Understanding Quality Management System: Essential Strategies to Improve Laboratory Performance

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Our Common Goal

Quality Excellence in Clinical Laboratory Practice

Principles of high –quality laboratory testing are the same anywhere in the world.
It is one area of health care that can be, and should be, highly standardized.

Presentation Outline

- Quality Management System (QMS) background information
- Overview of international QMS standards and guidelines
- Comparison of ISO 15189 and CLSI
- Challenges to QMS Implementation
- Describe the stepwise approach to QMS
- Describe the "Laboratory Quality Continuum" as a tool to achieve quality excellence
- Describe the sources of laboratory errors
- Describe the culture of quality, relation to the patient safety and the role of leadership
- Describe the excellence in quality awards

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The Quality Management System (QMS)

Provides a framework for managing and monitoring activities to address quality standards and achieve organizational goals.

Standardization in the Medical Laboratory

The right laboratory test at the right time with the right result leads to quality diagnostics, improved patient care, and improved public health around the world

Standardization International Bodies

	ISO – International Organization of Standardization	• World's largest developer and publisher of international standards • Standards are applicable to many kinds of organizations including clinical and public health labs • Use consensus process in developing standards
	CLSI – Cinical and Laboratory Standards Institute	• Global, nonprofit, standards-developing organization • Detailed, standards apply specifically to medical labs • Documents are developed by experts working on subcommittees or working groups (consensus process)
	CEN – European Committee for Standardization	• Founded by the national standards bodies in the European Economic Community and associated countries • General terms include openness and transparency, consensus and integration
	WHO – World Health Organization	• Developed several standards for disease-specific diagnostic labs, such as polio, tbc, influenza, measles • Provides with Laboratory Quality Management System Tool Kit

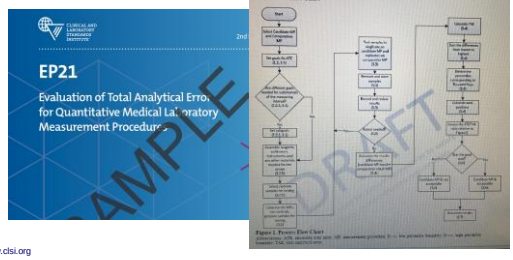
Quality Systems Models

There are two major models for QMS used globally.

ISO 15189:2012	CLSI GP26-A4 (CLSI GP26 A4-12 QSE's)
• Broad –based	• Specific – standards, guidelines, and best practices for quality in medical lab testing
• Overarching standards	• Practical implementation – detailed; applies specifically to medical labs
• 15 Management requirements • (Section 4)	• 12 Quality system essentials
• 10 Technical requirements (Section 5)	
• 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	

www.clsi.org, www.iso.org

CLSI = how to do it



www.clsi.org

CLSI – 12 QSE

Laboratory Path of Workflow

Preexamination → Examination → Postexamination

Quality System Essentials: The Building Blocks

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

GP26-A4-Quality Management System: A Model for Laboratory Services; Approved Guideline – Fourth Edition

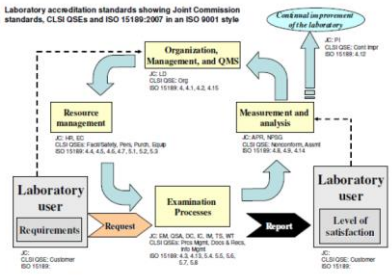
CLSI QMS and How Quality System Essentials (QSE) fits within the QMS

2011 CLSI QMS Model for Laboratories

International and CLSI Standards Applicable to Medical Laboratories

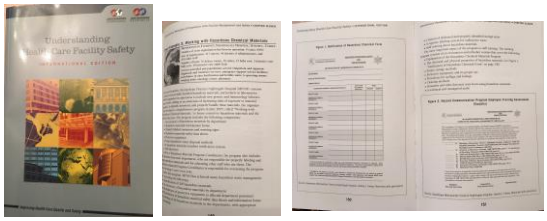
International Standards	Definition
ISO 15190:2003	Medical laboratories -- Requirements for safety
ISO 10012:2003	Measurement management systems – Requirements for measurement processes and measuring equipment in medical laboratory
ISO/IEC 17025:2005	General requirements for the competence of testing and calibration laboratories
ISO 22870:2006	Point-of-care testing (POCT) -- Requirements for quality and competence
ISO 20776-1:2006	Clinical laboratory testing and in vitro diagnostic test systems -- Susceptibility testing of infectious agents and evaluation of performance of antimicrobial susceptibility test devices -- Part 1: Reference method for testing the in vitro activity of antimicrobial agents against rapidly growing aerobic bacteria involved in infectious diseases
ISO/TS 22367:2008	Medical laboratories -- Reduction of error through risk management and continual improvement
ISO 15189:2012	Medical laboratories – Particular requirements for quality and competence
ISO 15197:2013	In vitro diagnostic test systems – Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus
CLSI	CLSI in US developed the quality management framework and organized the topics as the "12 Quality System Essentials" based on both ISO 15189 and CLSI GP26-A3 documents
SLIPTA	Stepwise Laboratory Quality Improvement Process Towards Accreditation implemented by ASLM in Africa

