

# From Quality Management Systems to EP23-The Right QC:

## What's New From CLSI

Glen Fine, MS, MBA, CAE  
Chief Executive Officer  
Clinical and Laboratory Standards Institute



## Objectives

1. Quality Management Systems (QMS)
  - Brief update on the state of QMS
  - Review of new CLSI guidelines and tools
2. Laboratory-Developed Tests (LDTs)
  - Anticipated US Food and Drug Administration (FDA) guidance document
  - CLSI's upcoming guidelines and job aids to assist laboratories performing LDTs



## Objectives

### 3. Imminent CMS/CLIA\* Quality Control (QC) Interpretive Guidelines (IGs)

- What are they? Why now?
- Potential impact on your laboratory
- Essential elements of a risk-based QC plan (QCP)
- CLSI's role

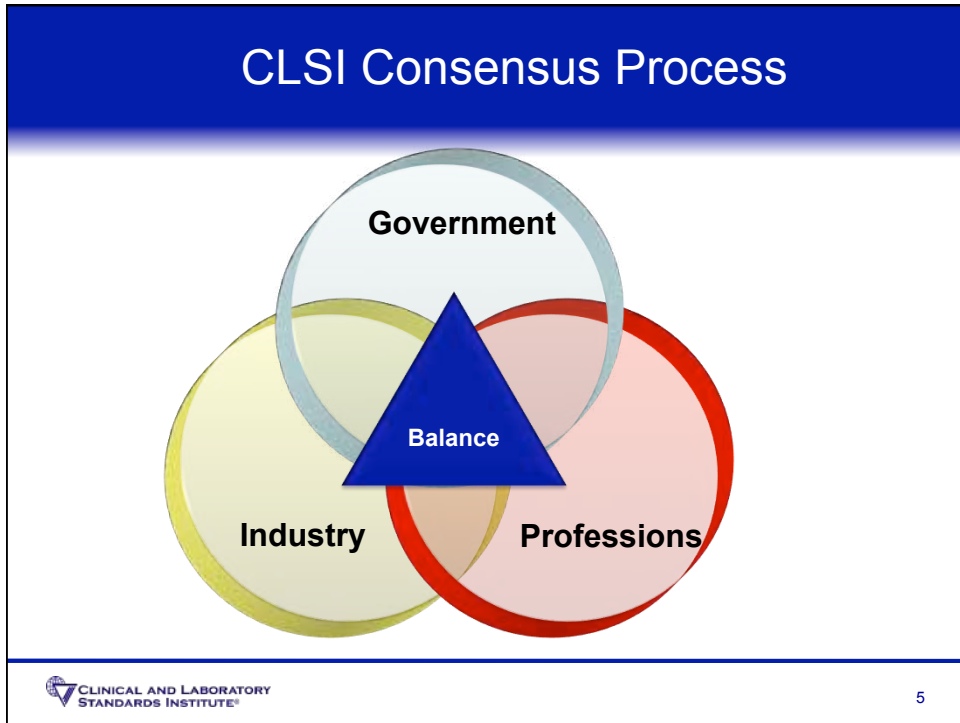
\*CMS/CLIA, Centers for Medicare & Medicaid Services/Clinical Laboratory Improvement Amendments



## CLSI Mission

To develop best practices in clinical and laboratory testing and promote their use throughout the world, using a consensus-driven process that balances the viewpoints of industry, government, and the health care professions.





# Quality Management Systems

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## Quality Management Systems Models

