

# The Future is Now

## Global Application of CLSI and ISO:15189 Quality Management Systems

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### Key Discussion Points

Upon completion of this session, you will be able to:

- Define Quality Management System (QMS)
- Compare the organizational characteristics of ISO and CLSI
- Discuss global momentum of QMS acceptance and its impact on your lab



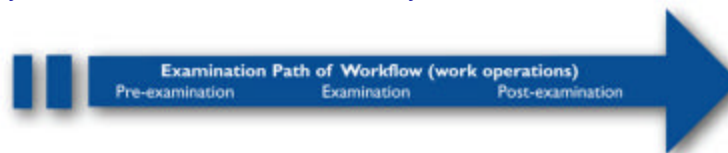
## Quality Management System

The Quality Management System (QMS) provides a framework for managing and monitoring activities to address quality standards and achieve organizational goals.

## Quality Management System

### Path of Workflow

Sequential processes (pre-examination, examination, and post-examination laboratory activities) that transform a physician's order into laboratory information.



# Quality Management System

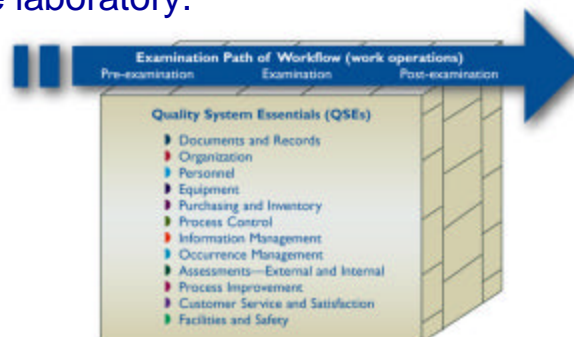
## Quality Systems Essentials

Set of coordinated activities that function as building blocks for quality management.

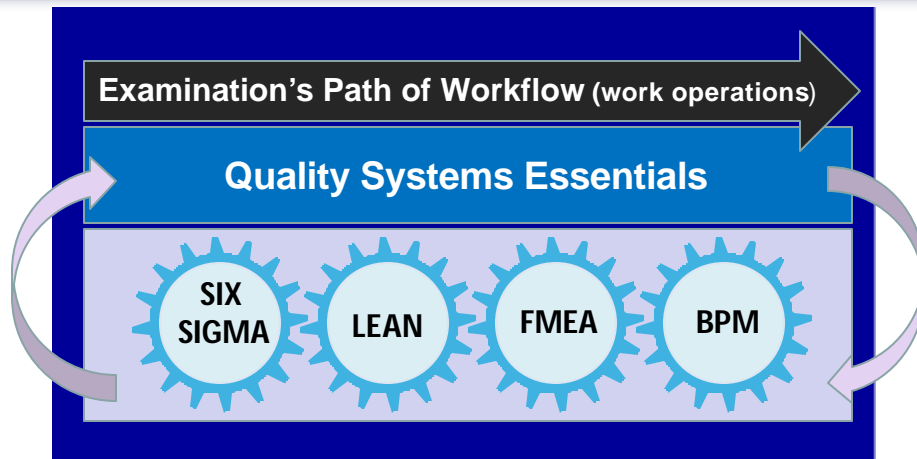
The CLSI model has 12.

# Quality Management System

QMS is a systematic approach of organizing all key work processes around the path of workflow in the laboratory.



## Practical Tools to Arrive at Quality



## Quality Systems Models

There are two major models for quality management systems used globally.

ISO:15189	CLSI: GP26-A3 & HS1-A2
<ul style="list-style-type: none"><li>• Broad-based</li><li>• Overarching standards</li><li>• 15 Management Requirements</li><li>• 8 Technical Requirements</li></ul>	<ul style="list-style-type: none"><li>• Specific</li><li>• Practical implementation guidelines</li><li>• 12 Quality Systems Essentials</li></ul>
Scalable	

# International Organization for Standardization

The **International Organization for Standardization** is the largest worldwide federation of national standards bodies.



It focuses on reducing barriers to trade and promoting international commerce through standards development.

- 157 member countries
- One country = one vote
- 300 technical committees
- 3,000 technical work groups

## ISO/TC 212

ISO technical committee TC 212, **Clinical laboratory testing and in vitro diagnostic test systems**, provides standardization and guidance in the field of laboratory medicine and in vitro diagnostic test systems (IVD).