A QMS View of Laboratory Accreditation Standards

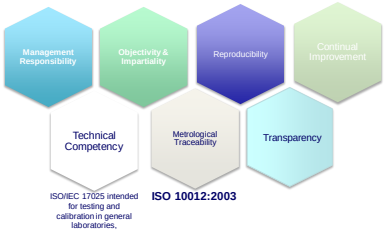


Working with Hazardous Chemical Materials. In: Understanding Health Care Facility Safety. International Edition. Joint Commission International. 2006; pp.149-152.

ISBN: 1-59940-010-3. Library of Congress Control Number: 2006923142.
http://tr.jointcommissioninternational.org/entr/Books-and-E-books/HEALTH-CARE-FACILITY-SAFETY-INTL-EDITION-SOFTCOVER/1229/



Principles of ISO 15189



ISO/IEC 17025 intended for testing and calibration in general laboratories,

ISO 10012:2003

ISO 15189: Where we are today

ISO 9001:2015 "Quality management systems - Requirements"

ISO 15189: 2012 "Medical laboratories - Requirements for quality and competence"

Are there guidelines to support metrology requirements (subchapter 5.3.1.4)?

ISO 10012:2003 "Measurement management systems - Requirements for measurement processes and measuring equipment" in medical laboratory

Are there guidelines based on the audit requirements (4.13)?

ISO 19011:2011 "Guidelines for auditing management systems"

Are there guidelines to support the safety specifications (5.2)?

ISO 15190: 2003 "Medical laboratories - Requirements for safety"

Depending on the accrediting bodies it may be possible for a medical laboratory to choose between ISO/IEC 17025 and ISO 15189 or even to have both accreditations. For instance, when a medical laboratory has ISO 15189 accredited tests and also has a calibration method intended to calibrate not only internal devices (which does not require an ISO/IEC 17025 accreditation) but also equipments for external customers.

ISO 14001:2004 and Environmental Management

Paulo Pereira, PhD
February and March 2017, www.westgard.com

What are the advantages of test accreditation according to ISO 15189?

The pros can be summarized as:

- The only **global standard** for the accreditation of medical laboratory results
- Based on **good laboratory practices**
- Focused on **technical specifications** in medical laboratory
- **Process approach** matching the pre-analytical, analytical, and post-analytical phases
- Oriented to **support accurate clinical decisions**
- **Identification and traceability information** of the different phases of the medical laboratory process
- **Monitoring and measuring of devices** that significantly contribute to the trueness and uncertainty of the reported results
- **Training and competence assessment of the staff** which is critical to good management and good laboratory practices, and;
- Infrastructure to correctly **support the operation practices**.

Paulo Pereira, PhD
February and March 2017, www.westgard.com

Let's Think outside the Box !

What are the drawbacks of test accreditation according to ISO 15189?

- The accreditation is **expensive** when compared to the ISO 9001 certification
- Its value is **not well understood by the physician and the customers** of clinical decisions
- It is **not used by most of the medical laboratory agencies** as the standard to accreditation
- It requires **auditors** with advanced matrix of skills
- It does **not require sustainability**
- The specifications sometimes are **generic**
- It does **not standardize critical practices** such as the validation, measurement uncertainty, IQC and EQA/PT of examination procedures, and;
- The **safety** specifications are basic.

Paulo Pereira, PhD
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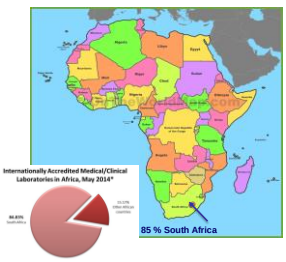
Global Momentum Toward QMS Adoption

- 40+ countries have implemented, or are in some stages of national adoption, of the QMS model approach to their laboratory services
- The WHO has fully adopted the QMS approach on a global basis and is in the process of education and training.
- In the US, the Centers for Medicare & Medicaid Services is encouraging labs to adopt a QMS approach to laboratory licensure and accreditation

What is happening with ISO 15189 implementation on a global perspective?



