THE REPUBLIC OF UGANDA
MINISTRY OF HEALTH

UGANDA Supranational® Reference Laboratory

Timely Accurate Diagonostics for a TB-Free Africa

Laboratory Quality Management System

Module 10: Process Control: Introduction

Venue:

Presenter:

Date:

Introduction

Quality control (QC) monitors activities related to the examination (analytic) phase of testing.

Learning Objectives

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

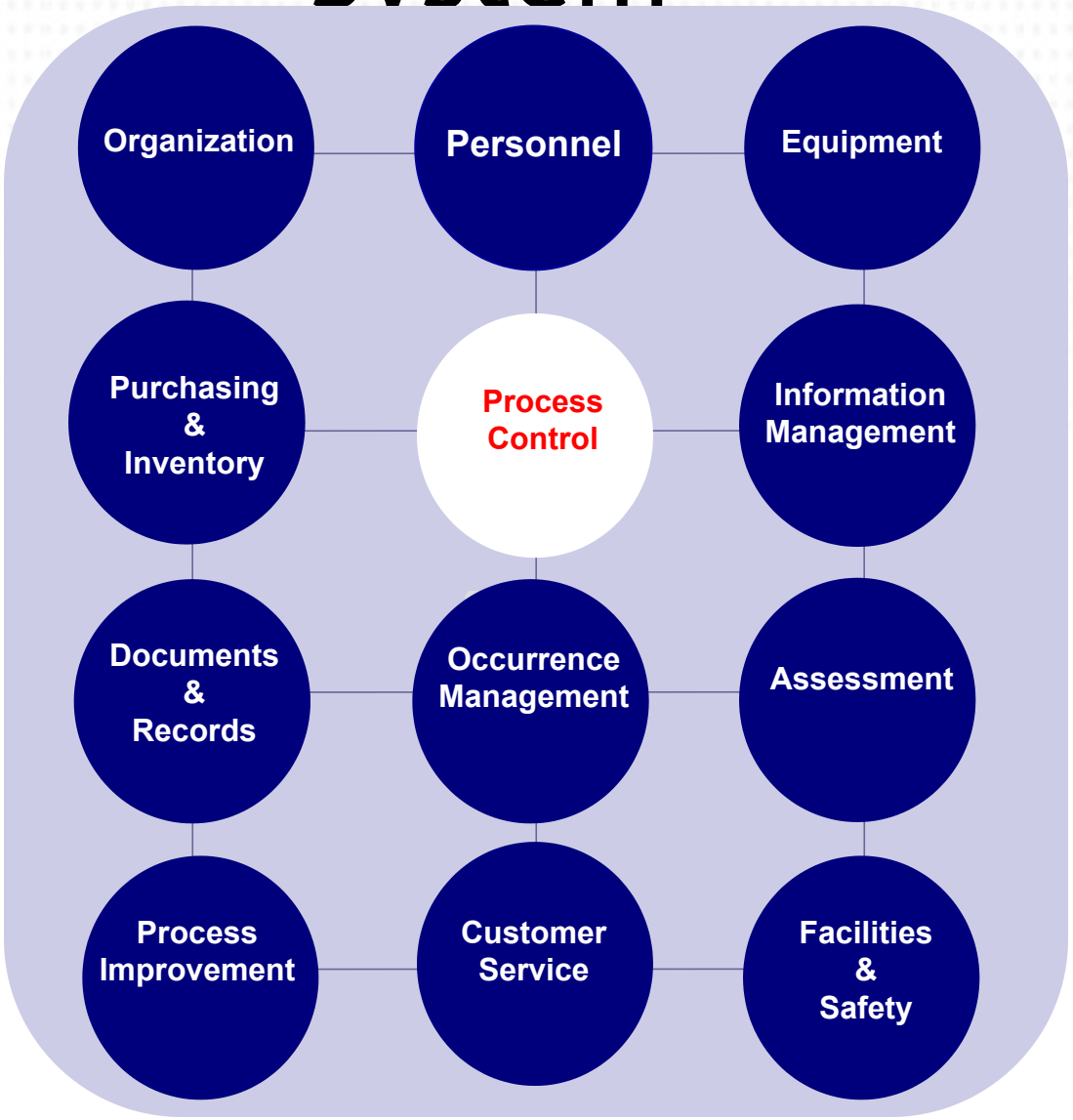
define quality control and describe its relationship to the overall quality management system;

Describe differences in quantitative, semi-quantitative, and qualitative examinations.

