INTERNATIONAL INSTITUTE FOR PATHOLOGY AND FORENSIC SCIENCE RESEARCH

COLLEGE of AMERICAN PATHOLOGISTS FOUNDATION

DAVID UMAHI FEDERAL UNIVERSITY OF HEALTH SCIENCES UBURU, EBONYI STATE.

Foundations of Laboratory Quality Management Systems (LQMS) & ISO 15189: 2022 Updates

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Week 1

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Advancing Laboratory Quality Management Systems for Better Patient Outcomes

Learning Objectives

- This session aims to:
  - Explain the fundamental principles of an LQMS and its role in laboratory operations.
  - Highlight key components of an effective quality management system.
  - Discuss the latest updates in ISO 15189:2022 and their impact on laboratory accreditation.
  - Provide strategies for implementing and maintaining ISO 15189:2022 compliance.

Question 1

Which of the following is a core principle of Laboratory Quality Management Systems (LQMS)?

a) Emphasis on cost reduction over quality

b) Standardization of procedures to ensure consistency

c) Reliance solely on external quality assessment (EQA)

d) Elimination of all documentation requirements

Question 2

A significant update introduced in ISO 15189:2022 is…

a) Prioritization of customer's opinions and requests

b) Separation of ISO 15189 from the regulatory standards like CLSI

c) Exclusion of POCT from laboratory quality management

d) Stronger emphasis on risk-based thinking.

Question 3

Effective leadership in laboratory quality management involves:

a) Delegating all quality responsibilities to a single quality officer to prevent confusion

b) Prioritizing regulatory compliance over staff engagement

c) Actively promoting a culture of quality and continuous improvement

d) Relying on periodic external audits as the main basis for quality assessment

Introduction

- LQMS – a coordinated set of **policies**, **procedures**, and **practices** implemented in a laboratory to ensure consistent quality and accuracy in its operations.
- It is essential for ensuring **accurate**, **reliable**, and **timely** test results.
- A well-structured LQMS **minimizes errors**, enhances efficiency, and promotes compliance with standards.
- Poor laboratory quality can lead to misdiagnoses, inappropriate treatments, increased healthcare costs, and loss of patient trust.
- Various standards and regulations outline specific requirements for implementing LQMS, such as **ISO 15189:2022**, ISO 17025:2017, and FDA 42 CFR Part 493.

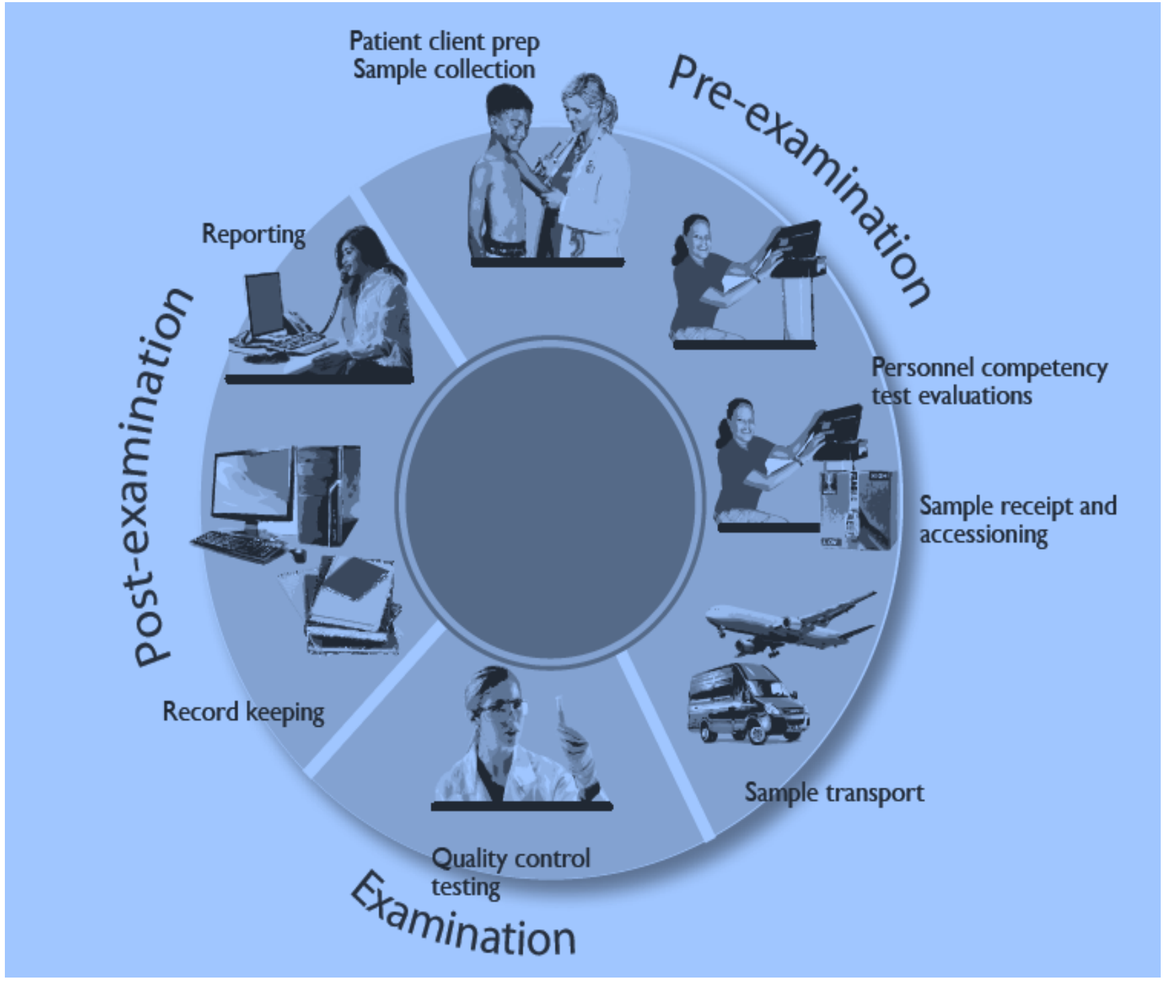
Minimize Errors

Fundamentals of LQMS

- DEFINITION: ***Coordinated activities to direct and control an organization with regards to quality (ISO, CLSI)***.
- The primary purpose of an LQMS is to:
  - Ensure Reliable Test Results
  - Enhance Patient Safety
  - Achieve Regulatory Compliance
  - Improve Operational Efficiency
  - Promote Continuous Improvement
- LQMS is applicable to **all types of medical laboratories**, including *clinical*, *research*, and *public health laboratories*, ensuring that laboratory services consistently meet quality and competency standards.