The WHO's Regional Office for Africa (WHO AFRO) has established a framework for improving the quality of public health laboratories in developing countries to achieve ISO 15189 standards. This framework, implemented by ASLM in Africa, is the Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) program. The program was developed by the Centers for Disease Control and Prevention (CDC) and WHO AFRO, in partnership with the American Society for Clinical Pathology (ASCP) and the Clinton Foundation.
By the year 2020, 2,500 laboratories in Africa are expected to enroll in SLIPTA. So, towards a more widespread implementation of QMS is underway.

Bouchet N. 2015. http://www.ajlmonline.org

What is happening with ISO 15189 implementation on a global perspective?

- Currently, ISO 15189 is obligatory in Australia and Latvia.
- Since 2011, all new French medical laboratories must be accredited. Since November 1, 2016, all other public or private laboratories in France must be accredited on at least 50% of the tests, expanding to 70% of tests by 2018, and all tests by 2020.
- In the Netherlands, the CCKL accreditation has been changing to the ISO 15189 standard under the direction of the Dutch 'Raad voor Accreditatie' (RvA), with a target deadline of January 1, 2018.
- Belgium – only molecular tests
- Germany – only newborn screening
- Legal requirements exist in most countries.

Paulo Pereira, PhD
February 2017, www.westgard.com

Audience Response

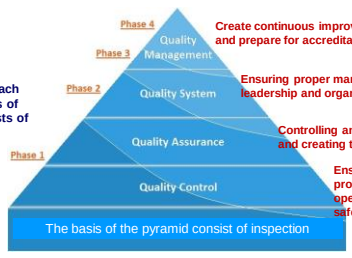
Does your laboratory currently have a Quality Management System (QMS) based on the ISO 15189 standards?

1. **Yes**
2. **No**

Logical structure and a stepwise plan to the process of implementing the QMS

by WHO, CDC, CLSI

QMS affects each single process of lab and consists of several layers



Create continuous improvement and prepare for accreditation

Ensuring proper management, leadership and organization

Controlling and assuring quality and creating traceability

Ensuring that the primary process of the laboratory operates correctly and safely

https://www.who.int/lqsi/

The Stepwise plan is constructed such that, even when a laboratory does not reach full implementation of the QMS, it has already improved its quality service provision from Phase 1, and as such has benefited already.

	Stepwise plan for implementing a QMS	Ensuring that the primary process of the laboratory operates correctly and safely	Controlling and assuring quality and creating traceability	Ensuring proper management, leadership and organization	Create continuous improvement and prepare for accreditation
#	QUALITY SYSTEM ESSENTIALS	PHASE 1	PHASE 2	PHASE 3	PHASE 4
1	Facilities and Safety	Upgrading laboratory biosafety	Hazardous Materials	Retention schedule for storing materials	NONE
2	Organization	Quality Management and Quality Project Team	Leadership	Development of a quality manual, Quality Year Plan, Budget planning	Compliance of required elements defined in the SOP
3	Personnel	Job description, Training of staff members	Competency Assessment	Replacement matrix, Potential conflicts of interest among laboratory staff	Continous Education Program
4	Equipment	Equipment register, SOP	Equipment maintenance system	NONE	Validation of equipment
5	Purchasing and Inventory	Stock inventory register	Adequate stock and ordering system	Selection and evaluation of suppliers, referral laboratories, contracts	NONE
6	Process Control	SOPs for all the tests routinely performed	Sample Management	Validation of methods and equipment, IQC activities, TAT, CAPA	Quality indicators
7	Documents and Records	Master SOP	Document control system	NONE	NONE
8	Information Management	NONE	Information management system	Archive for Laboratory Records	NONE
9	Customer Service/Focus	NONE	Biological Reference Intervals, Decision values	Client satisfaction survey	Communication with clients
10	Assessment	NONE	IQC, QC for Quantitative, Qualitative & SemiQuant. procedures	Setting up an internal audit system	External Audit, Action plans
11	Occurrence (Nonconformity) Management	NONE	NONE	NONE	SOP for handling complaints
12	Continous Improvement	NONE	NONE	NONE	FMEA for proactive risk management

What are the Challenges to QMS Implementation?

