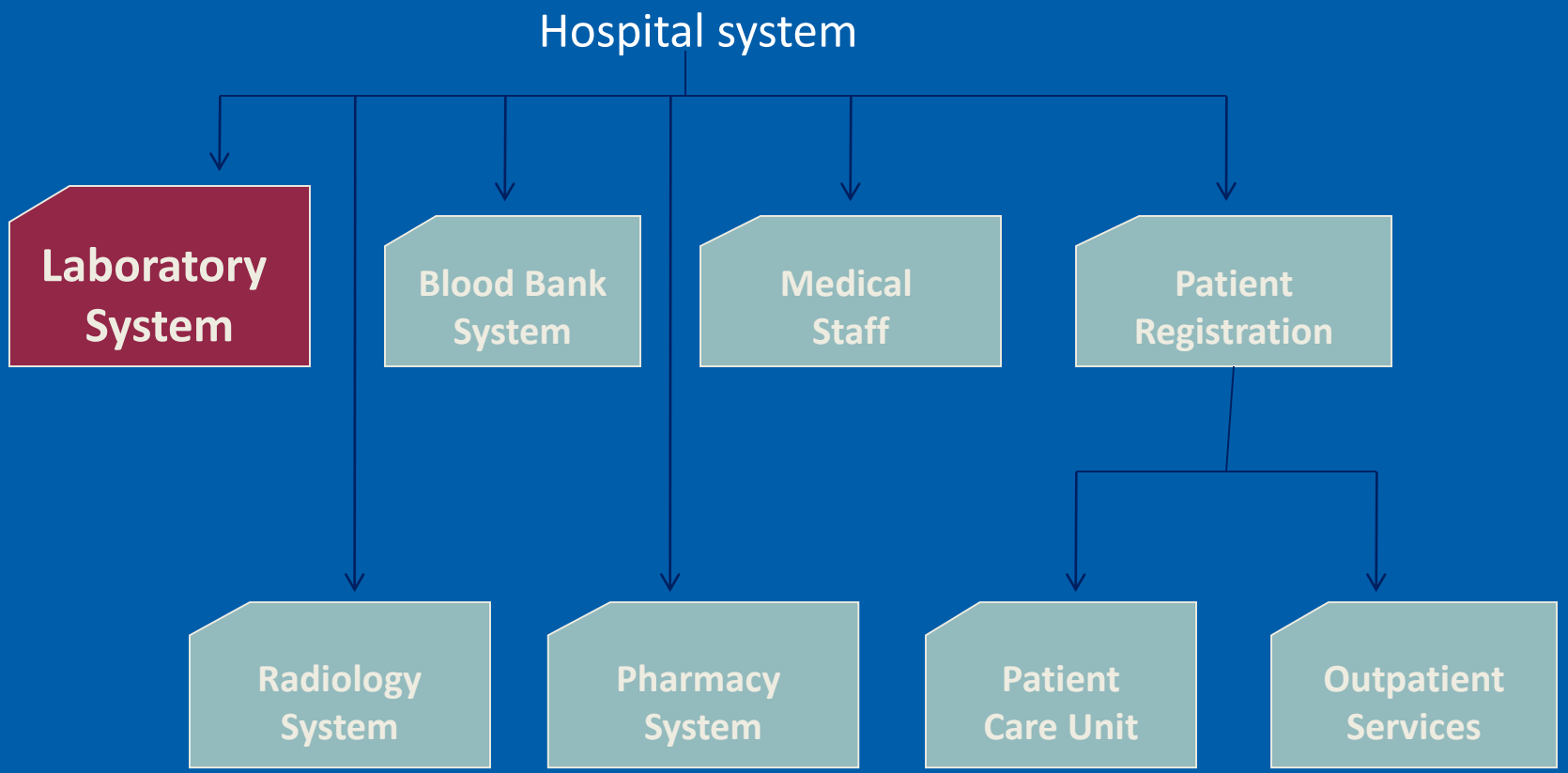
Today's Agenda

- Systems Overview
- Total Quality Management
- Quality Systems Essentials
- QSE Activities
- Quality Organization
- Module Summary

Systems Overview

- The laboratory is a system
- The laboratory is also an important part of the entire patient care system
- The outputs of one system are often the inputs of another system

Patient Care System



What is a Quality System?