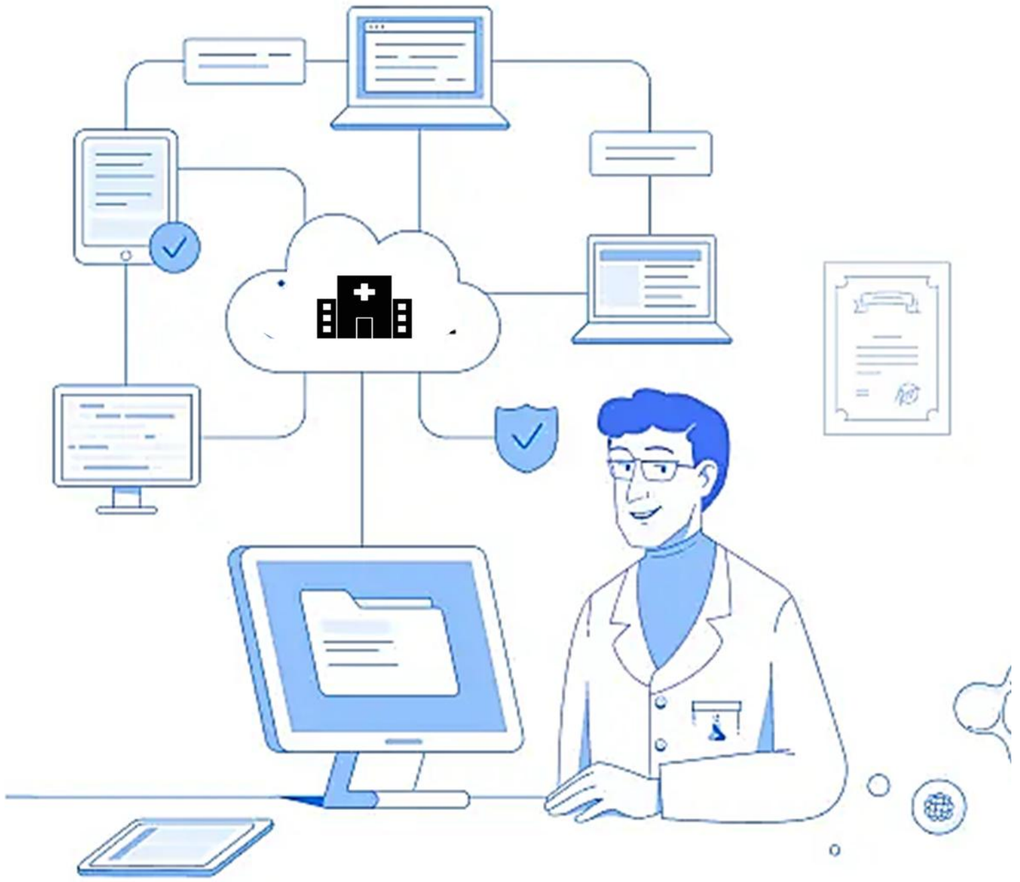
Quality in ALL operations of the Laboratory!!!

- The complete sequence of operations in lab testing is known as the **path of workflow**.
- It starts with the patient and ends with reporting and interpreting results.
- The path of workflow is key to the quality management system, and **must be considered when developing quality practices**.
- Errors:
  - Preanalytical = 53 – 77%
  - Analytical = 3 – 23%
  - Post-analytical = 12 – 23%



The Laboratory and the Healthcare System…

- The labs are the hidden treasure of the healthcare system accounting for:
  - **94%** of objective data in medical records.
  - **60 – 70%** of lab results have significant influence on clinical decisions, and have frequently directed the course of patient management.
  - **37%** are part of practice guidelines.
  - **23%** define different diseases and… growing number of companion diagnostics.

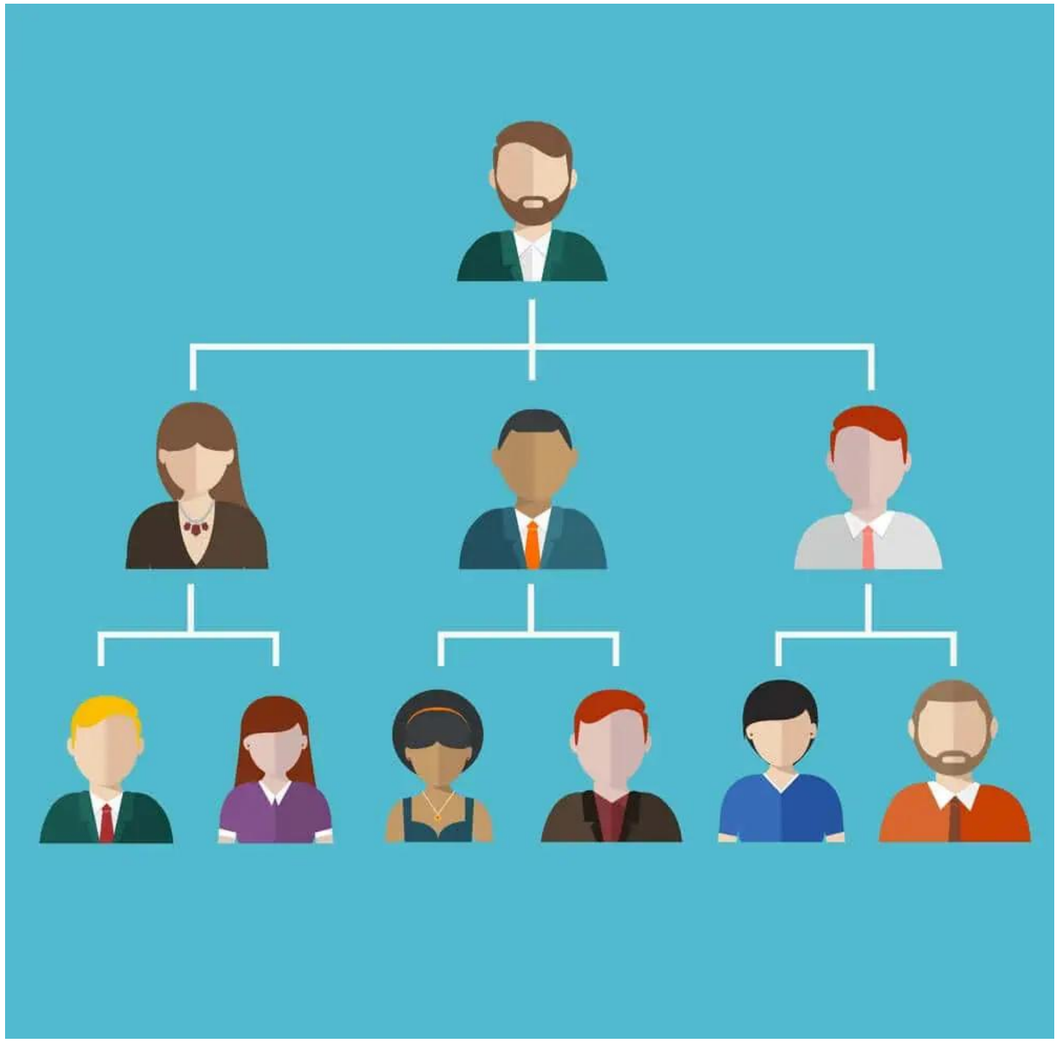


The Quality Management System Model

- Organizing laboratory procedures into a structured system improves management and ensures proper oversight.
- The quality model consists of **12 quality system essentials**, which are coordinated activities forming the foundation of quality management.
- This system, developed by CLSI, aligns fully with ISO standards for laboratory quality improvement.