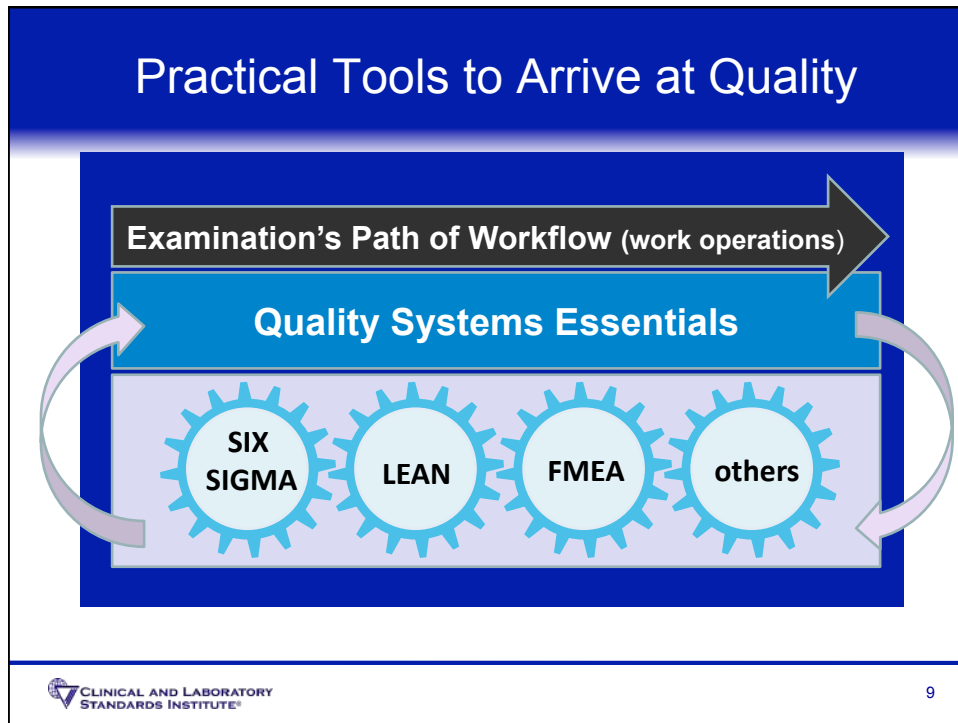
There are two major ones in use globally.

ISO: 15189	CLSI: GP26-A4
<ul style="list-style-type: none"> <li>• Broad-based</li> <li>• Overarching standards</li> <li>• 15 management requirements</li> <li>• Eight 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>
<p>Both are built on the same concepts, but differ in the amount of specificity described. ISO is broader and CLSI is more specific. ISO = what to do; CLSI = how to do it.</p>	

## CLSI's Quality Management System

QMS is a logical and systematic approach of organizing work processes around the path of workflow





## CLIA and Quality Management Systems

- *The 2003 CLIA regulation changes align with a path of workflow model.*
- *CLIA clearly encourages US laboratories to align with a more holistic QMS approach.*

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## Expanding the CLSI Quality Management System Library

- CLSI's master QMS document is GP26.
- CLSI is creating a consensus guideline for each of the 12 Quality Systems Essentials (QSEs)
- Recently published
  - *Quality Management System: Continual Improvement* (GP22)
  - *Quality Management System: Equipment* (GP37)
  - *Quality Management System: Qualifying, Selecting, and Evaluating a Referral Laboratory* (GP09)

## Expanding the CLSI Quality Management System Library (cont'd)

- Guidelines in development
  - *Quality Management System: Leadership and Management Roles and Responsibilities* (QSE Organization; GP38)
  - *Quality Management System: Laboratory Internal Audit Program* (QSE Assessments; GP39)
  - *Quality Management System: Inspections and Accreditation Assessments* (QSE Assessments; GP43)

## Expanding the CLSI Quality Management System Library (cont'd)

- Guidelines in revision
  - *Quality Management System: Development and Management of Laboratory Documents* (QSE Documents and Records; GP02)
  - *Quality Management System: Laboratory Design* (QSE Facilities and Safety; GP18)
  - *Quality Management System: Using Proficiency Testing to Improve the Clinical Laboratory* (QSE Assessments; GP27)

## New *Key to Quality*™

- A new revision of the *Key to Quality* companion product will be available in early 2013.
  - Provides clear and concise explanations to implement a QMS.
  - Helps laboratories achieve and maintain a QMS.
  - Includes comprehensive gap analysis tools that correspond to each QSE.
  - Helps laboratories with implementation of QMS and accreditation preparedness.