- Organizational structures, resources, processes, and procedures needed to implement a quality product or service
- Systems approach ensures the quality of the entire laboratory system of processes
- Doing the right thing right, the first time and every time

Quality Systems Approaches

- Purpose is to provide quality system models for healthcare and laboratories
- ISO 15189 – International Organization for Standardization
  - Provides guidance for quality in laboratories; can be used for laboratory accreditation
- CLSI GP26-A3– Clinical Laboratory Standards Institute
  - Provides guidance on quality systems for laboratory services

What questions do you have so far?

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Total Quality Management (TQM)

ISO 9001 Definition:

- "Coordinated activities to direct and control an organization with regard to quality"

NCCLS (CLSI) Definition:

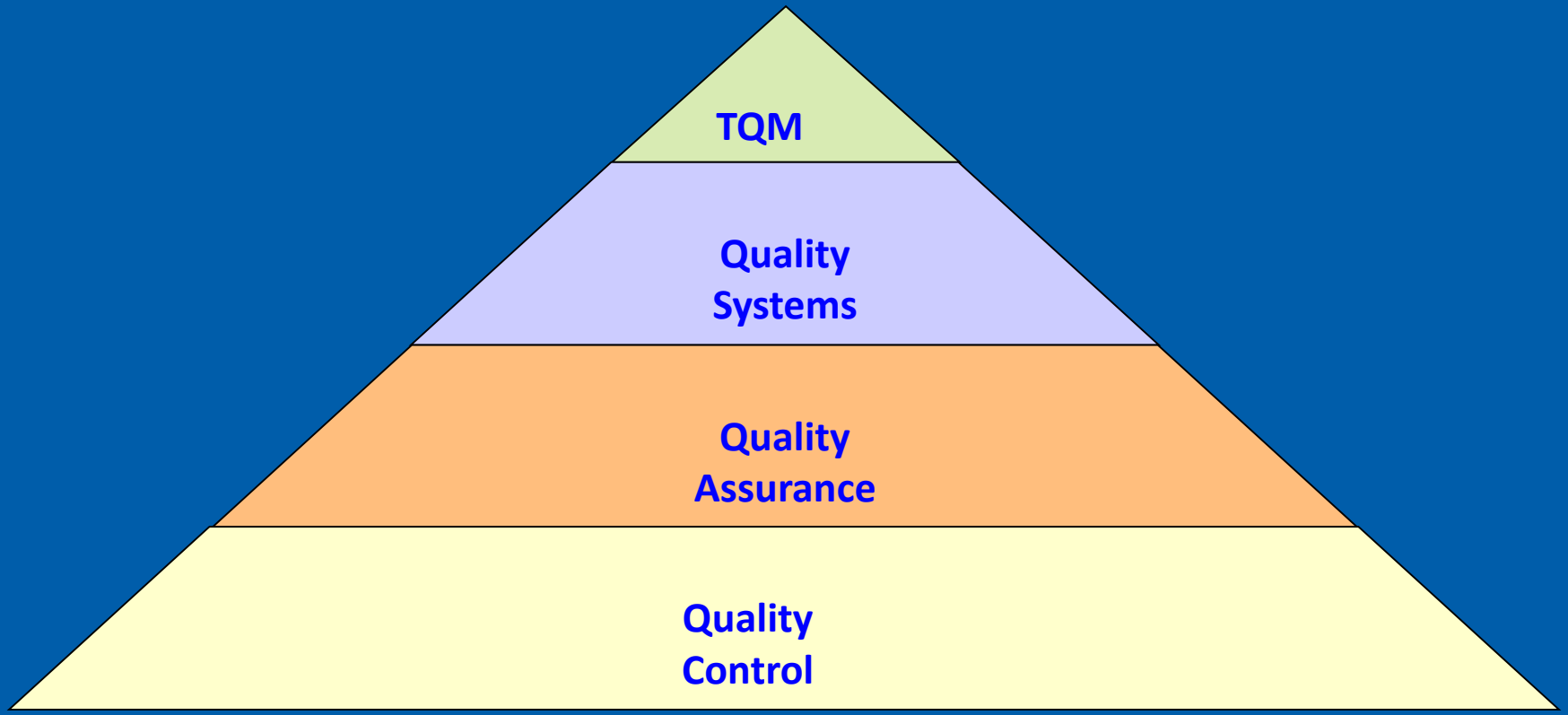
- "A management approach centered on sustained high quality by focusing on long-term success through customer satisfaction"