- Established 15 years ago
- 33 participating countries
- 18 observing countries
- CLSI is the Executive Secretariat for ISO/TC 212

## ISO/TC 212 - Working Groups

Working Group 1: Quality and competence in the medical laboratory (5 standards)

Working Group 2: Reference systems (6 standards)

Working Group 3: In vitro diagnostic products (6 standards)

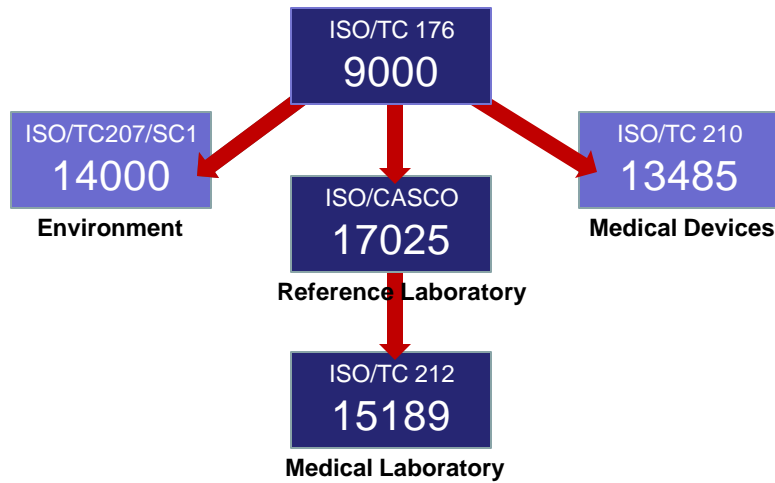
Working Group 4: Antimicrobial susceptibility testing (2 standards)

## ISO/TC 212

TC 212 has produced 19 International laboratory standards. Examples include:

- ISO 15190:2003  
Medical laboratories - Requirements for safety
- ISO 22870:2006  
Point-of-care testing (POCT) - Requirements for quality and competence
- ISO 15189:2007  
Medical laboratories - Particular requirements for quality and competence

## ISO Family of Quality Management Standards



## ISO 15189

The Core of the 15189 are 15 *Management Requirements* and 8 *Technical Requirements*.

*For the most part, these elements align with CLSI's 12 Quality System Essentials.*

# CLSI

Clinical and Laboratory Standards Institute (CLSI) is a not-for-profit developer of global voluntary consensus standards.



*CLSI Board of Directors*

## CLSI Members & Volunteers

Diverse representation from three constituencies

Industry	Government	Professions
IVD Manufacturers	Public Health Agencies	Hospitals and Laboratories
LIS Vendors	Regulatory Bodies	Healthcare Delivery Systems
Startup Companies	Accrediting Organizations	Educational Institutions
Suppliers	Others	Professional Societies
Trade Organizations		



## CLSI Consensus Process



## CLSI

CLSI has over 200 best practice standards, guidelines and companion products for the clinical lab community.

There are over 75 active projects in development at any given time.



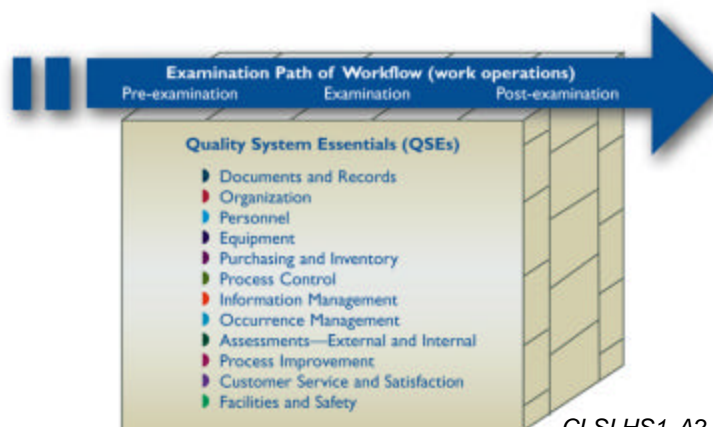
# CLSI – Quality Management System

CLSI produces several Quality Management System guidelines



- HS1 - *A Quality Management System Model for Health Care*
- GP26 - *Application of a Quality Management System Model for Laboratory Services*
- “The Key to Quality”

# CLSI Quality Management System



CLSI HS1-A2 (2003)  
CLSI GP26-A3 (2004)

## ISO and CLSI Standards Development Models

Major differences between ISO and CLSI model are:

- Size and scope
- Standards development model
- Approach
  - ISO provides broad-based requirements
  - CLSI provides detailed, practical guidance
- Speed to development

## The ISO and CLSI Intersection

Both ISO and CLSI are focused on assisting health care testing facilities in achieving laboratory quality. By implementing a quality system, laboratories can:

- reduce or eliminate medical error
- Standardized consistent work processes and procedures
- Reduce costs
- satisfy regulatory requirements
- achieve quality objectives

## International Acceptance of Quality Management Systems

Of 50 countries recently surveyed, 35 (60%) have government requirements for laboratory practice.