## *New Key to Quality*

- Greatly expanded over the original version
- Available in an interactive electronic format
- Includes more than 175 downloadable templates to assist with QMS implementation
- Anticipated release date is January 2013

## Laboratory Quality Management System Certificate Program

- Brand new educational initiative from CLSI
- Earn an education certificate in QMS developed by experts on the 12 QSEs
- Online Web-based program for access 24/7
- Scheduled for launch in early 2013



## CLSI and Laboratory-Developed Tests



### Laboratory-Developed Tests in '80's

- Also called “home brew” or “in-house” testing
- Test methods generally well established, accessible
- Often for rare diseases, unmet needs
- Performed by specialists with advanced training and require expert interpretation (karyotype, immunohistochemistry)
- Small test volumes



## Laboratory Developed Tests Now

- Volume and types of LDTs have grown significantly
  - Over 2,500 diseases for which tests are available
- Often a mechanism for market entry of novel tests
- Often no clinician/pathologist/patient relationship
- Aggressively marketed to clinicians

## Laboratory-Developed Tests Now (cont'd)

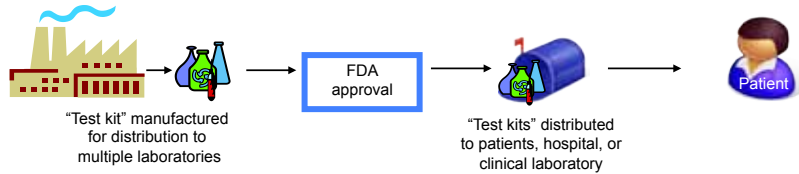
- Tests broadly advertised
- Direct-To-Consumer advertising
- Internet sales, overnight shipping
- Many incorporate automated interpretation & complex software

## Laboratory-Developed Tests Now (cont'd)

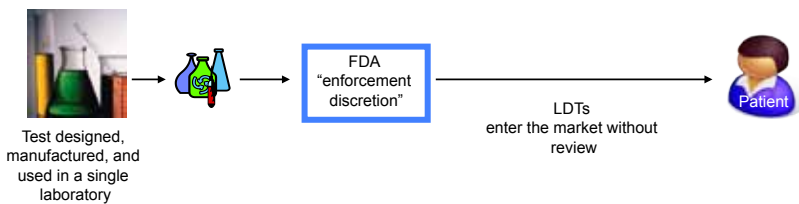
- Clinical validity not well understood
- More tests for predicting drug response, risk of disease
- Novel tests often developed by companies and “licensed” to a laboratory

## Current Regulatory Reality

### 1) Commercially Distributed Test Pathway:



### 2) LDT Pathway:



## Proposed FDA Approach

- Look at all LDTs
- Develop a framework to close regulatory gaps
  - Held public meeting to initiate stakeholder input
  - Held meetings with interested stakeholders

## Possible Elements of FDA Framework

- Risk-based oversight
  - FDA has always regulated on risk
- Some type of registration and listing
  - Need to know who is offering what
- Classification panels
  - Classify tests with no predicates or existing regulations

## How Is CLSI Helping?

CLSI is developing a series of modules to help laboratories performing LDT's understand the FDA's Quality System Regulations (QSRs).

## How Is CLSI Helping? (cont'd)

- Developed by a group of industry experts, the modules are written for the laboratory to answer the question:

***What do the QSRs require, above and beyond what we already do for CLIA?***

## Relevant Information

Each module:

- Explains each QSR requirement in plain English
- Explains the similarities and differences to CLIA requirements
- Provides helpful implementation notes and important tips
- Includes diagrams, charts, and pictures to make the information more understandable

## CMS/CLIA Quality Control

### Interpretive Guidelines

## Three Terms

- Individual Quality Control Plan (IQCP)
- CLSI document EP23-*Laboratory Quality Control Based on Risk Management*
- Interpretive Guidelines (IG)

## CMS/CLIA Individual Quality Control Plan

CLIA law allows the ability to provide “equivalent quality testing” via *Interpretive Guidelines* instead of changing regulations each time technology improves.