Knowledge
- **Uncertainty about starting point**
- **How the regulatory process works**

Awareness
- **Defining roles and responsibilities**
  - Personnel qualifications and associated records
  - Competency assessments
- **Cost and mobilization of resources**
  - Proficiency testing – enrollment (all regulated analytes) to review of results to corrective actions to maintaining records

Good Management Practices
- **Perception of lack of time**
- **Lack of management commitment and practical support**
  - Method comparisons
  - Calibration verification
  - Equipment maintenance and associated documentation
- **Resistance to change and managing change in evidence-based system**

N.Hess.CLIA and regulatory readiness: How can your lab always be ready. https://www.mlo-online.com/clia-and-regulatory-readiness-how-can-your-lab-always-be-ready

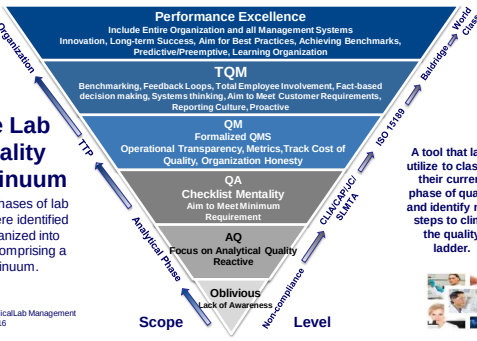
How to improve quality systems for a specific laboratory

The formulation for improvement

Take into account:
- The laboratory's **current level of quality**, which involves an assessment of the **culture of quality;**
- The **existing quality management system** (QMS) framework;
- The **lab's ability** to effectively implement a quality program.

The Lab Quality Continuum

Distinct phases of lab quality were identified and organized into phases comprising a continuum.



Dawson J. MedicalLab Management July/August 2016

A tool that labs utilize to classify their current phase of quality and identify next steps to climb the quality ladder.

Audience Response

According to what you know today about QMS:

1. **My existing QMS will need major revisions**
2. **My existing QMS will need moderate revisions**
3. **My existing QMS will need minimal revisions**
4. **My existing QMS is not based on a QSE model**
5. **I do not have a QMS yet**

What are the essentials of quality excellence and how to achieve it?

The Course of Lab Quality Continuum towards for excellence

- PHASE 1 • Analytical Quality (AQ) – Focus on Quality of the Analytical Phase
- PHASE 2 • Quality Assurance (QA) – The Checklist Mentality
- PHASE 3 • Quality Management (QM) – A Formalized Quality Management System
- PHASE 4 • Total Quality Management (TQM) – Incorporating the Voice of the Customer
- PHASE 5 • Performance Excellence – The Pursuit of Excellence

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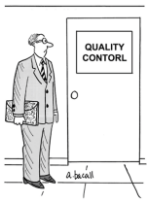
Phase 1

Analytical Quality (AQ) – Focus on Quality of the Analytical Phase



Activities that ensure analytical quality:

- Quality Control
- Validations and Verifications
- Instrument-to-instrument comparisons
- Linearity
- Proficieny Testing

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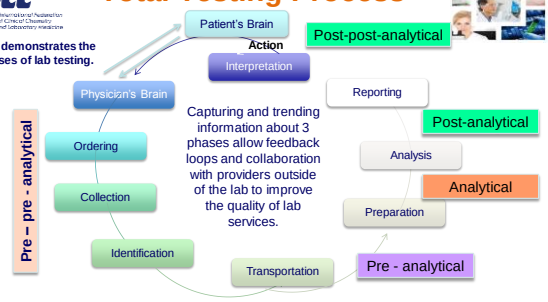
Total Testing Process

TTP demonstrates the phases of lab testing.



The Iceberg Model of Sources of Error

7 – 13% (1996), **15% (2016)**

Analytical, often the least, but so important and can't be neglected!

Preanalytical still remains the largest source of error

46 – 68.2% **62% (2016)**

18.5 – 47% **23% (2016)**

AM Simundic – Avoiding Titanic Errors: The preanalytical phase is subject to more error than any other part of the testing cycle – what can we do to improve it? www.thepathologist.com May 2015

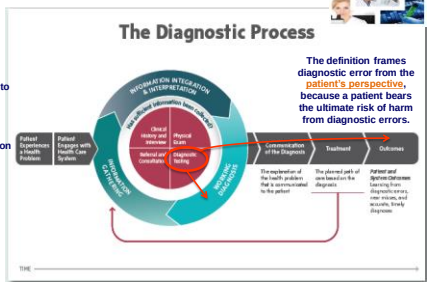
Diagnostic Errors vs Medical Errors

What is Diagnostic Error?

An IOM committee defines diagnostic error as the failure to

a)Establish an accurate and timely explanation of the patient's health problem(s) or b)Communicate that explanation to the patient.

Released: September 22, 2015



The definition frames diagnostic error from the patient's perspective, because a patient bears the ultimate risk of harm from diagnostic errors.