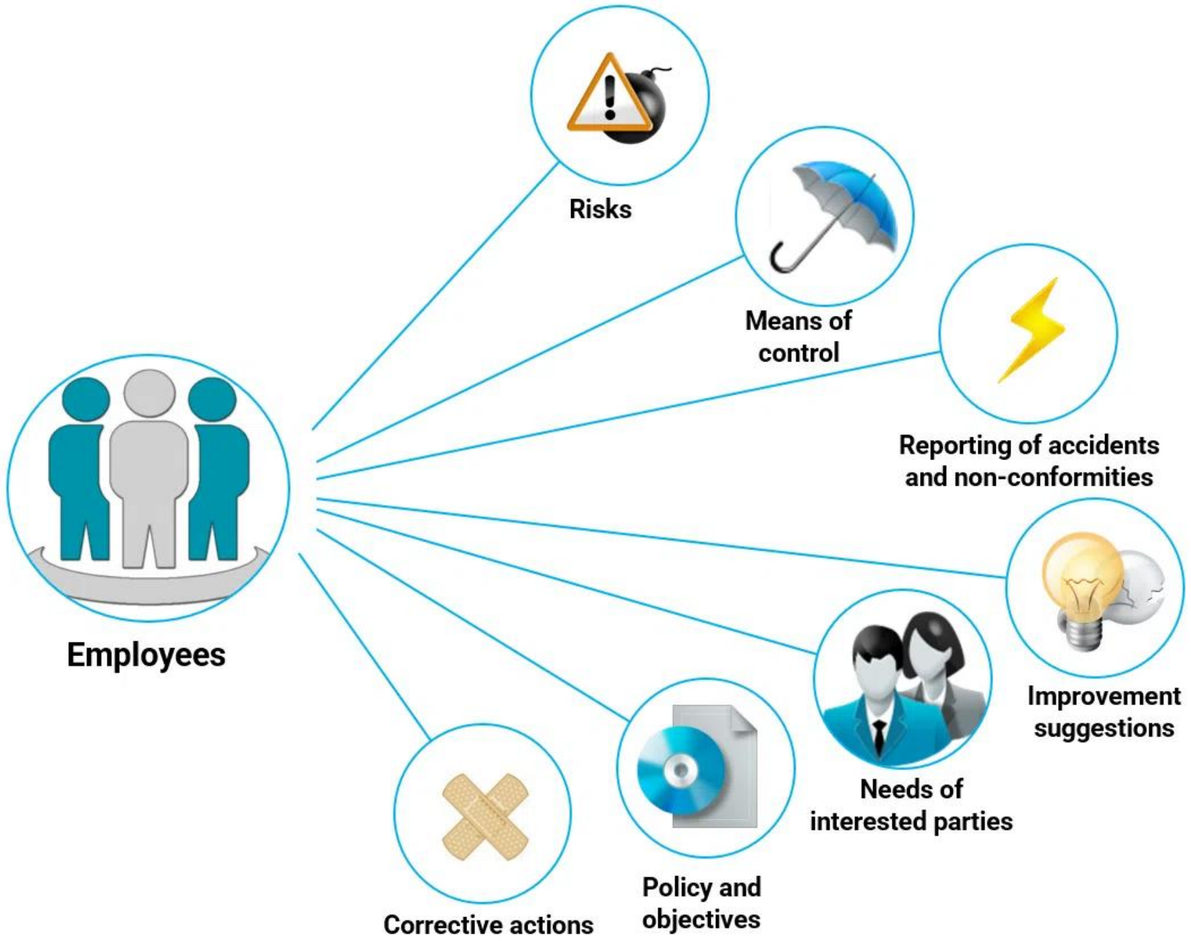
QSE: Organization

- A strong organizational structure supports quality policy implementation.
- Management commitment is crucial for success.
- Continuous monitoring ensures effective implementation.



QSE: Personnel

- Skilled and motivated staff are the most valuable resource.
- Involves:
  - Human resources and requirements
  - Job qualifications and Job descriptions
  - Orientation and training
  - Competency assessment
  - Professional development
  - Continuing education



QSE: Equipment

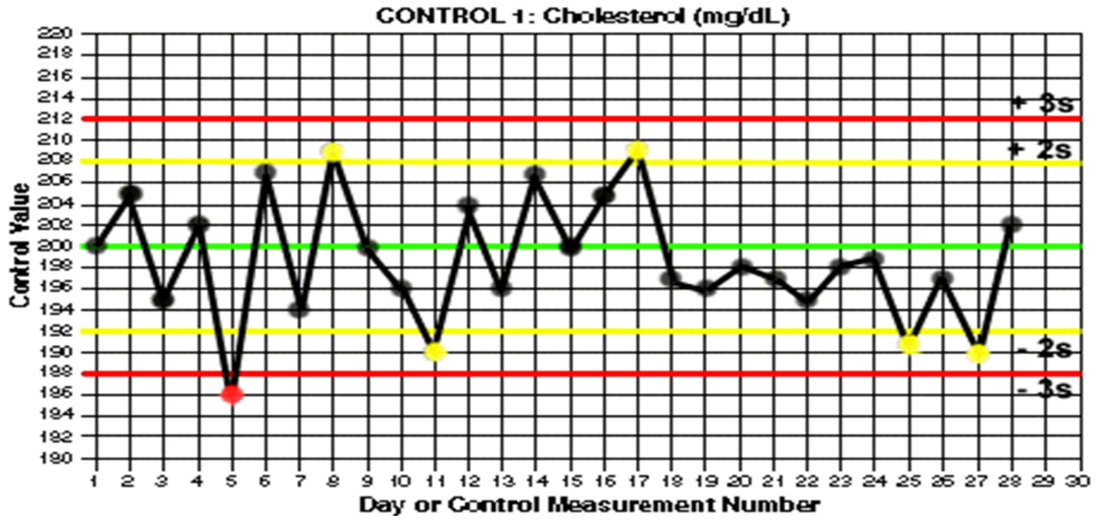
- Proper selection, installation
- Maintenance (servicing and repairs) ensure functionality
- Equipment validation and calibration prevent errors.
- A structured maintenance program enhances reliability.
- Equipment records and life history