*Disclaimer: What follows are CMS/CLIA concepts likely to delineated....*

## CMS/CLIA Individual Quality Control Plan

[www.cms.gov/regulations-and-guidance/  
Legislation/CLIA/Downloads/IQCPbenefits.pdf](http://www.cms.gov/regulations-and-guidance/Legislation/CLIA/Downloads/IQCPbenefits.pdf)

## Individualized Quality Control Plans

**Individualized Quality Control Plan (IQCP)**

**CLIA**

- ☑ **Customizes** QC Plan for each test in its unique environment
- ☑ **Optimizes** use of electronic/integrated controls
- ☑ **Offers** laboratories **flexibility** in achieving QC compliance
- ☑ **Adaptable** for future advancements in technology
- ☑ **Incorporates** other sources of Quality Information
- ☑ **Strengthens** Manufacturer/Laboratory partnerships
- ☑ **Formalizes** risk management data already maintained within the laboratory
- ☑ **Provides** equivalent quality testing to meet the CLIA QC regulations

**The Right Quality Control**





## CMS/CLIA Individual Quality Control Plan

IQCP guidelines are based on key concepts outlined in CLSI document EP23-*Laboratory Quality Control Based on Risk Management*

## CMS/CLIA Individual Quality Control Plan

- IQCP considers the entire testing process: pre-examination (pre-analytical), examination (analytical), and post-examination (post analytical).
- All CLIA specialties and subspecialties, except pathology, are eligible for an IQCP.

## CMS/CLIA Individual Quality Control Plan

An IQCP expands on existing QC procedures. It's not just the frequency and number of QC materials.

Information already available to assist in the laboratory's QC/risk assessment decisions may include:

- Proficiency testing/External quality assessment
- Quality assurance (QA) plans
- Key indicators
- Instrument performance specifications & verification
- Staff competency assessments
- Nonconforming events (incident reports)

## CMS/CLIA Individual Quality Control Plan

CMS does not prescribe how to perform the risk assessment or develop the IQCP.

- “Due to the myriad of potential circumstances, test systems...the laboratory has the flexibility to customize its QC based on the environment, clinical uses, patient population, test system stability, personnel, etc. for each test (new and existing).”

## CMS/CLIA Individual Quality Control Plan

There will be a publicized period for education and transition before IQCP becomes fully effective.

- No deficiencies will be cited during this timeframe, unless serious quality problems are identified.
- Upon the IQCP effective date, equivalent quality control (EQC) will no longer be acceptable to meet CLIA QC requirements and deficiencies will be cited for noncompliance.

## CMS/CLIA Individual Quality Control Plan

**IQCP is voluntary**; the default is the regulatory requirement for two levels of QC each day of testing, and all manufacturer's instructions must be followed in either case.

## CMS/CLIA Individual Quality Control Plan

IQCP may or may not reduce the laboratory's QC frequency.

It will enable a laboratory to develop their QC in order to provide reliable testing with a more comprehensive evaluation of its quality practices.

## CMS/CLIA Individual Quality Control Plan

The laboratory director has overall responsibility for the laboratory's risk assessment, QCP, and QA.

CMS will use its existing outcome-oriented survey process to assess compliance, and no QC regulations will change.

## CMS/CLIA Individual Quality Control Plan

CMS will continue to accept certain CLSI **Microbiology** QC documents as an option to meet specific CLIA Microbiology QC regulations, in lieu of IQCP or the regulatory requirements.

- M22**—Quality Control for Commercially Prepared Microbiological Culture Media
- M50**—Quality Control for Commercial Microbial Identification Systems
- M02**—Performance Standards for Antimicrobial Disk Susceptibility Tests
- M07**—Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically
- M100**—Performance Standards for Antimicrobial Susceptibility Testing

## CMS/CLIA Individual Quality Control Plan (cont'd)

Deemed agencies (e.g., College of American Pathologists (CAP), The Joint Commission, COLA and Exempt States (New York and Washington)) will decide if and when they will adopt the CLIA IQCP approach.

## CMS/CLIA Individual Quality Control Plan (cont'd)

- Aside from the IQCP IGs, there will be additional educational materials, tools, and brochures.
- Direct IQCP inquiries to: [IQCP@cms.hhs.gov](mailto:IQCP@cms.hhs.gov).

