

# The Future is Now: Global Application of CLSI and ISO:15189 Quality Management Systems

Executive War College  
May 5, 2009

Glen Fine, MS, MBA  
Executive Vice President, CLSI



## Key Discussion Points

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

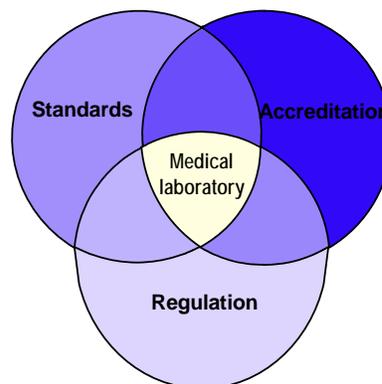
- Define Quality Management System (QMS)
- Compare the organizational characteristics of ISO and CLSI models
- Discuss global momentum of QMS acceptance and its potential impact on your lab environment

## Why Should I Care About This Talk?

- If you are a pathologist or lab administrative director
- If you have a business/marketing background and just happened to have landed in the laboratory field, or, if you work for Industry
- If you are remotely associated with the clinical laboratory at all...

## How It All Ties Together

- *Regulations* tell us WHAT to do?
- *Standards* (QMS) tells us HOW to do it?
- *Accreditation* verifies it is actually occurring



## Begin With the End In Mind.



## Quality Systems and the Lab

Principles of High Quality Lab Testing are the same anywhere in the world.

It is one area of health care that can be and should be highly standardized.



## Standards & the Laboratory

Most medical lab errors are caused by systems and process issues, not people.



They are the areas where this talk can help the most.

## Assumptions

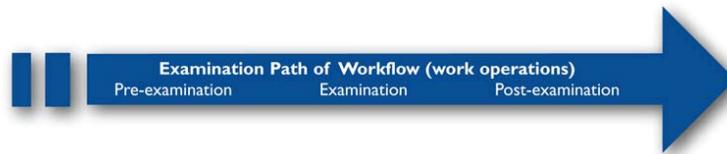
If we believe the previous assumption, then why isn't there a single common system for all labs to perform testing?

➤ **Why reinvent the wheel?**

# 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

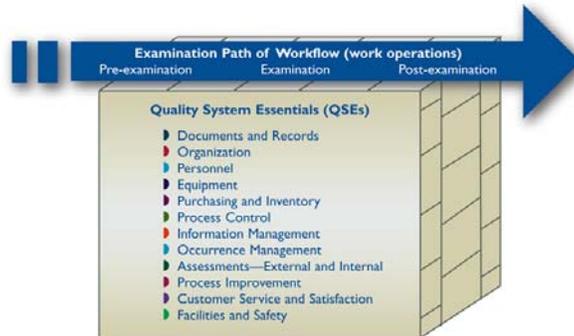
## Quality Systems Essentials

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

The CLSI model has 12.

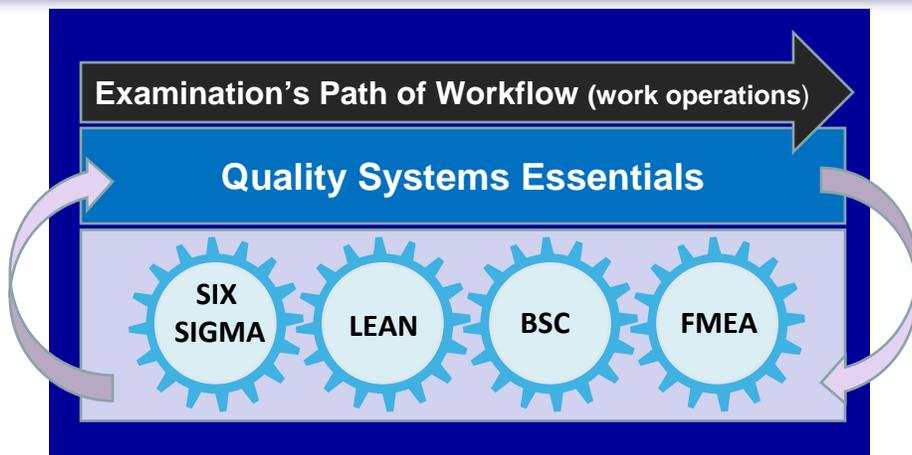
# Quality Management System

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



HS1-A2: A Quality Management System Model for Health Care  
GP26-A3: Application of a Quality Management System Model for Laboratory Services