Diagnostic Errors **vs** **Medical Errors**

A Framework for Thinking About Medical Errors

There are many possible ways to categorize **medical errors**, but no universally accepted taxonomy. Classifications have included:

- Type of health care service provided (e.g., classification of **medication errors** by the National Coordinating Council for Medication Error Reporting and Prevention).
- **Severity of the resulting injury** (e.g., sentinel events, defined as "any unexpected occurrence involving death or serious physical or psychological injury" by the Joint Commission on Accreditation of Healthcare Organizations [JCAHO]).
- Legal definition (e.g., **errors resulting from negligence** [Institute of Medicine, 1999]).
- Type of setting (e.g., outpatient clinic, intensive care unit).
- Type of individual involved (e.g., physician, nurse, patient).

https://archive.ahrq.gov/quic/report/mederr4.htm

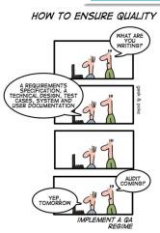
Diagnostic Errors: What is the role of laboratory?

Speaker
Michael Laposata, MD, PhD
Professor and Chairman, Department of Pathology
University of Texas Medical Branch, Galveston, TX

https://www.aacc.org/store/webinars/11200/diagnostic-errors-and-clinical-laboratories

Phase 2

Quality Assurance (QA) – The Checklist Mentality



- **Labs are focused on meeting minimum regulatory requirements and nothing more.**
- **The de facto goal at this level is to keep the lab in business and pass inspections, not necessarily to provide the best patient care and service possible.**
- **Labs at this phase are often reactive, waiting for problems to surface before addressing deficiencies.**
- **The quality professional is seen more as a compliance officer – a sheriff that polices compliance with requirements.**

Quality Viewed "As a Department, Not a Responsibility"

Phase 3

Quality Management (QM) – A Formalized Quality Management System

- The Lab's QMS has taken shape – requires a **lab –centric QMS**.
- CLSI's 12 QS Essentials and other standards and guidelines are incorporated into the quality program with policies and procedures describing the quality framework.
- The key element is lab's QMS is not merely aimed at meeting minimum regulatory requirements and inspections become the outlets to demonstrate achievements and to identify opportunities to further elevate the lab's quality program.
- Labs begin to track the costs associated with quality, both good and bad, and can demonstrate a **return on investment (ROI)** for their quality program and initiatives and trend a **comprehensive set of metrics**.

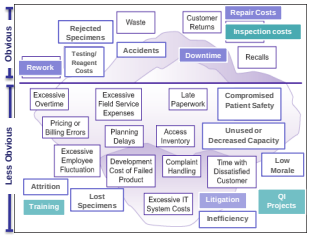
"…when you can measure what you are speaking about, and express it in numbers, you know something about it; but when you cannot measure it, when you cannot express it in numbers, your knowledge is of a meagre and unsatisfactory kind…"

- Lord Kelvin

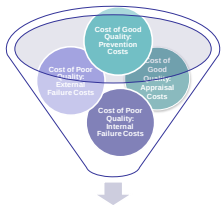
Stages of Quality (CLSI HS1-A2:2004)

Stages of Quality (CLSI HS1-A2:2004)		
Hierarchical Level		**Activities Performed**
Total Quality Management	Six Sigma Management Tool	Total management approach centered around customer satisfaction
Quality Cost Management		Activity to identify, measure, & control cost of quality
Quality Management System	New; ISO 15189; ISO 9001	Systematic process-oriented approach to meet quality objectives
Quality Assurance	CLIA/CAP; ISO 15189; ISO 9001	Organized activities to provide confidence that organization meets requirements for quality
Quality Control	CLIA/CAP; ISO 15189; ISO 9001	Operational process control techniques to meet requirements for quality & regulatory compliance

The Iceberg Model of Cost of Quality: Not Only Failure Costs



- https://www.isixsigma.com/implementation/financial-analysis/cost-quality-not-only-failure-costs/
- MedicalLab Management. September/October 2013



Total Cost of Quality

What is Six Sigma?

- Systematic approach to reduce the occurrence of errors or mistakes in terms of defects per million (DPM).
- Six Sigma offers to laboratories the way to make fewer mistakes in all their activities (ranging from filling in an order form to the most complicated analytical process and report delivery) by eliminating errors before they appear.
- If done properly, Six Sigma ensures that internal processes are running at optimum efficiency- it is a measure of quality i.e. DPM "before-and-after".