## CLSI Document EP23

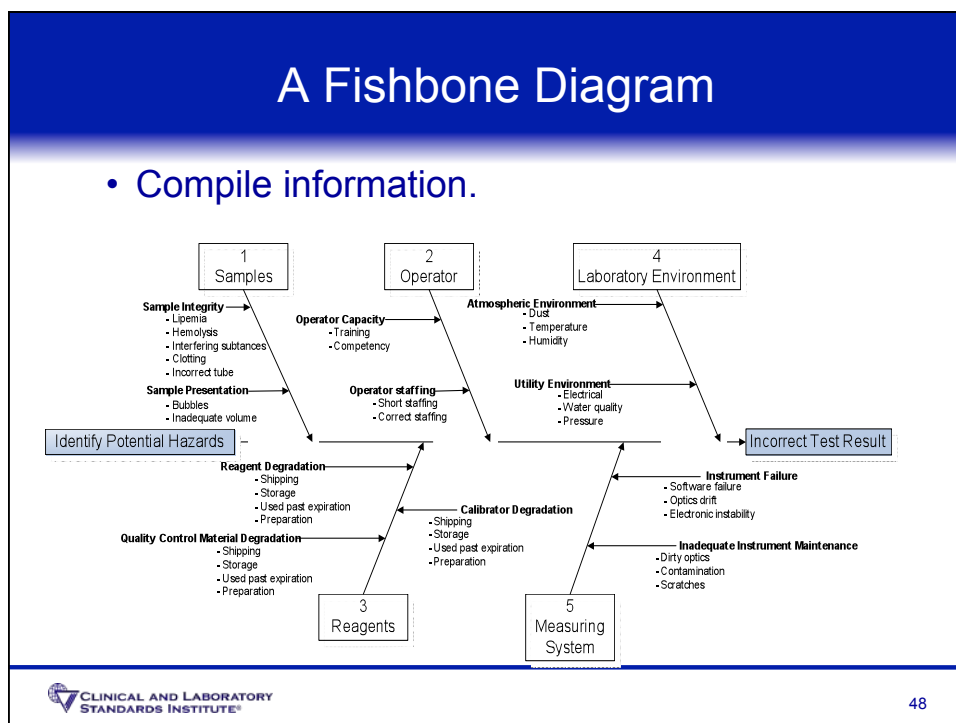
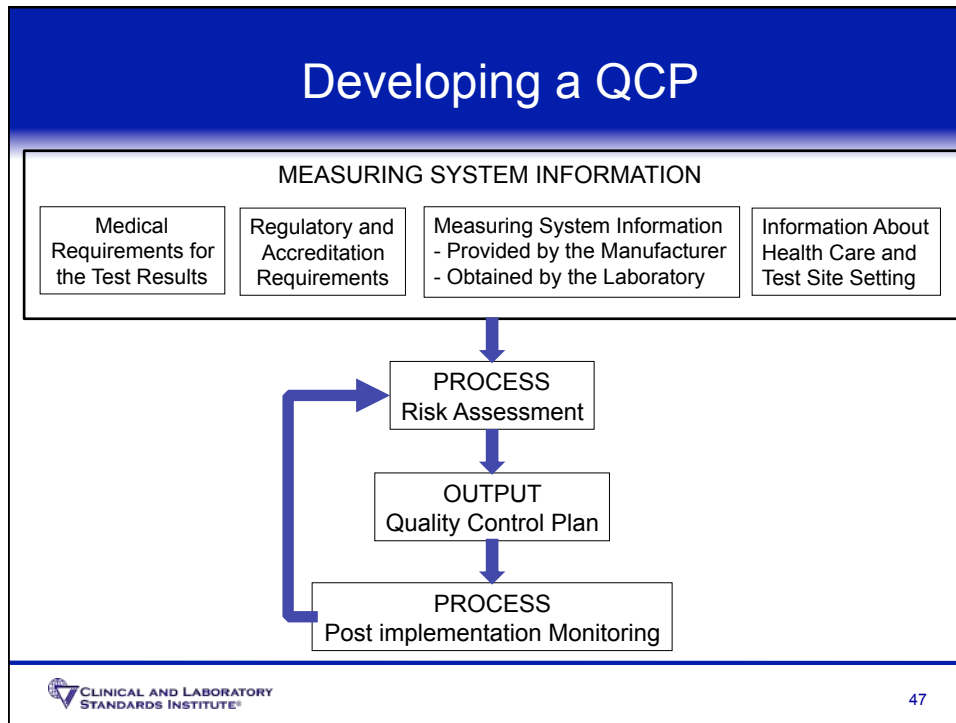
- *Laboratory Quality Control Based on Risk Management; Approved Guideline*
  - James H. Nichols, PhD, DABCC, FACB, Chairholder of the document development committee
- EP23 describes good laboratory practice for developing a QCP based on the manufacturer's risk mitigation information, regulatory and accreditation requirements, and the individual health care and laboratory setting.