# Practical Tools to Arrive at Quality



## Two Major Quality Systems Approaches: ISO and CLSI



broad, standard  
requirements

detailed help and  
practical guidance

*Complimentary, not conflicting, roles*

## 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).

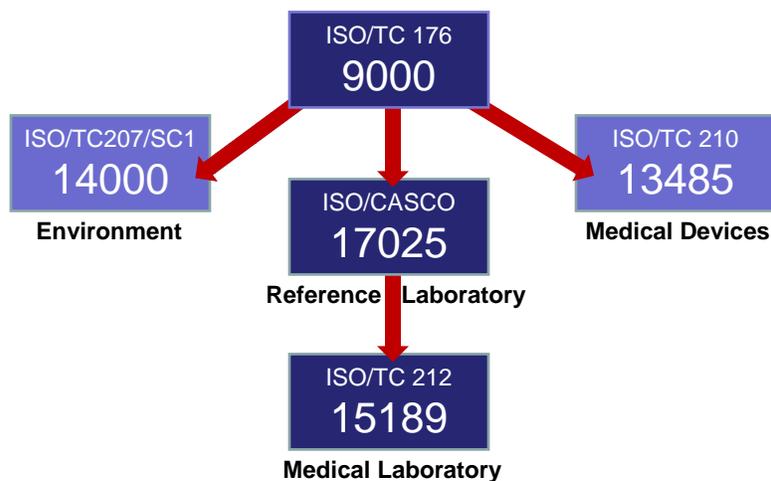
- Established 15 years ago
- 33 participating countries
- 18 observing countries
- CLSI is the Executive Secretariat for ISO/TC 212

## ISO/TC 212

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.



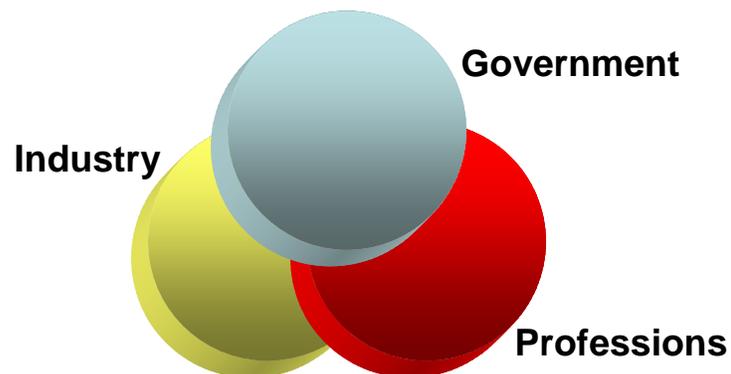
*CLSI Board of Directors*

## 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

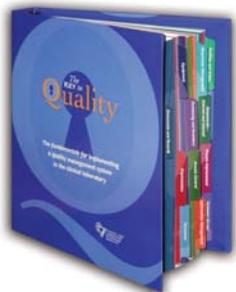
CLSI has over 200 best practice standards, guidelines and companion products for the clinical lab community.

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”

## 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

## ISO & 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 Challenge -

Convince me this is not just another  
Fad!?!

## International Acceptance of Quality Management Systems

DNV Healthcare recently  
received CMS approval to  
accredit hospitals, the first  
new player in 40 years.  
DNV uses an ISO based  
QMS approach to its  
accreditation process.



## International Acceptance of Quality Management Systems

“The first and only CMS approved accreditation service that surveys annually and **integrates ISO 9001 quality methods with Medicare Conditions of Participation**. It’s a revolutionary approach that turns accreditation into a **strategic business advantage** – by creating new standards of excellence from the skills, experience and ingenuity that already exist in your hospital.”

## International Acceptance of Quality Management Systems

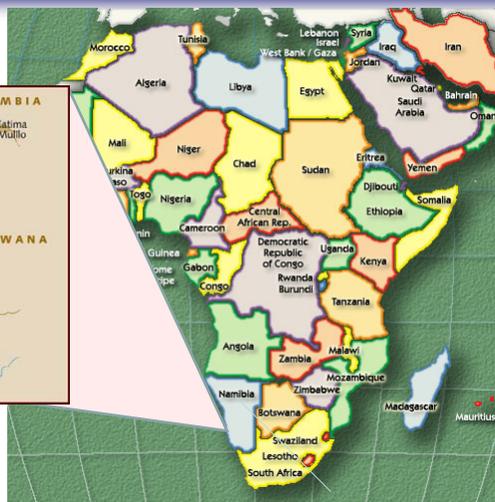
Of 50 countries recently surveyed, 35 (70%) have government requirements for laboratory practice.

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

# International Acceptance of Quality Management Systems

Developing Countries need an internationally recognized, scalable model appropriate to local conditions.....and affordable.