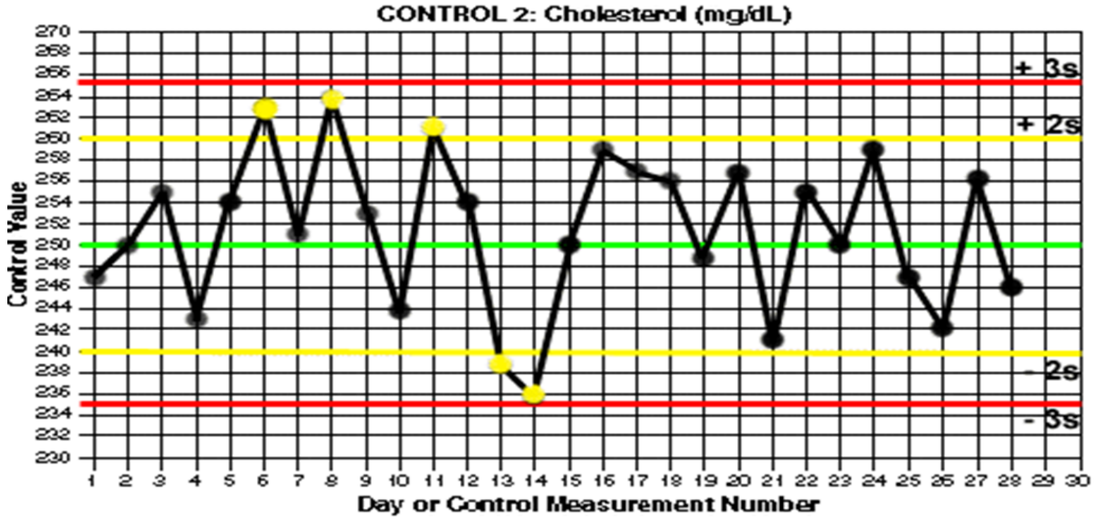
QSE: Purchasing & Inventory

- Ensures availability of high-quality reagents and supplies.
- Specify vendor qualification criteria
- Identify critical services
- Proper storage maintains integrity and reliability.
- Inventory management – very important
- Cost-effective management prevents wastage and shortages.

QSE: Process Control

- Ensures accuracy and reliability of test results.
- Prevents errors through structured quality practices.
- Involves:
  - Quality control,
  - Sample management, and
  - Method validation and verification.



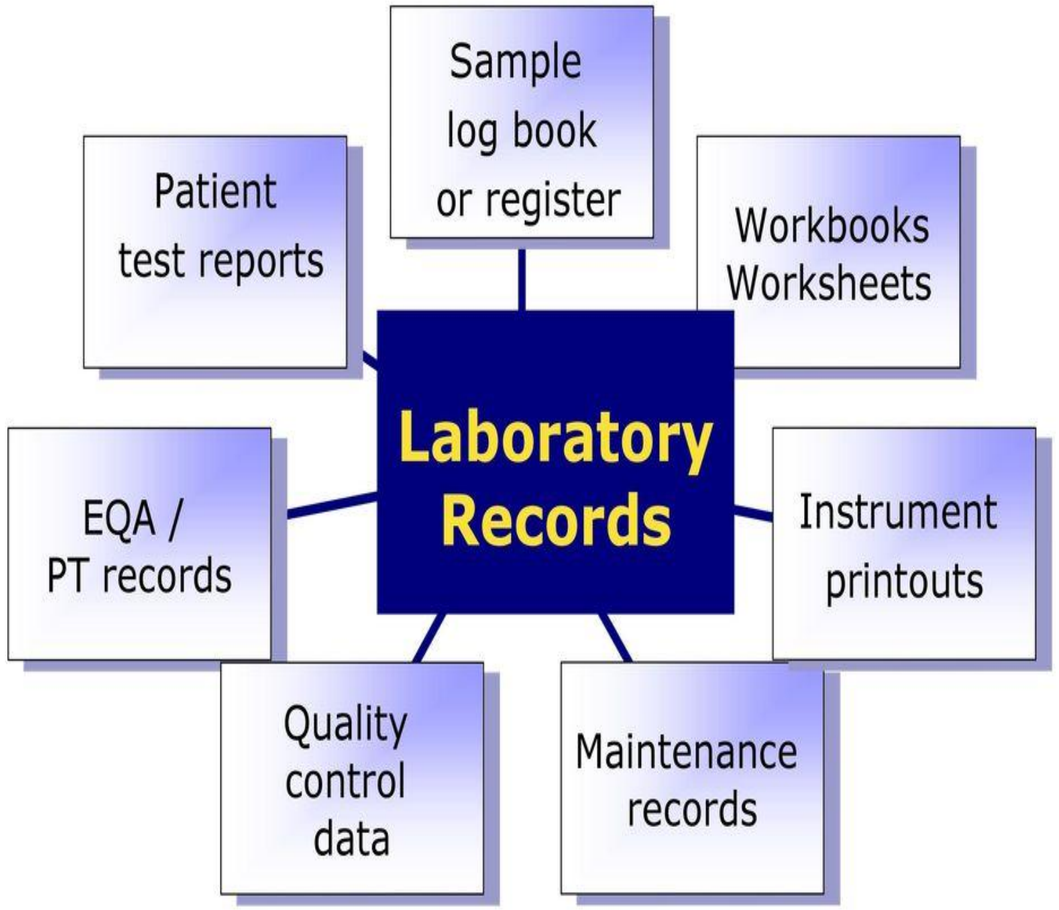


QSE: Information Management

- Involves proper handling of requisitions, reports, logs and records, complaints etc.
- Laboratory data must be accurate, confidential, and accessible.
- Managed via paper-based or computerized systems.
- Supports decision-making and patient care.