ISO 15189 contains many of the requirements of ISO 9001:2000 with sector-specific guidance for laboratories

What is the Purpose of TQM?

- It builds quality into every work process and procedure
- It prevents medical errors that can harm patients
- It saves money by preventing failures

TQM Quality Hierarchy



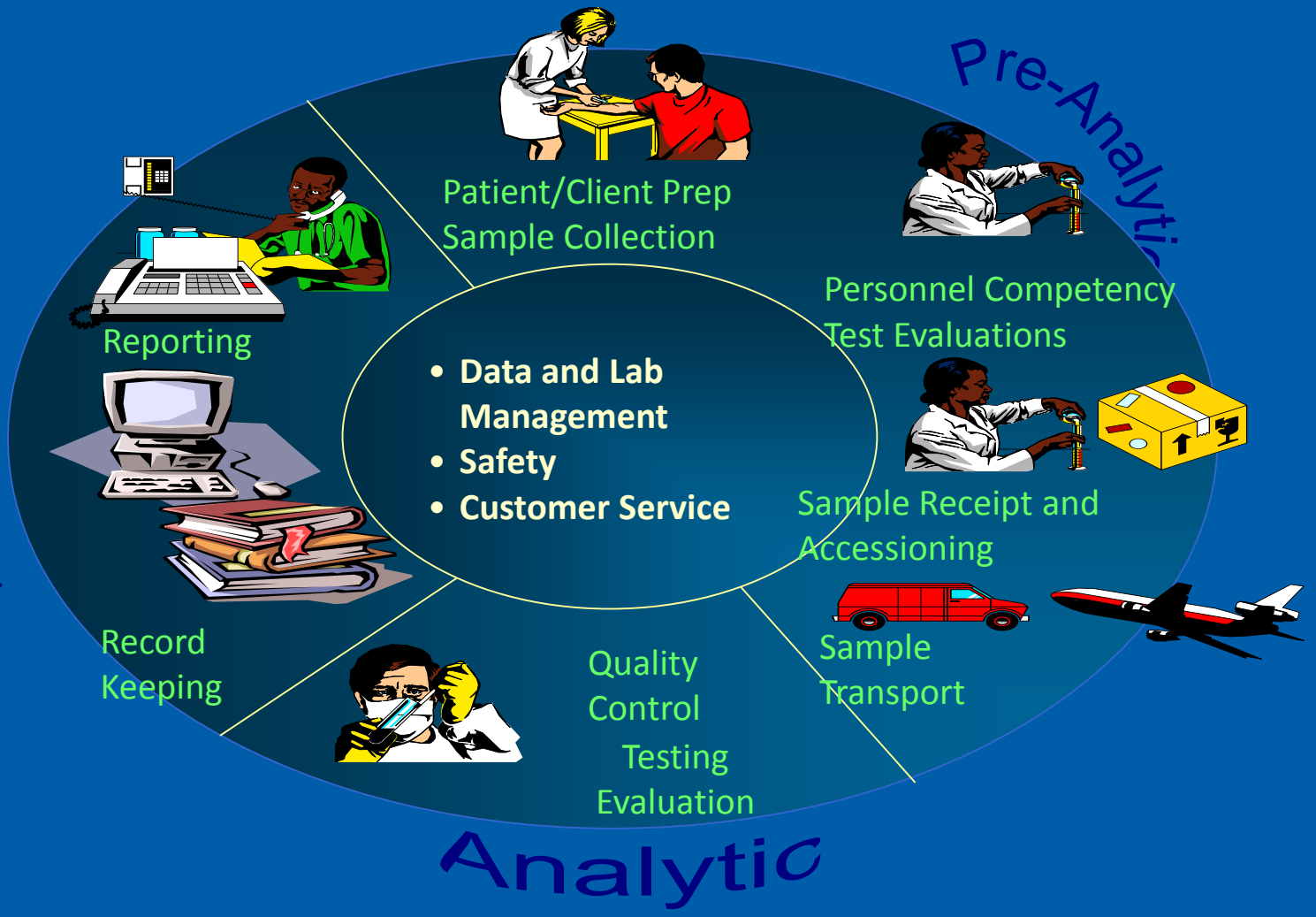
Quality Control

- Main focus is on analytical process control
- Set of procedures for continuously assessing the quality of laboratory results using internal quality control samples
- Operational techniques