## CLSI Document EP23 (cont'd)

- An implementation workbook is also available from CLSI, which guides the development of a sample IQCP for an analyte (PT/INR).

## For the Quality Confab Audience...

- Risk management is not a new concept
- Laboratories routinely:
  - Evaluate the performance of new devices
  - Troubleshoot instrument problems
  - Respond to physician complaints
  - Estimate harm to a patient from incorrect results
  - Take actions to prevent errors
- Developing an IQCP based on risk management expands upon what clinical laboratories are already doing every day.





## Perform the Risk Assessment

- Identify the potential failures and their causes.
- Assess each potential failure.
- Where a failure could occur, add an **action** to the QCP that will reduce the possibility of that failure, making residual risk acceptable.

## Perform the Risk Assessment

Probability of Harm	Severity of Harm				
	Negligible	Minor	Serious	Critical	Catastrophic
Frequent	Unacceptable	Unacceptable	Unacceptable	Unacceptable	Unacceptable
Probable	Acceptable	Unacceptable	Unacceptable	Unacceptable	Unacceptable
Occasional	Acceptable	Acceptable	Acceptable	Unacceptable	Unacceptable
Remote	Acceptable	Acceptable	Acceptable	Acceptable	Unacceptable
Improbable	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable

Definitions for categories are from ISO 14971

## Assemble the Quality Control Plan

- Assemble all of the identified actions into a QCP.

## Monitor Quality Control Plan for Effectiveness

- Verify that the QCP actually works.
- Continue to monitor errors and control failures.
- If an error occurs:
  - Take the appropriate corrective action.
  - Investigate the cause of the error.
  - Once the cause is understood, evaluate whether any changes need to be made in the QCP.

## Education Options

- **Companion products**
  - Implementation workbook
  - Risk assessment worksheet
  - Examples
  - Worksheet for industry (coming soon)
  
- **Workshops**
  - All-day sessions to learn about EP23
  - EP23 user's group on LinkedIn

## IQCP Summary

- CMS/CLIA has used concepts in EP23 in their Draft Interpretive Guidelines.
- Laboratories will either implement CLIA's IQCP approach or use traditional QC, two levels/day.
- Accrediting organizations are determining how to incorporate these guidelines moving forward.
- Together, CMS, CLSI, and others will be focused on education and training on this new approach to QC.

## Summary

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

- New/revised CLSI products include the full consensus guidelines for each of the 12 QSEs, *Key to Quality* and the Laboratory QMS Certificate program

## Summary

### 2. LDTs

- Update on the anticipated FDA guidance document
- CLSI's guidelines and job aids to assist laboratories performing LDTs in development

### 3. Draft CMS/CLIA QC IGs

- Perform QC based on actual risk to improve quality instead of running two levels/day or other manufacturer requirements
- Outline the essential elements to create a QCP based on risk management that optimizes your laboratory QC.
- CLSI Guideline EP23

## How to Contact CLSI

- Web: [www.clsi.org](http://www.clsi.org)
- E-mail: [customerservice@clsi.org](mailto:customerservice@clsi.org)
- Customer Service: 610.688.0100
- Me: [gfine@clsi.org](mailto:gfine@clsi.org)