Module Outline

- Introduction to Quality Control
- Assessment
- Summary
- References
- Acknowledgements

The Quality Management System



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Definition

Quality Control (QC) is part of quality management focused on fulfilling quality requirements ISO 9000:2000 (3.4.10)

QC is examining "control" materials of known substances along with patient samples to monitor the accuracy and precision of the complete examination (analytic) process.

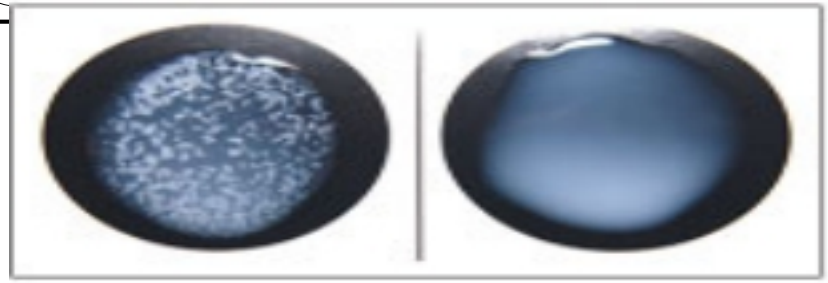
Purpose

The **goal** of QC is to detect errors and correct them before patients' results are reported

Qualitative Examination Methods

Examinations that do not have numerical results:

- growth or no growth
- positive or negative
- reactive or non-reactive
- color change



Semi-quantitative Examination Methods

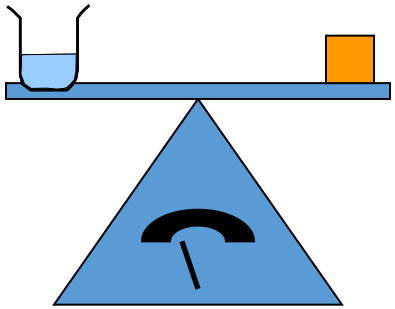
Results are expressed as an estimate of the measured substance:

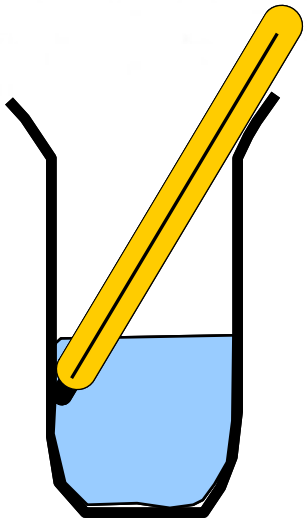
- "trace amount", "moderate amount," or "1+, 2+, or 3+"
- number of cells per microscopic field
- titters and dilutions in serologic tests