Sigma Levels and Cost of Quality

The higher the Sigma Value, the Better the Performance

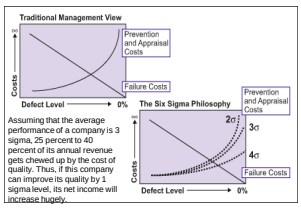
	Sigma Level	Detect rate (DPM)	Cost of Quality	Competitive Level
	6	3.4	< 10%	World Class
	5	233	10-15%	
Industrial Standards	4	6,210	15-20%	Industry Average
	3	66,807	20-30%	
	2	308,537	30-40%	Non Competitive
	1	690,000	> 40%	

How dramatically the cost of quality as a percentage of sales decreases if the process sigma improves.

https://www.isixsigma.com/implementation/financial-analysis/cost-quality-not-only-failure-costs/

What is the relation between the cost of good quality and the cost of poor quality?

Traditional Management View vs. Six Sigma Philosophy



- https://www.isixsigma.com/implementation/financial-analysis/cost-quality-not-only-failure-costs/
- MedicalLab Management. September/October 2013

Quality Cocktail

Be it Lean, Six Sigma and/or ISO 15189

2017 Top Challenges and Priorities for Quality Management

Based on the survey results conducted by American Productivity & Quality Center

Sources: 2017 Process and Performance Management – Survey Summary. The ASQ Global State of Quality 2016. www.apqc.org

Phase 4

Total Quality Management (TQM) – Incorporating the Voice of the Customer

- Lab's QM program hits its stride and is characterized by the establishment of a culture of quality that permeates throughout the organization.
- No solitary quality manager, but a comprehensive, fully ingrained, top down culture of quality with all staff working toward the same goal.
- A culture of quality is fostered where employees are encouraged to report non-conformities in order to improve lab operations and quality.
- Labs in this phase may seek external validation for their quality achievements through accreditation programs which asses cinformance to ISO 15189.

"Culture is a little like dropping an Alka-Seltzer into a glass – you don't see it, but somehow it does something."

- Hans Magnus Enzensberger

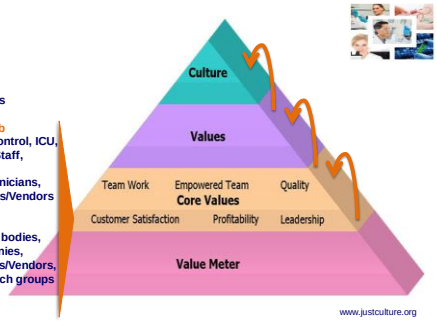
Potential Lab Customers

- **Hospital – Based Lab**

Emergency, Infection Control, ICU, Medical Staff, Nursing Staff, Outpatients, Pharmacy, Radiology, Referring Clinicians, Research labs, Suppliers/Vendors

- **Reference labs**

Clinicians, Government bodies, Pharmaceutical Companies, Referring labs, Suppliers/Vendors, University based research groups



www.justculture.org

"Right" Culture Requires Shift in Thinking

Not Effective Thinking	Effective thinking
Who did it?	What happened? Why?
Punitive	Fair and just
Bad people	Bad systems
Penalize the reporter	Thank the reporter
Confidential	Transparent learning
Investigation	Root cause analysis
Independent silos; no/little communication	Inclusive and interdisciplinary team; lots of communication

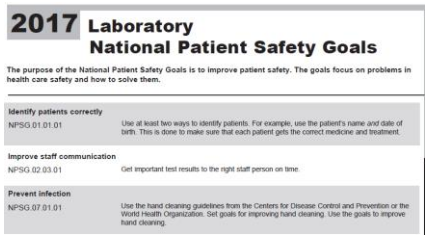
www.dana-farber.org/pat/patient-safety/patient-safety-journey.html

"Right" Culture Requires Shift in Thinking

Not Effective Thinking	Effective thinking
Thinking errors are rare	Realizing errors are everywhere
Great care	Great care in a high-risk environment
Lack of direction; staff make it up as they go along	Principles of fair and just culture, guidelines algorithms, flow charts
Risk of disclosure/confidentiality	Moral duty, risk of non-disclosure
Great staff; poor systems	Great staff; great systems
Deliver care to patients	Partner with team, patients and families

www.dana-farber.org/pat/patient-safety/patient-safety-journey.html

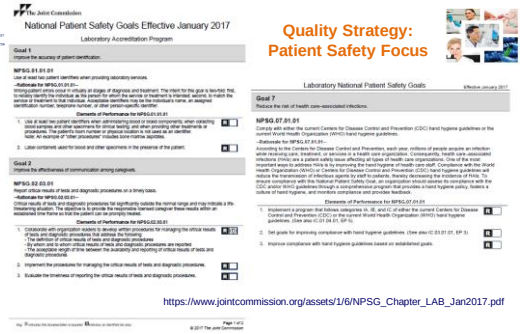
Quality Strategy: Patient Safety Focus and Organizational Culture



