Laboratory Medicine Enters the Era of Quality Management Systems:

ISO 15189 as a a Global Standard

ROBERT L. MICHEL
Editor In Chief

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rmichel@darkreport.com
ph: 512-264-7103
fax: 512-264-0969

Major Points Today

- "Quality Management Systems" (QMS).
- International scheme of ISO standards.
- Why QMS and ISO are relevant to operation of clinical laboratories and histopathology laboratories.
- Importance of "Information Centers" about QMS and social networking.

First, Challenges Ahead for Laboratories

- **One:** Aging populations, increased incidence of chronic and acute disease.
- **Two:** Not enough money in health budgets to meet rising demand and cost of health services.
- **Three:** Complexity of genetic testing and molecular diagnostics even as—in USA—many U.S. Baby Boomer pathologists and lab professionals retire.
- **Four:** Expect more multi-analyte lab tests—microarrays and multiplex assays.

A New Premise In Lab Testing

Medical laboratories must now perform to a higher standard of quality—and that standard is increasing.

How Is "Quality" Changing?

- Primary emphasis: increased precision of analytical test results that directly support improved patient outcomes.
  - *Integrity, accuracy, reproducibility, quality*
- Secondary emphasis: quality service as experienced by patients.
  - *Lab appointments, specimen collection, billing, patient service calls, and more*

New Quality Mindset for Labs

- Perfect timing for labs to use Lean, Six Sigma, and similar methods specifically to improve quality of analytical test results.
- Leader in this objective were assembled at *Lab Quality Confab* last November.
- It was nation's first-ever look at the intersection of process improvement methods with lab test analytical quality.

Review of the Basics

QMS is Not QC and QA

- **Quality Control (QC) :** is this test method working correctly now with this batch of specimens?
- **Quality Assurance (QA):** asks different questions about processes.
  - "How many lab reports have errors in them that need correction?
  - How many of identified lab errors adversely affect the patient?

Lean, Six Sigma Are Not QMS

- Lean, Six Sigma, Process Improvement techniques are methodologies.
- They are used to improve processes.
- They support improvement in workflow.
- These are not comprehensive QMS models.

Defining a QMS

- ***Quality Management System (QMS)***—*Collective policies, plans, practices, and the supporting infrastructure by which an organization aims to reduce and eventually eliminate non-conformance to specifications, standards, and customer expectations in the most cost-effective and efficient manner.*

FROM: www.businessdictionary.com

Quality Assurance (QA)

- Measurements of aspects of pre-analytic, analytic, and post-analytic laboratory work processes to verify whether the process is performing as intended. Examples:
  - Number of unacceptable samples received for testing/analysis.
  - Number of unaccounted for ("lost") samples.
  - Number of times QC controls did not give the correct values and reasons for same.
  - Number of times laboratory instrumentation was not functional and reasons for same.

Quality Control (QC)

- Testing performed with samples of known values to verify that a given test method worked as intended so that patient results can be considered valid. Examples:
  - Control reagents that are positive and negative—or reactive and nonreactive—for a qualitative analyte.
  - Control reagents with abnormally low, normal, and abnormally high quantitative values.

Quality Management System (QMS)

- Proactively designed management processes and procedures that build quality into the daily work processes. Includes:
  - Document and record control
  - Management plan for each piece of equipment
  - Training in job tasks, initial competence assessment
  - Ongoing competence assessment
  - Complaint resolution process
  - Nonconforming event reporting and analysis
  - Internal auditing program
  - Ongoing continual improvement

Now Meet ISO 9001

- Created by the **International Standards Organization** (ISO) in 1987.
- Most widely-accepted global standard by which all other quality management systems are judged.
- Used worldwide in all industries.
- Used by both manufacturers and service organizations, including healthcare providers.

Then Came ISO 15189

- First issued in 2003, thus "ISO 15189:2003 Medical Laboratories."
- Update issued in 2007 and new update soon to be issued.
- ISO 15189 derives from the ISO 9001 QMS and is tailored specifically for medical laboratories.

Medical Lab-Specific QMS

- First, it is a system, which means a collection of approaches, ideas, and processes organized to act in a unified way.
- Second, it is designed to improve quality.
- Third, it is based on the process model of the mother of all quality management systems: ISO 9001.