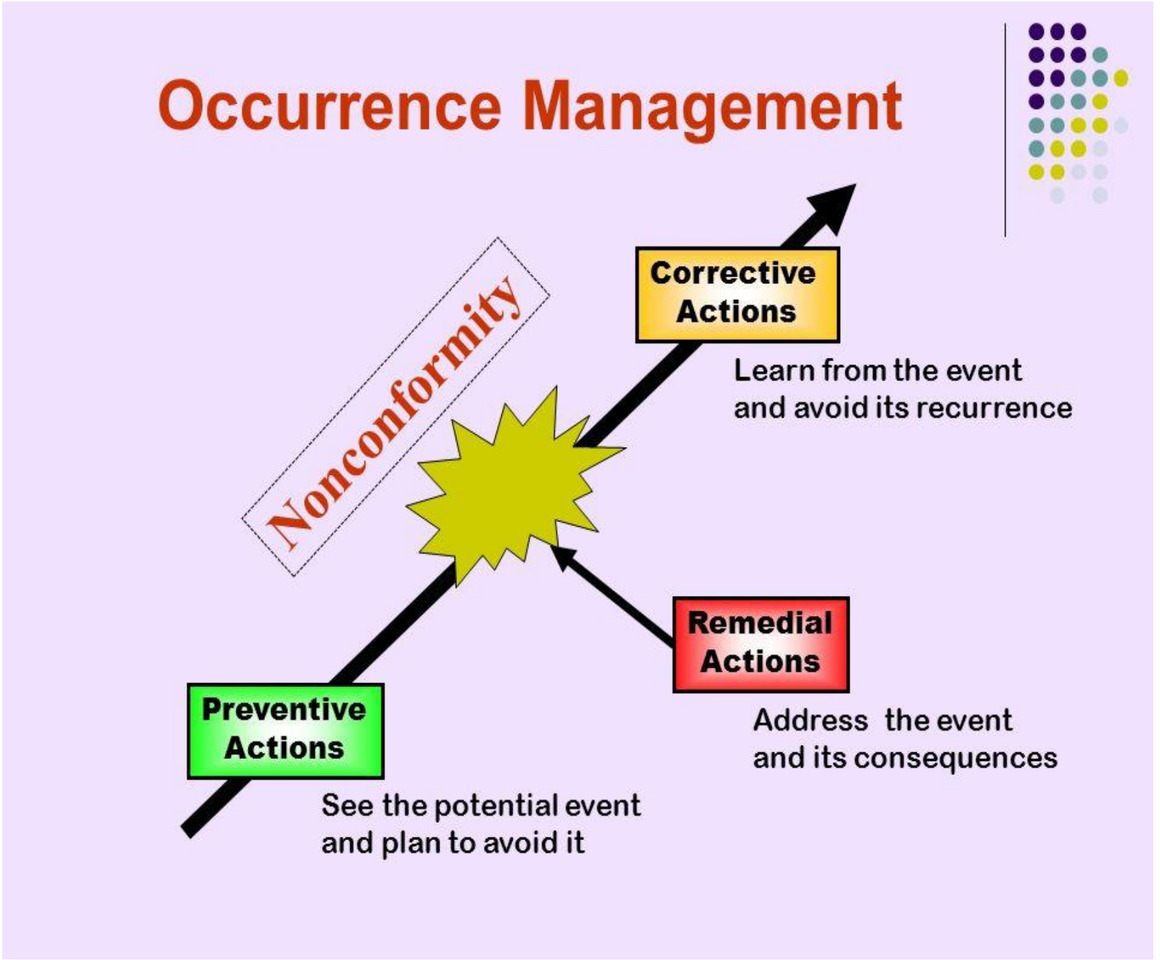
QSE: Documents & Records

- Provide guidelines on laboratory procedures.
- Involves:
  - Collection
  - Revisions and reviews (updated for relevance)
  - Control and distribution
  - Storage and retention
- Essential for regulatory compliance and quality assurance.
- Ensure accessibility and accuracy of information.



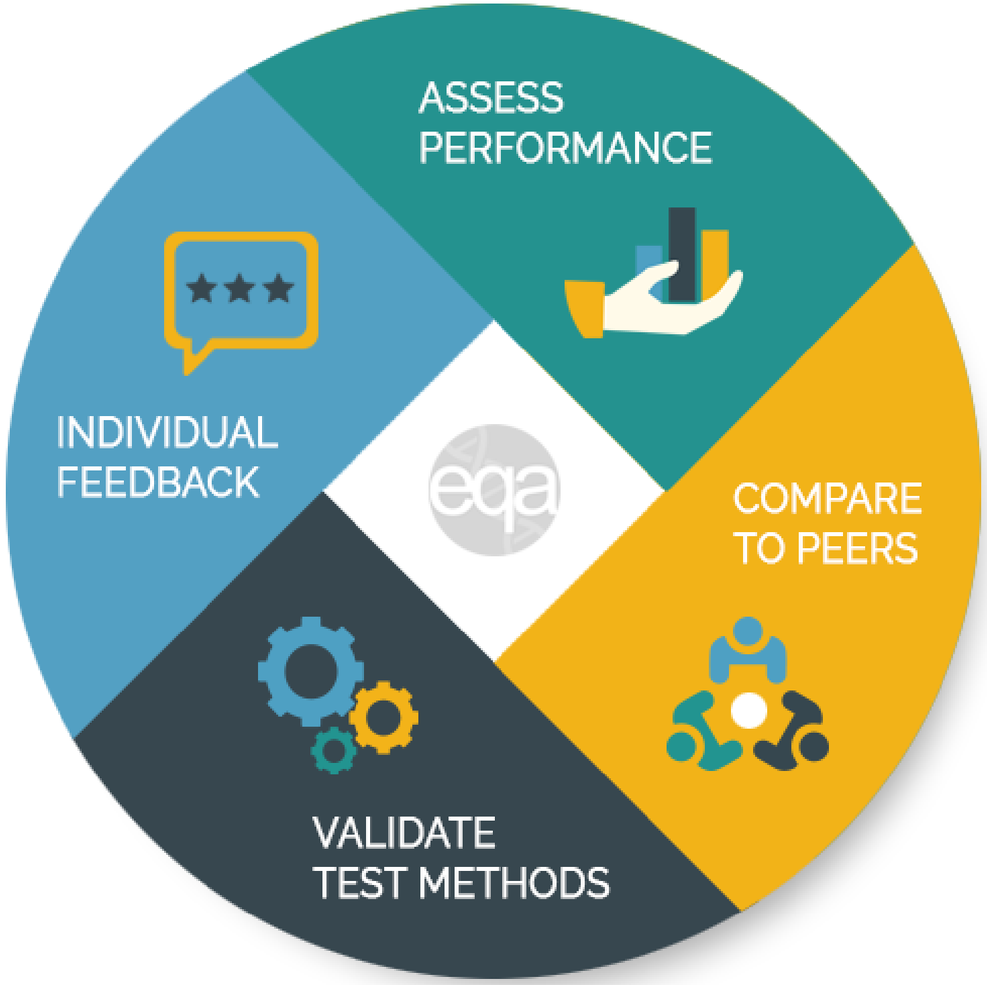
QSE: Occurrence Management

- Identifies and corrects laboratory errors and unexpected events.
- Aims to prevent recurrence.
- Involves:
  - Complaints
  - Mistakes and problems
  - Proper documentation of occurrences
  - Root cause analysis
  - Actions – immediate, corrective and preventive
- Promotes continuous learning and improvement.



QSE: Assessment

- Evaluates laboratory performance against benchmarks.
- Identifies areas for improvement and compliance gaps.
- Internal:
  - Quality indicators
  - Audit program
  - Audit review
- External:
  - Proficiency testing (EQA)
  - Inspections
  - Accreditations



QSE: Process Improvement

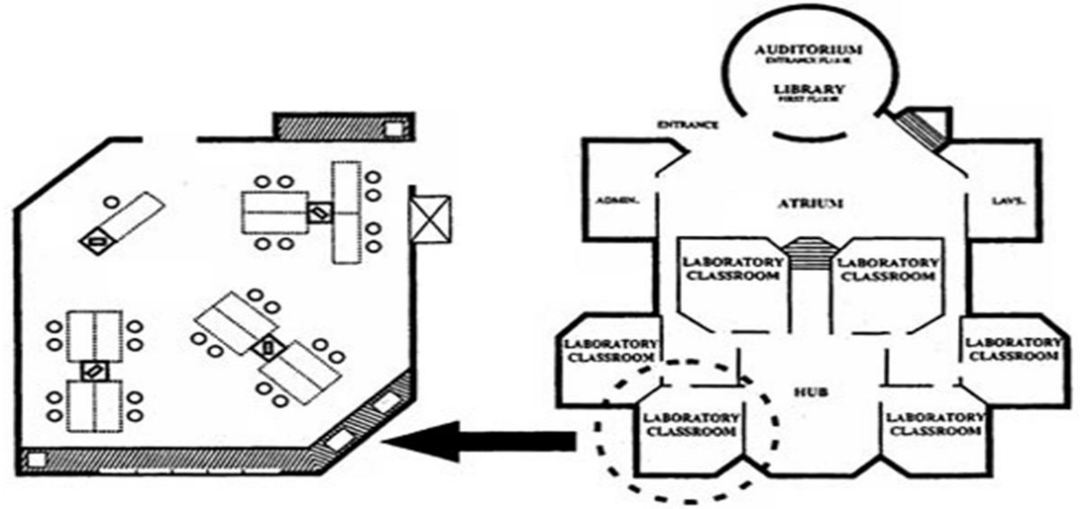
- Focuses on continuous enhancement of laboratory operations – consciously seeking out opportunities for improvement
- May include:
  - Stakeholder feedbacks
  - Problem resolutions
  - Risk assessment
  - Corrective and preventive actions
- Uses structured tools for identifying and fixing inefficiencies.
- Aims for higher accuracy and efficiency.