- The National Patient Safety Goals (NPSGs) were established in 2002 to help accredited organizations address specific areas of concern in regards to patient safety.
- The first set of NPSGs was effective January 1, 2003.
- The Patient Safety Advisory Group advises The Joint Commission on the development and updating of NPSGs.

https://www.jointcommission.org/assets/1/6/NPSG_Chapter_LAB_Jan2017.pdf

Quality Strategy: Patient Safety Focus



https://www.jointcommission.org/assets/1/6/NPSG_Chapter_LAB_Jan2017.pdf

ECRI Institute Names Top 10 Patient Safety Concerns for 2017

Since 2009, when ECRI Institute PSO began collecting patient safety events, the PSO and partner PSOs have received more than 1.5 million event reports and reviewed hundreds of root cause analyses. "The 10 patient safety concerns listed in our report are very real," says Catherine Pusey, RN, MBA, associate director, ECRI Institute PSO. "They are causing harm—often serious harm—to real people." This year's list includes:

- Information Management in EHRs
- **Unrecognized Patient Deterioration**
- Implementation and Use of Clinical Decision Support
- **Test Result Reporting and Follow-Up**
- Antimicrobial Stewardship
- **Patient Identification**
- Opioid Administration and Monitoring in Acute Care
- Behavioral Health Issues in Non-Behavioral-Health Settings
- Management of New Oral Anticoagulants
- Inadequate Organization Systems or Processes to Improve Safety and Quality

ECRI Institute Patient Safety Organization (PSO) has been designated by the U.S. Department of Health and Human Services as a federal Patient Safety Organization (PSO) under the Patient Safety and Quality Improvement Act of 2005. ECRI Institute is designated as an Evidence-based Practice Center by the U.S. Agency for Healthcare Research and Quality. www.ecri.org/pso

2017 Top Challenges and Priorities for Process management

Based on a short survey results to understand conducted by American Productivity & Quality Center

The difference between formal and informal leadership and the importance of informal leadership roles in managing quality*

*) CLSI - GP38

Visit C-CLM Webpage

http://www.ifcc.org/ifcc-education-division/emd-committees/c-clm/6-c-clm-publications-and-survey-reports/

Phase 5

Performance Excellence – The Pursuit of Excellence

- **The culmination of the laboratory quality continuum.**
- **Achieving excellence for the entire organization and all management systems, including leadership, strategy, customers, measurement systems and analysis, knowledge management, workforce, operations, and results.**
- **Labs foster innovation,continous improvement, achieving/exceeding benchmarks, and long-term success.**
- **Labs continously strives to operate at a best-practice level and to achieve recognitions that differentiate their lab as world-class as the National Malcolm Baldridge Quality Award in US.**

Excellence in Quality Awards

TABLE 5.1: VALUE, PRINCIPLES AND CONCEPTS COMPARED

BALDRIGE AWARD Values and Concepts	CAE – QUALITY Principles	EUROPEAN QUALITY AWARD Concepts
Visionary leadership	Leadership through involvement	Results oriented
Customer-driven excellence	Primary focus on stakeholders/customers and the market place	Customer focus
Organizational and personal learning	Cooperation and teamwork	Leadership & constancy of purpose
Valuing employees and partners	Prevention based process management	Management by process & facts
Agility	Factual approach to decision making	People development & involvement
Focus on the future	Continuous learning and people involvement	Continuous learning, innovation & improvement
Managing for innovation	Focus on continuous improvement and breakthrough thinking	Partnership development
Management by fact	Fulfill obligations to all stakeholders and society	Public responsibility
Public responsibility and citizenship		
Focus on results and creating value		
Systems perspective		

Performance Excellence – The Pursuit of Excellence

- **DGMC Lab supports 325,000 annual patient visits and 6000 admissions.**
- **Largest POC testing program in the Air Force, managing 23 sites**
- **Serves in a 116-bed medical treatment facility**
- **Performs 1.2 million tests per year in Chemistry, Special Chemistry, Hematology, Coagulation, Immunology, Microbiology, POCT, Histology, Cytology and Transfusion Services**
- **MLO asked those submitting nominations for the 2017 Lab of the Year award to discuss their lab in terms of Six Criteria:**

  Customer Service, Productivity, Teamwork, Education and Training, Strategic Outlook, and Lab Inspections

https://www.mlo-online.com/

3 Questions to Ask About Your QMS in your laboratory

1. Are you cultivating quality management leaders in your organization - **laboratory**?
2. What is the proper ratio of corporate versus local quality management?
3. What is the role of technology in building a quality culture **in your laboratory**?