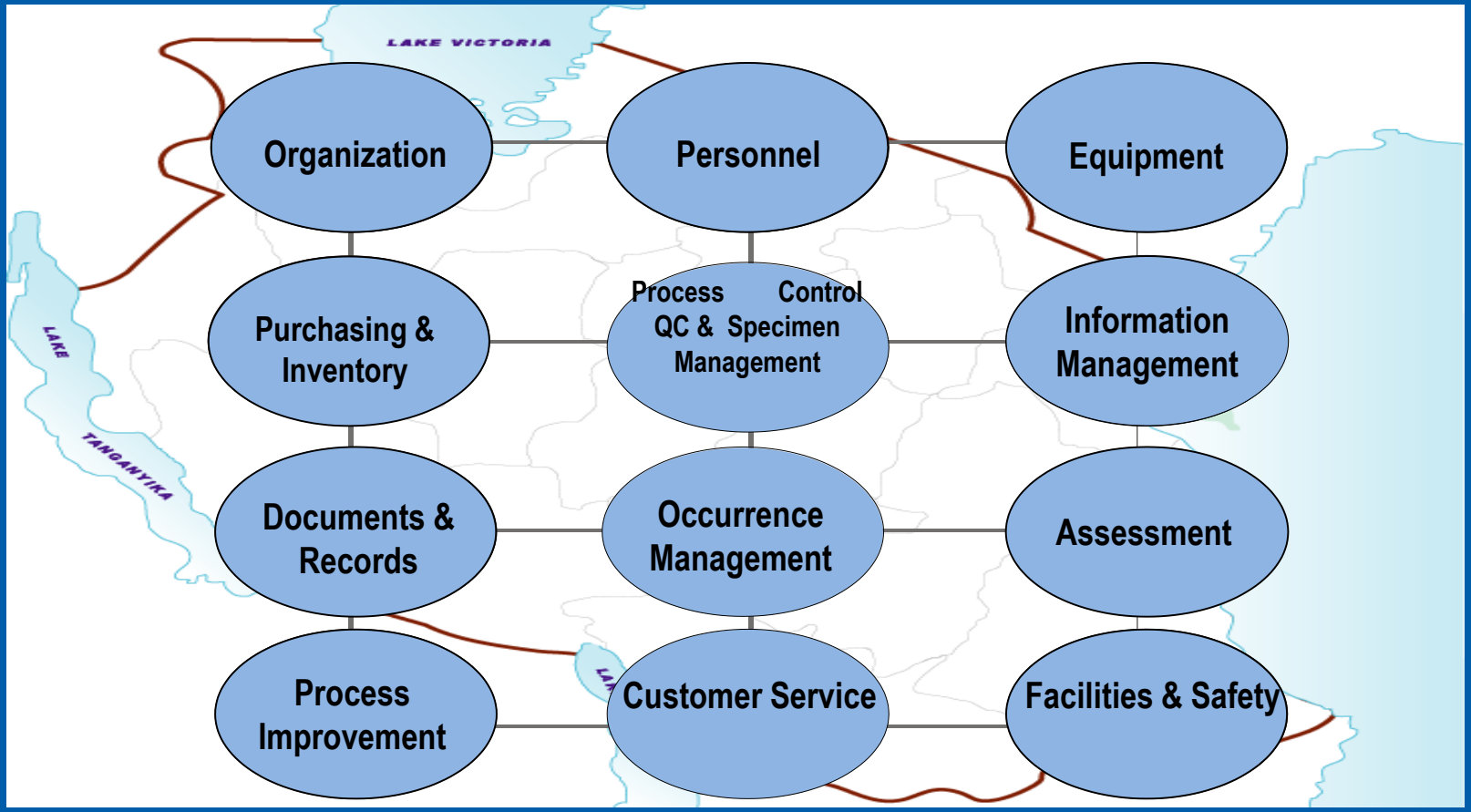
Quality Assurance

- Planned and systematic activities to assure quality and reliability of the entire testing process from test order to test interpretation
- Includes pre-analytical, analytical, and post-analytical quality assurance monitors

The Quality Assurance Cycle

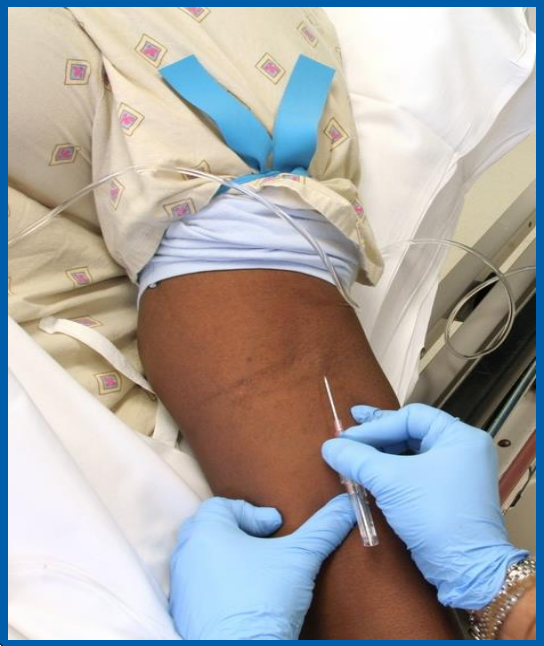