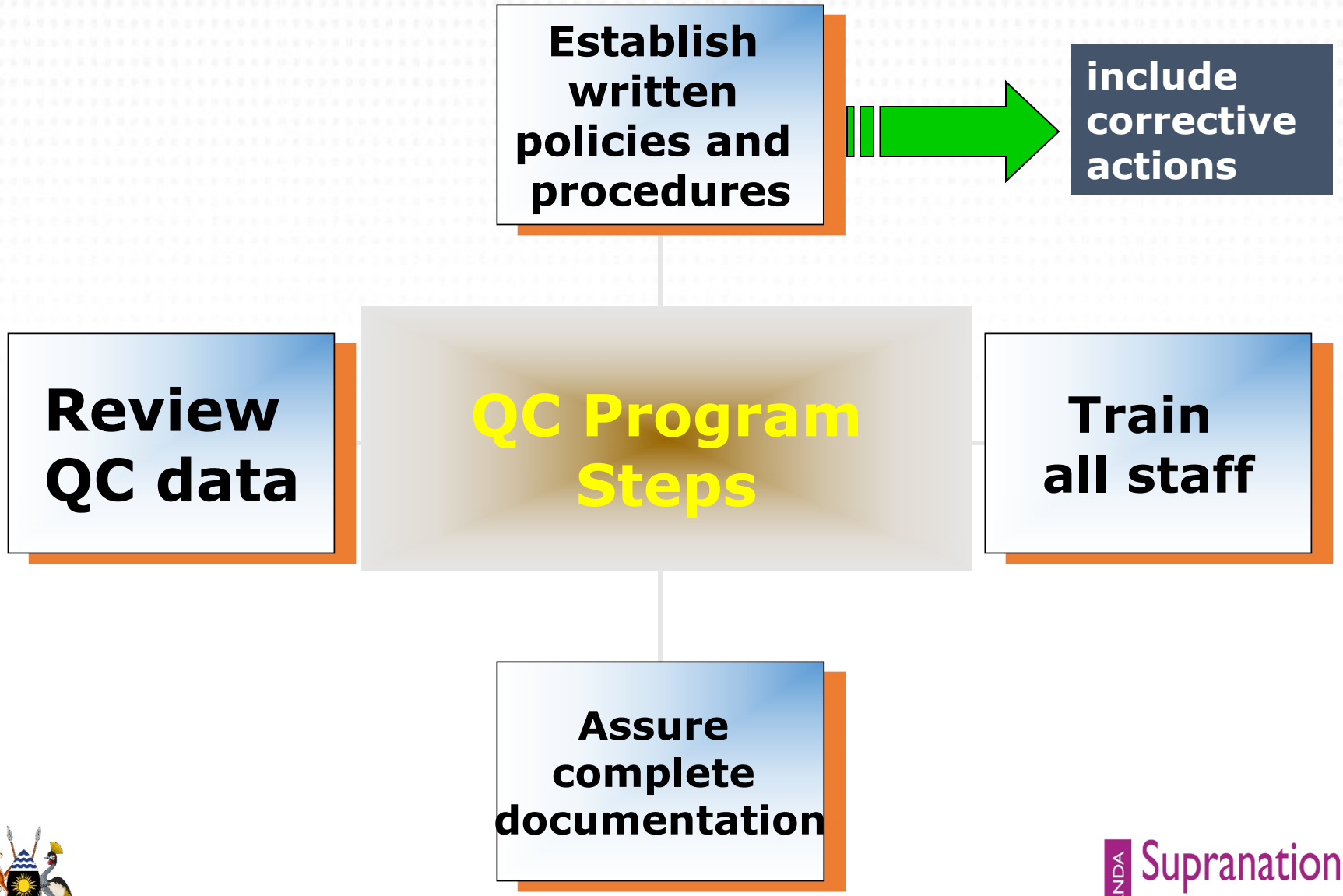
Quantitative Examinations

Measure the quantity of a particular substance in a sample

Measurements should be both accurate and precise






Establish written policies and procedures
include corrective actions
Review QC data
QC Program Steps
Train all staff
Assure complete documentation

Assessment

1. Define Quality Control
2. Why is Quality Control Important in the Laboratory?
3. Differentiate between Qualitative, Quantitative and Semi-Quantitative Examinations
4. Mention 4 steps in Establishing a QC program

Summary

- Important part of quality management system
- Goal is to identify errors and eliminate them before reporting patient results
- Different methods applied for quantitative, qualitative, and semi-quantitative results

References

- ISO 15189:2012 Medical Laboratories – Requirements for Quality and Competence

  « Clause 5.6.2, 5.6.3 & 5.6.4»

- CLSI

- ASLM

Acknowledgement