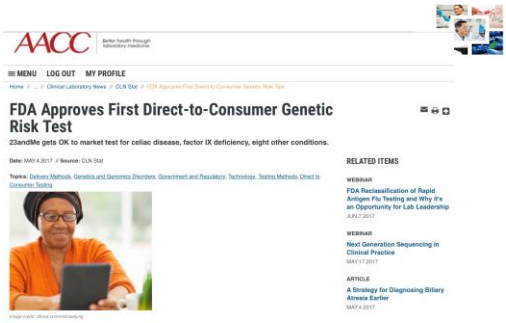
Audience Response

According to what you know about QMS from today's presentation:

1. **There is no change in my previous answer regarding the amount of revision necessary.**
2. **My existing QMS needs more revision than I previously thought.**
3. **My existing QMS needs less revision than I previously thought.**
4. **My existing QMS is not based on a QSE model.**
5. **I do not have a QMS yet.**

The early physician's laboratory was certainly more modest than the 21st-century POL.

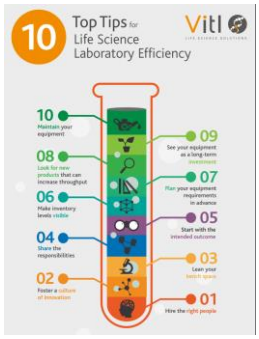
The urinalysis was commonly performed not only at the bedside but also in the physician office laboratory during the nineteenth century.



Summary

- Standards form the basis for quality practices. They are developed by the organizations.
- QMS improve laboratory practice.
- **Where to Start** - Approaches to implementation for QMS will vary with local situation. Start with the easiest, implement in stepwise process.
- **Raising Quality Awareness** - Continuous progression along the lab quality continuum will reduce costs, result in the strategic advantage of differentiation in the marketplace through quality and offering the very best care for the patients.
- Embedding an emphasis on patient safety into the lab's organizational culture can reap many benefits for the overall organization.
- Accreditation is an important step in the continual improvement of the QMS.
- The implementation case of ISO 15189 at a global perspective could be seen as currently unsuccessful, since only a few countries here and there have adopted it wholesale. This is very different than the rapid and widespread adoption of ISO/IEC 17015 in other science fields. On a harmonization perspective of good laboratory practices, the slow uptake of 15189 is a major concern. Nevertheless, while ISO 15189 is not mandatory in most countries, this standard does remain the most common global reference for quality in medical laboratories. Its influence around the world cannot be overstated.

Needless to say!



Committee on Clinical Laboratory Management Educational Workshop

IFCC WorldLab Durban 2017

Educational Workshop

"Intelligent Clinical Laboratory Management: Impacts on Quality System Improvement"

October 22, 2017 • Durban, South Africa

Educational Workshop
Intelligent Clinical Laboratory Management: Impacts on Quality System Improvement
October 22, 2017 • Durban, South Africa

Workshop Schedule

8:00 – 8:45 a.m.	Workshop Registration	
8:45 – 9:00 a.m.	Welcome and Introductions	
9:00 – 9:35 a.m.	Defining analytical performance specifications	Martinus Olthr
9:35 – 10:10 a.m.	Principles of effective verification/validation strategies for laboratory analytical methods and reagents	Edward KANDELL
10:10 – 10:30 a.m.	Coffee/Tea Break	
10:30 – 11:05 a.m.	Which should QMS Standard be chosen for the structural quality of a medical laboratory?	Martinus Olthr
11:05 a.m. – 11:35 a.m.	Use of Delta Checks: A requisite method in Quality Control	Sedef YENICE
11:35 a.m. – 12:00 noon	Discussion	
12:00 noon – 1:00 p.m.	Lunch	
1:00 – 1:35 p.m.	Management responsibility in Good Laboratory Practice	Praveen SHARMA
1:35 – 2:05 p.m.	Control of laboratory error through 'Corrective and Preventative Actions' (CAPA)	Edward KANDELL
2:05 – 2:30 p.m.	Coffee/Tea Break	
2:30 – 3:05 p.m.	'How-To' implement an effective proactive risk management strategy	Sedef YENICE
3:05 – 3:35 p.m.	Ethics in clinical laboratory practice	Praveen SHARMA
3:35 – 3:50 p.m.	Discussion and Closing Remarks	

Committee on
Clinical Laboratory Management
Educational Workshop

Symposium

"Improvement in clinical laboratory services: Approaches to adding value"
October 25, 2017 • Durban, South Africa

Everything is well, that ends well…

- Ioana Brudaşca

Mulţumesc

Comments and Questions