Laboratory Quality Systems



Total Quality Management

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



What questions do you have on total quality management?

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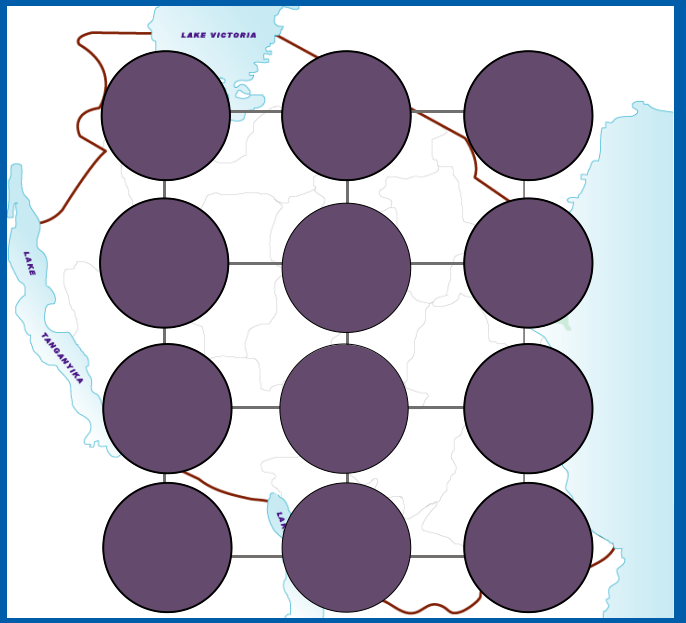
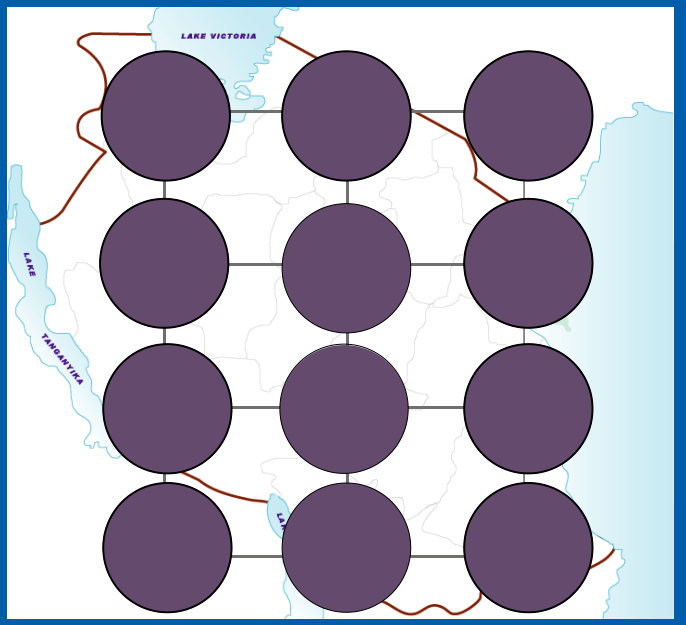
Quality System Essentials (QSE)