QSE: Customer Service

- Recognizes laboratories as service providers.
- Addresses client needs through feedback and quality assurance.
- Enhances patient and clinician satisfaction.
- Relies largely on Customer feedback
- Customer group identification:
  - **Physicians** vs **Patients**

QSE: Facilities & Safety

- Ensures security, containment, and worker safety.
- Prevents risks to staff, visitors, and the community.
- Also involve:
  - Transport management
  - Ergonomic concerns
  - Containment and restriction of high-risk areas
  - Waste management
  - Lab safety



The Quality Management System Model – contd:

- All 12 Quality System Essentials must be addressed for accurate, reliable, and timely laboratory results.
- Implementation order can vary based on local needs and resources.
- Without a quality management system, errors and problems will occur and may go undetected.
- A strong system does not eliminate errors but ensures early detection and prevention of recurrence.
- Continuous quality improvement leads to a high-performing, and trustworthy laboratory.

International Laboratory Standards

- Need for international laboratory standards:
  - A part of quality management is assessment, measuring performance against a standard or benchmark, a concept that was led by industries
- **ISO Standards for Laboratories**
  - ISO 9001:2000 – General QMS requirements for laboratories.
  - ISO/IEC 17025:2005 – Competence of testing & calibration labs.
  - ISO 15189:2007 – Quality & competence in medical labs.
- **Clinical and Laboratory Standards Institute (CLSI)**
  - Develops lab standards through a consensus process.
  - QMS Model – 12 quality system essentials.
  - Key documents:
    - **HS1-A2** (QMS model for healthcare, 2nd edition, 2004), and
    - **GP26-A3** (QMS model for lab services, 3rd edition, 2004)

International Laboratory Standards

ISO/IEC 17025	General requirements for the competence of testing and calibration laboratories
ISO 15189	Medical laboratories – particular requirements for quality and competence
ISO/IEC 17043	Conformity assessment – general requirements for proficiency testing
ISO 13528	Statistical methods for use in proficiency testing by inter laboratory comparison
OECD GLP	OECD principles on good laboratory practice
ISO Guide 34	General requirement for the competence of reference material producers
ISO 8402	Quality management and quality assurance – vocabulary
ISO 19011	Guidelines for quality and/or environmental management system auditing
ISO 9001	Quality management systems – requirements

Overview of ISO 15189

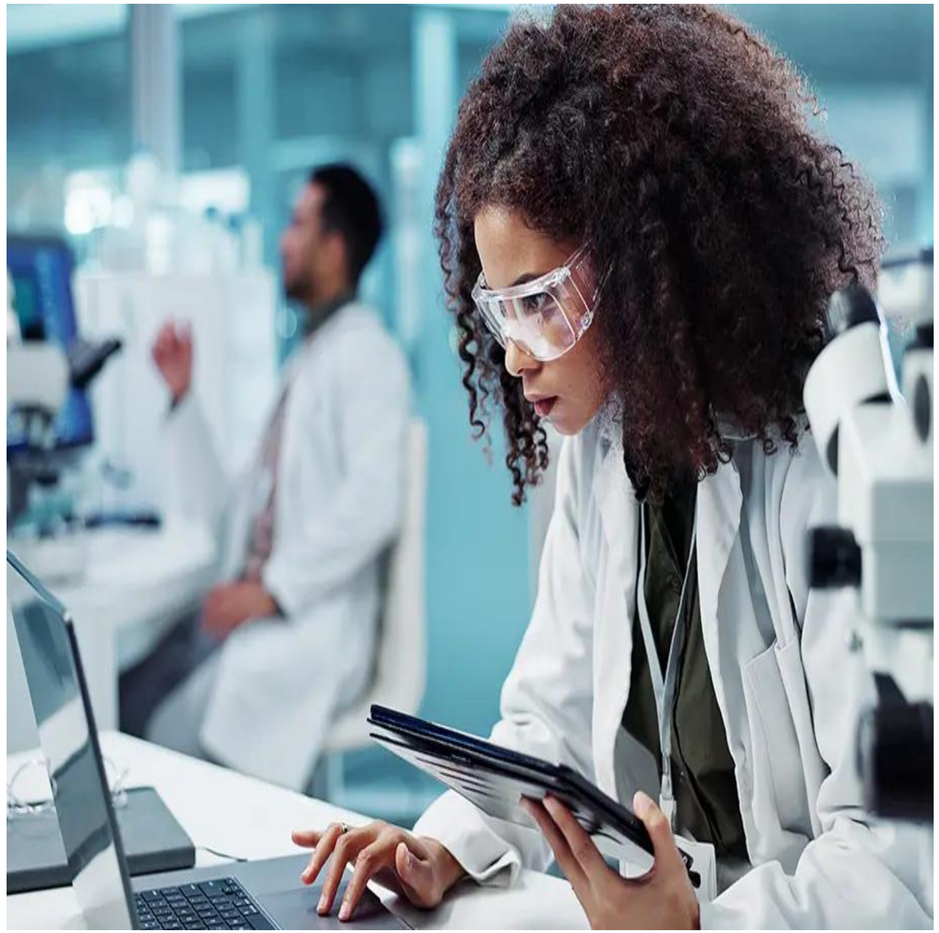
- ISO 15189 is the internationally recognized standard that specifies the **quality and competence requirements** for medical laboratories.
- Provides a **framework for establishing and maintaining QMS** that ensures accurate, reliable, and timely test results.
- Compliance with ISO 15189 is **critical for accreditation**, which enhances credibility, improves patient safety, and ensures compliance with national and international regulatory requirements.

Evolution of ISO 15189 Standards

ISO Version	Year	Key Features	Improvements over time
ISO 15189:2003	2003	First dedicated standard for medical laboratory quality and competence.	Established **quality & technical requirements** for laboratory accreditation.
ISO 15189:2007	2007	Strengthened focus on **competency assessment** and **customer service**.	Introduced structured **staff training** and **patient-centered approaches**.
ISO 15189:2012	2012	Revised structure; better alignment with **ISO/IEC 17025**.	Emphasized **risk management** and **quality improvement** strategies.
ISO 22870:2016	2016	Specific requirements for **Point-of-Care Testing (POCT)**.	Provided separate guidance for **POCT implementation & oversight**.
ISO 15189:2022	2022	Fully integrates **risk-based thinking, POCT, digital transformation & competency-based assessments**.	- **POCT integrated** into ISO 15189. - **Stronger risk management** and quality assurance. - **LIMS & cybersecurity** requirements updated. - Greater agreement with **ISO 17025 & ISO 9001**. - **Competency-based staff assessments** introduced.