## 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

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

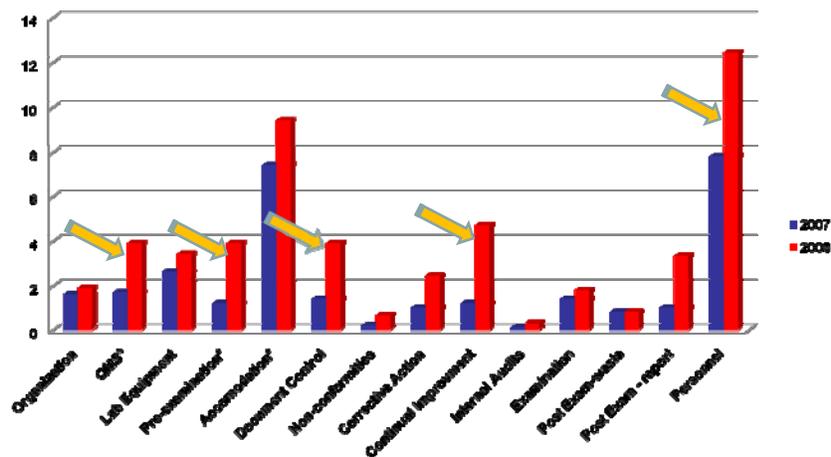
## Proof of Concept

Recent CLSI-based implementations

- Tanzania – Broader scale implementation
- Mali – Smaller scale implementation

## Findings 2008

Section Improvements (Means)



## 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:

- International Health Regulations
- Advocacy “white paper” on the subject
- 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.

## International Health Regulations

The critical importance of health laboratory quality in this process is now widely recognized and greater demands arise for **implementing laboratory quality systems, including the universal setting up of national laboratory quality standards.**

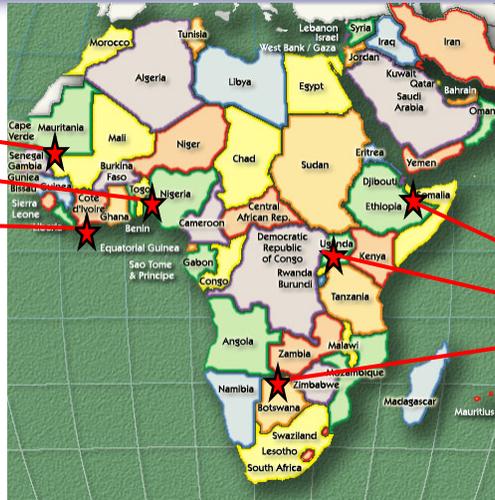
## QMS Training Package

Through the collaboration of WHO, CDC, and CLSI, a comprehensive training package will be available in May 2009 to any laboratory entity interested in establishing and training on QMS.

- Based largely on blended concepts of CLSI and ISO 15189 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

## Countries Currently Moving Forward with WHO/AFRO Accreditation Activities

- ★ Cote d'Ivoire
- ★ Nigeria
- ★ Senegal



- ★ Ethiopia
- ★ Rwanda
- ★ Botswana

## 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 active consideration
- AABB: A pioneer advocate in QMS based accreditation

### Others Entities

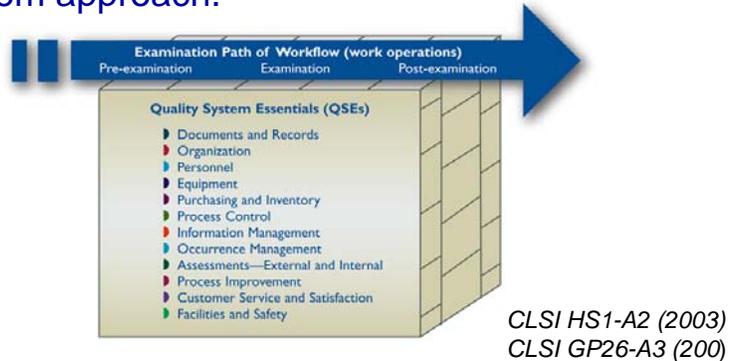
- American Association for Laboratory Accreditation (A2LA)

## 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...



## Summary

- Clinical Lab processes and procedures can be highly standardized on a worldwide basis using a Quality Management Systems (QMS) approach
- A QMS has 2 parts – Path of Workflow & Quality System Essentials

## Summary

- There are 2 major QMS models in use – ISO/15189 and CLSI. They differ primarily in the level of detail presented in the standards.
  - There is a substantial international momentum in their adoption
- WHO has become very active in the standardization of lab practices based on a QMS approach
- 2 QMS-based case studies reviewed
  - Namibia and Tanzania

## End Result.



## 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
- [gfine@clsi.org](mailto:gfine@clsi.org)