- Organization
- Personnel
- Equipment
- Purchasing and Inventory
- Process Control
- Information Management
- Document and Record Control



Quality System Essentials (Continued)

- Occurrence Management
- Assessment
- Process Improvement
- Customer Service
- Facilities and Safety



Quality Systems Essentials

- Apply to all processes in the laboratory workflow
- Provide the building blocks of quality
- Constitute the manager's "procedure manual"

What questions do you have on quality systems essentials so far?

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QSE - Specimen Management Process

- Organization
- Personnel
- Equipment
- Process Control
- Purchasing and Inventory
- Information Management
- Document and Record Control
- Occurrence Management
- Internal Assessment
- Process Improvement
- Service and Satisfaction
- Facilities and Safety

QSE Example: Specimen Management Workflow

- Organization – Define the organizational structure within the specimen procurement department. Define qualifications, roles and job descriptions for the phlebotomist and supervisor.
- Personnel – Create orientation and training programs that focus on the core competencies for phlebotomy.

QSE Example: (Continued) Specimen Management Workflow

- Equipment – Provide specimen collection equipment that meets the quality standards of the organization such as blood draw tubes/needles, and sharps disposal containers.
- Purchasing/Inventory – Develop a system to track and store supplies.

QSE Example: (Continued) Specimen Management Workflow

- Process Control – Use standardized patient identification and labeling SOPs; define collection tube handling procedures; measure phlebotomy performance against standards and procedures through observation of the process; define reasons for specimen rejection and redraw.
- Occurrence Management – Document and investigate all specimen errors and phlebotomy incidents with corrective actions taken.

QSE Example: (Continued) Specimen Management Workflow

- Information Management – Develop policies that address patient confidentiality and privacy issues. Develop a system that tracks the specimen from order entry to result reporting.
- Document and Record Control – Develop a procedure that outlines the storage, retrieval and destruction of specimen collection forms.

QSE Example: (Continued) Specimen Management Workflow

- Internal Assessment – Define criteria that are used periodically to assess the quality of the specimen collection process. Collect the data and report the results to management.
- Process Improvement – Evaluate the data from occurrence reports and modify identified procedures that will result in an improvement in specimen collection processes.

QSE Example: (Continued) Specimen Management Workflow

- Customer Service – Develop a customer survey that measures the patient's satisfaction with the phlebotomy procedure.
- Facilities and Safety – Establish a procedure to assure that the phlebotomy section meets safety and regulatory standards.

Activity: QSE Based Process

- Work in groups of four
- How do we apply QSE principles to the hematology analyzer process?

QSE for the Hematology Analyzer

- Organization
- Personnel
- Equipment
- Process Control
- Purchasing and Inventory
- Information Management
- Document and Record Control
- Occurrence Management
- Internal Assessment
- Process Improvement
- Service and Satisfaction
- Facilities and Safety

QSE Example: Automated CBC Process

- Organization – Define the roles in Hematology – particularly the quality assurance tech role and supervisor role
- Personnel – Define the instrument orientation training checklist, core competencies, and competency assessment (for example: interpreting data, and calibrating instrument)
- Equipment – Define a decision matrix for instrument selection; define SOPs for calibration and maintenance

QSE Example: Automated CBC Process

(Continued)

- Process Control – Define instrument validation procedures; write quality control policy and procedures; enroll in PT or other EQA; write and enforce criteria for specimen rejection
- Supplies – Define a good vendor relationship and inventory management process. Monitor critical supply levels.