Significance of ISO 15189

- Expands application **beyond medical laboratories** to include diagnostic imaging, physiological sciences, respiratory therapy, and blood transfusion services.
- Facilitates **cooperation between medical laboratories and other healthcare services** for better patient management.
- Strengthens risk management and patient-centered care.
- Aligns more closely with **ISO/IEC 17025** (Testing & Calibration Laboratories) and **ISO 9001** (Quality Management Systems).



Why ISO 15189:2022?

- Improved patient care
- Global harmonization
- Risk-based approach
- Updated requirements
- Accreditation and certification

Generally,

The 2022 revision introduces major updates that reflect **advances in laboratory medicine**, a stronger **focus on risk-based thinking**, and better **agreement with other ISO standards**.

Major Revisions in the 2022 Update:

- Risk-Based Thinking and Process Approach
  - Shift from procedural compliance to risk-based management.
  - Identify, assess, and mitigate risks proactively to improve patient safety.
  - Aligns with ISO 9001's process-driven approach for continuous quality improvement.
- Integration of Point-of-Care Testing (POCT) Requirements
  - POCT now included within ISO 15189 (previously in ISO 22870).
  - Standardized quality control, validation, and risk management for POCT devices.
  - Ensures seamless integration of POCT results into LIMS & patient records.

Major Revisions in the 2022 Update – contd :

- Emphasis on Patient-Centered Quality
  - Strengthens laboratory responsibility for sample integrity & result accuracy.
  - Improves patient identification, sample collection, and test result communication.
  - Encourages closer collaboration between laboratories and clinicians.
- Greater agreement with ISO/IEC 17025 & ISO 9001
  - Incorporates method validation, measurement uncertainty, and proficiency testing.
  - Promotes structured internal audits and risk-based quality management.
  - Enhances global standardization of laboratory operations.

Major Revisions in the 2022 Update – contd :

- New Requirements for Laboratory Information Management Systems (LIMS)
  - Introduces strict guidelines for data security, traceability & interoperability.
  - Strengthens cybersecurity measures to protect patient data.
  - Encourages automated tracking of samples & results integration with hospital e-Health Records.
- Changes in Personnel & Competency Assessment
  - Expands competency assessment beyond initial qualifications.
  - Moves towards practical skill validation & continuous professional development (CPD).
  - Laboratories must document ongoing training & re-evaluation for compliance.

Implementation Steps for LQMS and ISO 15189:2022 Compliance

- This involves systematically addressing all aspects of laboratory operations, ensuring accuracy, efficiency, and regulatory compliance.
- Successful compliance requires a structured, phased approach:
  - Preparation
  - Implementation
  - Sustainability

Phase 1: Preparation

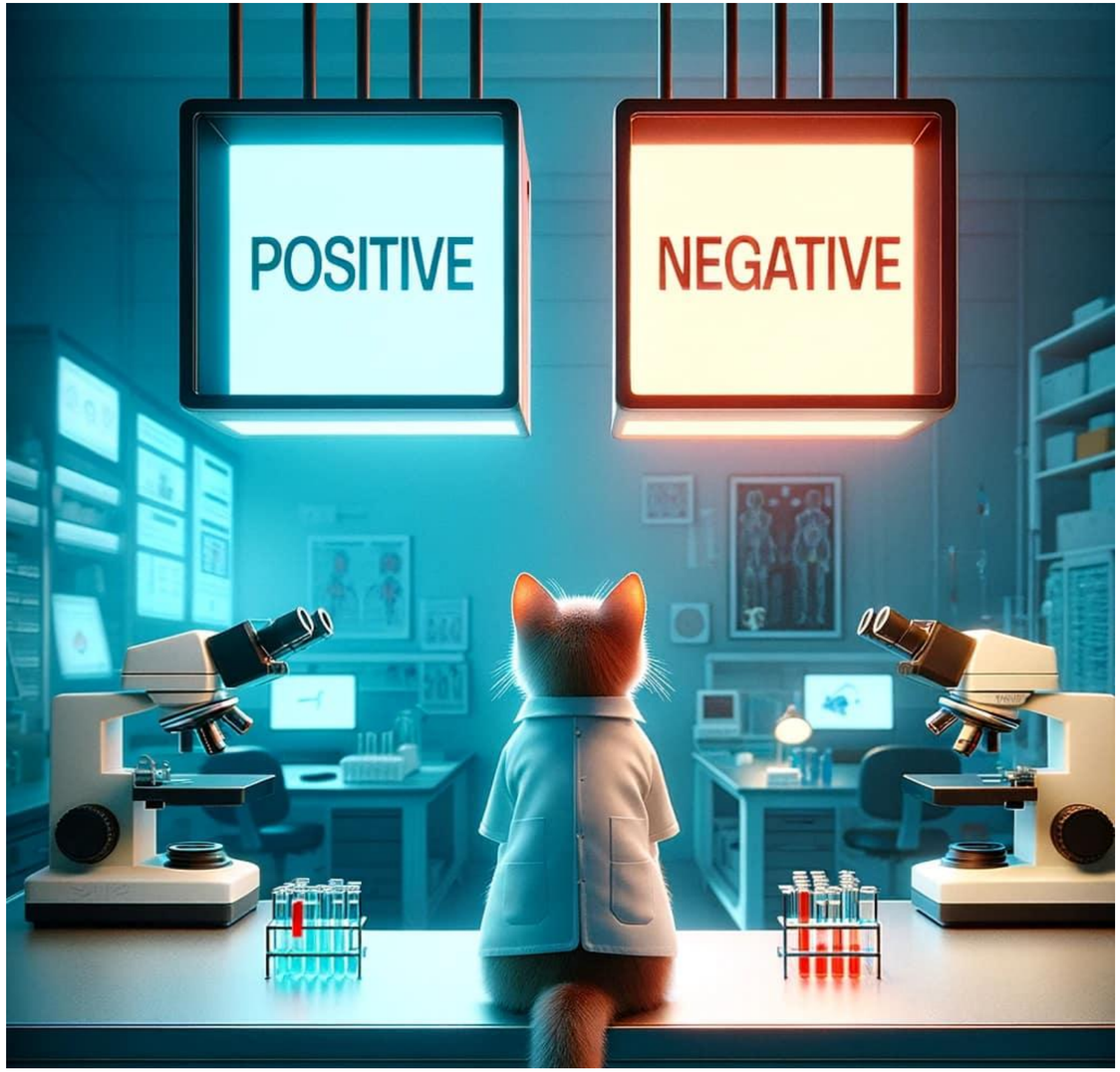
- **Conduct Gap Analysis** – Identify gaps in existing processes using ISO 15189:2022 checklists.
- **Update Quality Policies & Documentation** – Revise SOPs, risk management plans, and competency frameworks.
- **Training & Capacity Building** – Educate staff on risk-based thinking, POCT integration, and LIMS compliance.