ISO 15189 Is QMS for Labs

- **ISO 15189:2007 Medical Laboratories**—*specifies requirements for quality and competence particular to medical laboratories.*
- **ISO 15189:2007** *is for use by medical laboratories in developing their quality management systems and assessing their own competence, and for use by accreditation bodies in confirming or recognizing the competence of medical laboratories.*
- From ISO website at: *http://www.iso.org*

Goal of Global Standard

- International Standards Organization (ISO) was founded in 1947.
- ISO was born from the union of two organizations:
  - ISA (International Federation of the National Standardizing Associations), established in New York in 1926; and
  - UNSCC (United Nations Standards Coordinating Committee), established in 1944.

Accreditation to 15189

- In the ISO scheme, "accreditation" is different than "certification."
- This can be complicated, so let's keep it simple.
- ISO does not certify nor accredit.
- Third parties perform these functions.

Certification—Three Ways

1) Organization may simply declare compliance (first party declaration); or
2) The organization's customers may accept compliance (second party recognition): or,
3) The organization can seek recognition by an organization (third party certification).

Note: Certification denotes "conformance."

Accreditation

- For testing laboratories (industrial, research, and clinical), accreditation differs from certification in one important way.
- Compliance with the QMS throughout the organization is audited; PLUS…
- Accreditation includes audit of the quality of the testing processes by auditors knowledgeable about these processes.
- This is independent evaluation of lab's technical competence.

Global Accreditation

- Names to know.
- **International Accreditation Forum** (IAF) accredits "accrediting bodies" using ISO 17021.
- **International Laboratory Accreditation Cooperation** (ILAC).
- ILAC is a separate organization of accreditation bodies, specifically for accreditation of laboratories, including their QMS.

ISO 15189 is the Future

- Increasingly, people and products move freely across the world.
- Concept of "open borders" drives expansion of international trade.
- ISO 15189 is an accreditation vehicle that creates an audit process that is accepted by participating nations.
- Example of 15189-accredited medical labs that perform clinical trails testing.

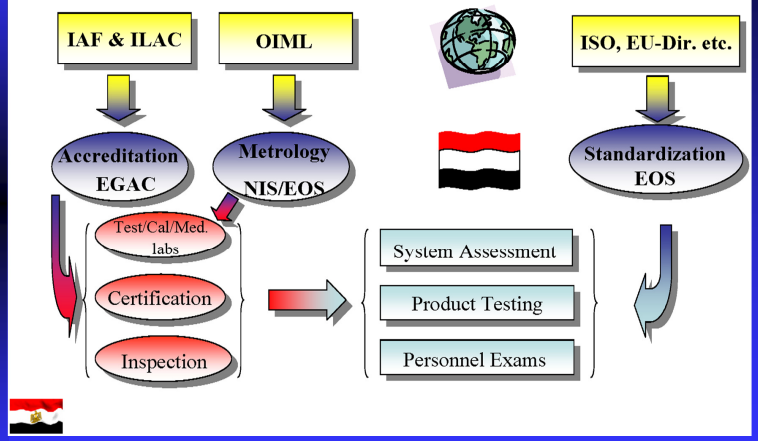
ISO 15189 is Important

- Across the globe, nations are passing laws to require ISO 15189 accreditation to meet national licensing and/or accreditation requirements.
- Australia requires ISO 15189 for pathology laboratories since 2005. *(administered by its National Association of Testing Authorities—NATA)*
- In Canada, since 2003, Ontario Province mandates ISO 15189 as the requirement medical laboratories must use to meet accreditation laws.