QSE Example: Automated CBC Process

(Continued)

- Information Management – Develop policies that address patient confidentiality and privacy issues to ensure results are reported to authorized individuals only. Develop a system for reporting lab results including critical hematology results.
- Document and Record Control – Develop a procedure that outlines the storage, retrieval, and destruction of hematology reports. Maintain instrument maintenance and function check logs.

QSE Example: Automated CBC Process

(Continued)

- Occurrence Management – Document all instrument malfunctions/failures, complaints, and quality assurance problems in an occurrence log and have quality assurance tech and management investigate. Take corrective action.
- Internal Assessment – Define quality control criteria used to regularly assess analyzer operations. Collect and review data. Report the results to management.

QSE Example: Automated CBC Process

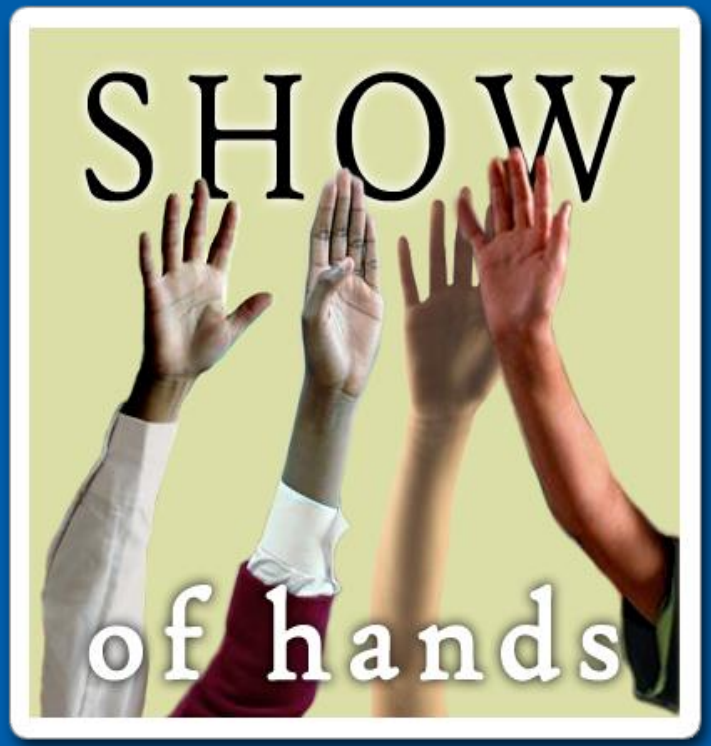
(Continued)

- Process Improvement – Evaluate the data from occurrence reports. Modify procedures to decrease the number of erroneous hematology report results.

QSE Example: Automated CBC Process
(Continued)

- Customer Service – Develop a customer survey to measure the physician satisfaction with the turnaround time for receiving hematology results.
- Facilities and Safety – Develop a procedure to properly dispose of analyzer biohazard waste.