Phase 2: Implementation

- **Integrate Risk-Based Thinking** – Establish preventive measures to minimize errors.
- **Upgrade LIMS & Digital Systems** – Ensure secure data management, interoperability, and cybersecurity.
- **Strengthen Process Control & POCT Compliance** – Validate test methods, ensure traceability, and enforce competency checks.

Phase 3: Sustainability

- **Conduct Regular Internal Audits** – Monitor compliance, identify weaknesses, and implement corrective actions.
- **Continuous Quality Improvement (CQI)** – Use performance data, feedback, and root cause analysis for ongoing enhancements.
- **Engage with Accreditation & External Assessments** – Participate in proficiency testing (EQA) and maintain certification readiness.



Training and Capacity Building for Compliance:

- Who needs training?
  - Lab directors, quality managers, technical staff, auditors
- What to cover?
  - Risk-based thinking, POCT integration, LIMS updates, competency assessment
- How to implement?
  - Workshops, online courses, proficiency testing, external partnerships

Common Challenges and Solutions

Challenge	Solution
Limited resources (financial, human, technical)	Seek **government & donor funding**, prioritize cost-effective strategies, and phase implementation gradually.
Resistance to change	Involve **staff in decision-making**, communicate benefits, and provide incentives for compliance.
Lack of trained personnel	Implement **structured training programs, mentorship, and continuous professional development (CPD)**.
Data security and LIMS integration	Upgrade **LIMS software**, ensure **cybersecurity compliance**, and provide IT training.
Maintaining accreditation compliance	Conduct **regular internal audits, proficiency testing, and corrective action tracking**.

Case Scenario for Discussion

- Background:
  A large hospital laboratory receives complaints from clinicians about **delayed test results** and **inconsistent reporting**. A recent internal audit reveals **frequent transcription errors, uncalibrated equipment, and missing SOPs for Point-of-Care Testing (POCT)**.

- Key Findings:
  - **Pre-analytical issues** – Mis-labeled samples and long processing times.
  - **Analytical challenges** – Equipment maintenance delays and **expired reagents**.
  - **Post-analytical gaps** – Poor result documentation and lack of clinician-laboratory communication.
  - **ISO 15189:2022 Non-Compliance** – No risk-based quality management or competency

Questions!

- 1 What immediate corrective actions should the laboratory take?
- 2 How can risk-based thinking and process improvement prevent future issues?
- 3 How should POCT be properly integrated into the laboratory's quality system?
- 4 What training and competency measures would ensure compliance with **ISO 15189:2022**?

Answers!

1 What immediate actions should the lab take?

- Make sure all samples are properly labeled to prevent mix-ups.
- Fix and calibrate equipment so test results are accurate.
- Train staff on following clear procedures (SOPs) for testing and reporting.
- Assign a Quality Manager to oversee these improvements.

2 How can risk-based thinking help?

- Identify where errors happen most (e.g., sample handling, testing, reporting).
- Set up routine equipment checks to avoid breakdowns.
- Perform regular audits to catch and fix problems early.
- Learn from past mistakes to prevent them from happening again.

Answers!

3 How should POCT be properly managed?

- Train staff to use POCT devices correctly and interpret results properly.
- Ensure POCT results are recorded and linked to the main system.
- Regularly check POCT devices for accuracy (like normal lab equipment).

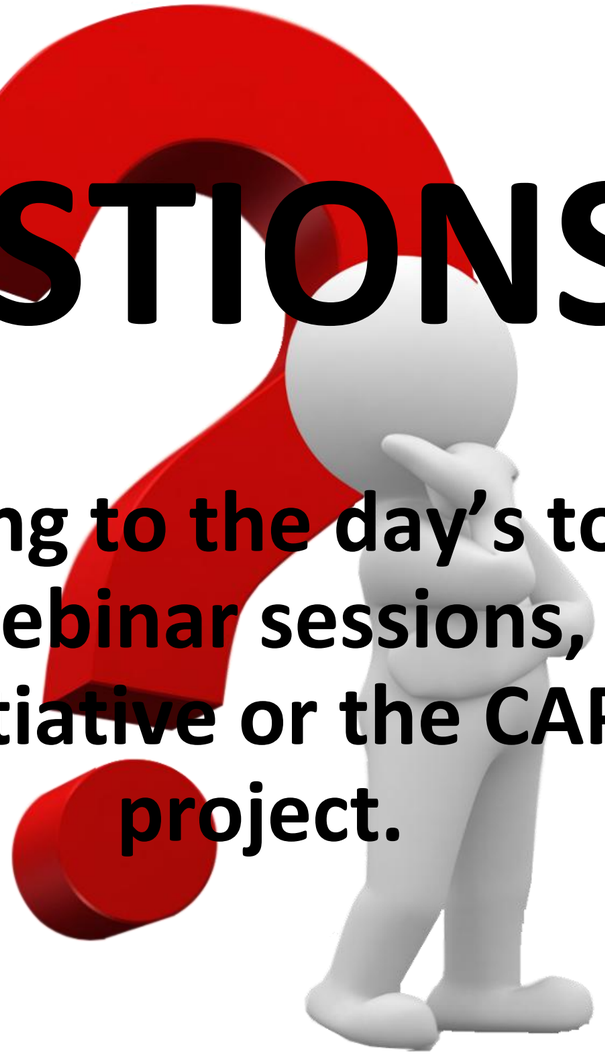
4 What training is needed for compliance?

- Teach staff why quality management matters and how it affects patient care.
- Provide hands-on training on risk management, proper documentation, and POCT use.
- Have ongoing assessments to ensure staff keep up with best practices.
- Conduct practice audits to prepare for accreditation checks.

Recap: Key Takeaways

- ✅ **LQMS Ensures Accuracy & Compliance** – Reliable results for patient safety & accreditation.
- ✅ **ISO 15189:2022 Key Updates** – Risk-based approach, POCT integration, patient-centered quality.
- ✅ **Stronger Personnel Competency Requirements** – Ongoing training & structured assessments.
- ✅ **LIMS & Data Security Enhancements** – Improved traceability, cybersecurity & digital integration.
- ✅ **Implementation Requires Gap Analysis & Training** – Align processes, update SOPs & build capacity.
- ✅ **Overcoming Challenges** – Phased implementation, stakeholder engagement & continuous improvement.

QUESTIONS???



Relating to the day's topic, the webinar sessions, the initiative or the CAP project.

Final words:

🚀 **Small, consistent improvements lead to big changes in lab quality!** 🚀

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Thank You

NEXT WEEK:

Best Practices in Sample Management & Pre-analytical Quality Control – Dr. B K Myke-Mbata.

- Essential protocols for sample collection, handling, and transport.
- Strategies to minimize pre-analytical errors and maintain sample integrity.
- Digital tracking systems and automation for improved sample management.

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