Examples in Europe and Africa

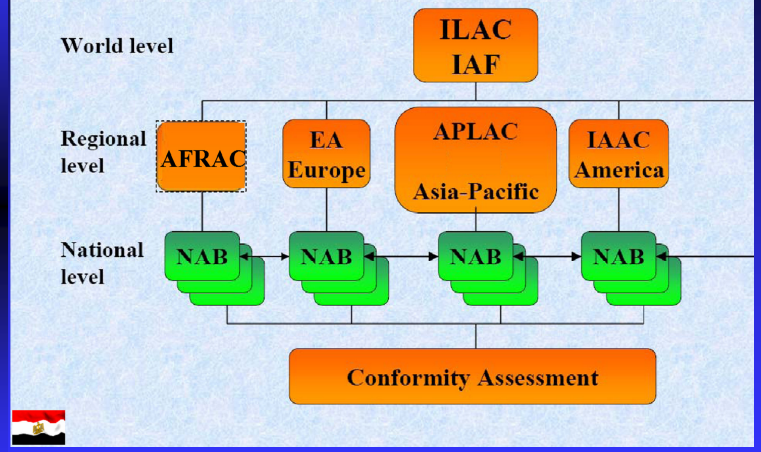
- European Union required blood banks to accredit to ISO 15189.
- Egypt has active accreditation program utilizing ISO 15189 and other ISOs.

Quality Structure (general)



Presentation by HASSAN SHAARAWI
Executive Director, EGAC (Egyptian Accreditation Council), May 2010

Co-operation in Accreditation



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There's More To ISO Scheme

- Along with ISO 15189, there are ISO standards relating to *in vitro* diagnostic (IVD) analyzers, instrument systems, and test kits.
- **Technical Committee 212** is responsible for ISO 15189.
- It has published more than 20 standards.

Other IVD ISO Standards

ISO TS 22367: Reduction of error through risk management and continual improvement

ISO 22870: Point-of-care testing

ISO 15190: Requirements for Safety

ISO 18113: Information Supplied with IVD Medical Devices (Labeling)

Other IVD ISO Standards

ISO 15198: Validation of User Quality Control Procedures by IVD Manufacturers

ISO 15197: Requirements for blood glucose monitoring systems for managing diabetes mellitus

ISO/TS 25680: Calculation and expression of measurement uncertainty for medical laboratories

ISO 17511: Traceability of values assigned to calibrators and control materials

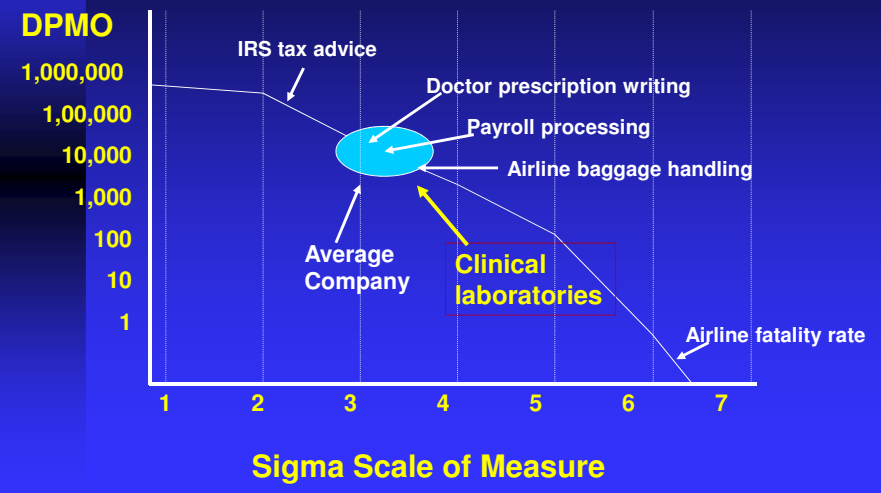
Moving Toward A Goal

- End Game: ISO standards for each IVD instrument, test kit, reagent.
- Medical laboratories accredited to ISO 15189.
- Ideal that an ISO-accredited medical laboratory should consistently produce patient test results that meet the manufacturer's specifications, are accurate, and are clinically useful.

Understanding Six Sigma Quality

Sigma Level	Defects per Million Opportunities	Yield
6	3.4	99.9997%
5	233	99.977%
4	6,210	99.379%
3	66,807	93.32%
2	308,537	69.2%
1	690,000	31%

Where Does the Laboratory Industry Stand?