Of the 35 countries with government oversight of medical laboratories, approximately 30 (85%) have QMS-based approach to regulatory and accreditation requirements.

## A Case Study: Namibia



## A Case Study: Namibia

Namibia is located in southwest Africa with a population of two million.

The laboratory system consists of a national network of 34 labs.



## A Case Study: Namibia

The goal for the laboratory system is to achieve South African National Accreditation System (SANAS) accreditation (ISO 15189 based) by the 3 largest labs in 3 years.

Rationale is to:

- Use an established QMS model for system-wide implementation of sustainable lab capacity
- Standardize laboratory systems and processes
- Implement a system-wide training program resulting in consistent personnel performance
- Reduce the timeline to expedite implementation

## A Case Study: Namibia

As a result of system-wide implementation of standards

- Two labs recently received SANAS accreditation
- One lab is working on the accreditation process
- Other labs in network have seen the benefits and have implemented practical steps towards QMS implementation

## World Health Organization

The **World Health Organization (WHO)**, part of the United Nations, carries substantial clout, respect and influence, particularly in the developing world.



WHO has been very active in development, dissemination, and promotion of lab quality management systems globally, specifically:

- Recent International conference
- Advocacy paper
- QMS training package

## WHO QMS Activities

WHO jointly hosted an international conference in Lyon, France in April 2008 with the Centers for Disease Control and Prevention (CDC).

- Attended by 260 senior level Ministry of Health (MOH) officials representing 70 countries
- Reviewed the status of lab quality management systems around the world and strategies to ensure accurate, reliable, and timely lab test results in all countries.

## WHO QMS Activities

Conference delegates endorsed an advocacy paper championed by respective governments. Significant collaborative efforts on:

- helping to enhance health laboratory quality with a particular focus in resource-limited settings
- cultivating proposed guidance on QMS development and implementation at national level.

## WHO QMS Activities

### Advocacy Paper Authored:

Each country should establish its own set of standards according to country-specific needs based on internationally recognized standards.

National laboratory standards need to take into account local factors, including any pertinent regulations, organization of the country's laboratory system(s), and resource constraints.

## WHO QMS Activities

Limited resource countries should take a staged approach with scalable implementation requirements based on complexity of testing.



## QMS Training Package

Through the collaboration of WHO, CDC, and CLSI, a comprehensive training tool will be available in late 2008 to any laboratory entity interested in establishing and training on QMS.

- Based largely on blended concepts of ISO and CLSI using a variety of presentations, training aids, and templates
- Scalable for use in smallest to most complex laboratory settings
- Supportive processes for use with an accreditation program

## What About the United States?

CLIA, CLIA, CLIA ...

CLIA is enforced by Centers for Medicare & Medicaid Services (CMS) through direct oversight and on-site inspections.



- CMS Central Office and CMS Regional Offices
- State agencies (including states with licensure requirements)
- Accreditation organizations (deemed agencies)
- States with CMS approved state laboratory programs (exempt-status) (New York, Washington)

## What About the United States?

### Deemed Agencies

- CAP: currently implementing its corollary ISO:15189 program
- COLA: accreditation program is ISO:15189-based; offers a variety of related educational products.
- Joint Commission: under consideration
- AABB: A pioneer advocate in QMS based accreditation

### Others Entities

- American Association for Laboratory Accreditation (A2LA)

## CLIA and QMS

- *The 2003 CLIA regulation changes align around a Path of Workflow model*
- *CLIA clearly encourages US laboratories to align around a more holistic Quality Management Systems (QMS) approach.*

## CLIA and QMS

CMS is encouraging labs to adhere to the CLIA Regulations by using a Quality Management System approach.



## To Add a Final Point

All of the top 10 deficiencies cited by CLIA tie directly to a lab's Quality Management System.

- §493.1239 The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements
- §493.1407 The laboratory director is responsible for the overall operation and administration of the laboratory, including all systems, processes and procedures.

## Global Momentum towards QMS Adoption

35+ countries have implemented or are in some stages of national adoption of QMS model approach to their lab services.

WHO has fully adopted the QMS approach on a global basis and is in the process of education and training.

In the US, the CLIA program is aligned around a path of workflow model and encourages labs to adopt a QMS approach to lab licensure and accreditation.

## Global Momentum towards QMS Adoption

The Future is Now...



## Global Momentum towards QMS Adoption

Where are you in adopting of a holistic Quality Management Systems approach to managing your laboratory operations?

## How to Contact CLSI

- Web: [www.CLSI.org](http://www.CLSI.org)
- Email: [customerservice@clsi.org](mailto:customerservice@clsi.org)
- Customer Service: 1.610.688.0100