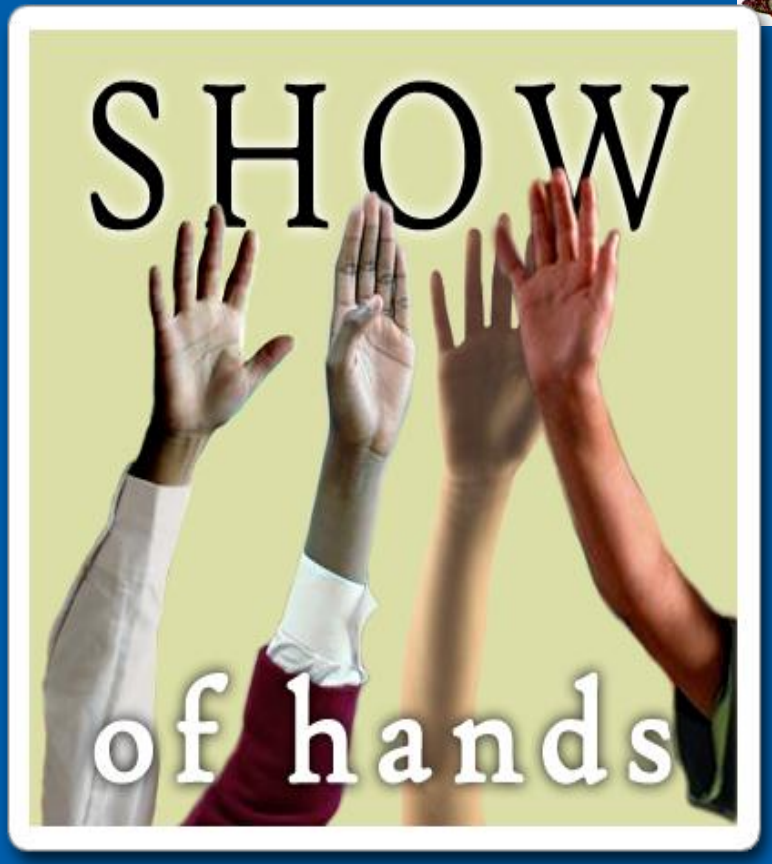
What questions do you have on applying quality systems essentials to common lab processes?



Quality Organization

- A written plan for quality defined
- Leadership commitment – management commits to this approach and commits sufficient resources
- Roles in quality are defined from quality coordinator to bench staff – all staff must commit to follow quality assurance/control procedures
- All staff are trained on the quality plan

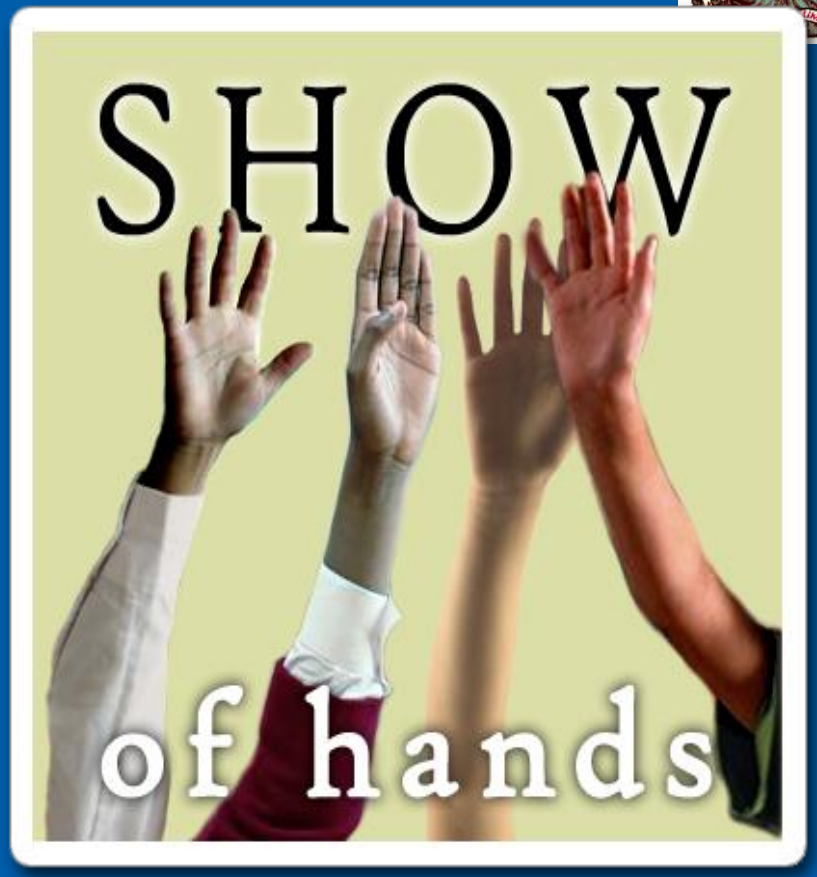
What questions do you have on developing a quality organization?



Module Summary

- Described the importance of quality systems
- Listed the components of a total quality management system
- Identified the quality system essentials
- Described the laboratory's path of workflow

What questions or suggestions do you have on the Overview of Quality Systems?



Thank you