Six Sigma for Lab Processes

Q-Probe QUALITY INDICATOR	% ERROR	DPM	SIGMA*
TDM timing errors	24.4	244,000	2.2
Cytology specimen adequacy	7.32	73,700	2.95
Surgical pathology specimen accessioning	3.4	34,000	3.3
PAP smear rescreening false negatives	2.4	24,000	3.45
Order accuracy	1.8	18,000	3.6
Surg path froz sect diagnostic discordance	1.7	17,000	3.6
Duplicate test orders	1.52	15,200	3.65
Laboratory proficiency testing	0.9	9,000	3.85
Wristband errors (not banded)	0.65	6,500	4
Hematology specimen acceptability	0.38	3,800	4.15
Chemistry specimen acceptability	0.3	3,000	4.25
Reporting errors	0.0477	477	4.8
*Conversion using table with allowance for 1.5s shift			

The following Sigma metrics are drawn from Nevalainen D, Berte L, Kraft C, Leigh E, Morgan T.: "Evaluating Laboratory Performance on Quality Indicators with the Six Sigma scale." *Arch Pathol Lab Med 2000*;124:516-519.

Lab Medicine Is Moving Forward

- Use of Quality Management System is tool for clinical laboratories to continuously improve quality while reducing errors and cutting costs.
- ISO 15189 is growing as the globally-accepted QMS for medical laboratories.
- Use of Lean, Six Sigma, and process improvement are effective complements to ISO 15189.

Creating the "Quality

Creating a "Quality Community"

- Cornerstone of continuous improvement is "benchmarking" in an industry.
- Identifying "best practices" is the necessary first step.
- Among laboratories, this requires active communication and sharing of both data and knowledge.
- Use of QMS and the Six Sigma methods will enable this activity.

Raising Awareness Among Labs

- Use The Dark Report as an example.
- Robert Michel's Quality Journey:
  - 1989-"Quality is Free" at Centex Corp.
  - 1991-W. Edwards Deming at Nichols Institute
  - 1992-Member ASQC (Now ASQ).
  - 1992-Deming's four-way seminar.
  - 1993 First "Total Quality Management" (TQM) projects at Nichols Institute Portland.

Sharing the Quality Story

- The Dark Report launched in 1995.
- *Executive War College on Lab and Pathology Management* launched in 1996.
- Both were opportunities to have innovative laboratories share their "best practices" in a way that is public and accessible.
- At this time, no lab association or society had a focus or emphasis on lab management and lab operations.

Now to the 2000s

- Johnson & Johnson's Ortho-Clinical Diagnostics was first to create a Lean consulting resource.
- Regional meetings in 2001-2002 to introduce Lean to lab community.
- First major Lean Projects in 2003, each was at a sizable hospital laboratory.
- The Dark Report published stories about these innovations.
- Lean Labs presented case studies at *Executive War College* in 2003

Lean in UK, Canada, Australia

- We did Lean presentations in United Kingdom at FiLM in 2004.
- We did Lean presentations in Canada, fall of 2004 at *Executive Edge*.
- We did Lean presentations in Australia in 2006.
- In each country, within 12 months, at least one laboratory had initiated a Lean project.

Lab Quality Confab

- Each year since 2008, a two-day meeting devoted to process improvement, Lean, Six Sigma, ISO 15189.
- 250-300 attendees, 50 speakers, case studies, and presentations.
- Next Lab Quality Confab will be in San Antonio on November 15-16, 2012.
- Visit **www.LabQualityConfab.com** for details.

Then There's DarkDaily.com

- Launched in 2006.
- **Free** e-briefing service to laboratory managers.
- Delivers 3-4 topics each week.
- Now has 12,000 subscribers from 183 different countries!
- ***www.DarkDaily.com*** web site is resource center for QMS, Lean, ISO 15189 and more.
- About 20,000 visitors per month.

Dr. Noble's Quality Resource

- "Making Medical Lab Quality Relevant "
- Blog that is easy to access.
- Launched in 2010.
- Now gets 1,500 visitors per month.
- Currently has 95 topics in blog archives.

Ontario's QMP-LS

- Quality Management Program-Laboratory Services (QMP-LS).
- Web site is useful resource on QMS in clinical laboratories.
- Don't have statistics on web site traffic.

Conclusion

- Laboratory medicine is on a journey to improve quality.
- QMS will be a gamechanger, compared to earlier lab quality initiatives.
- ISO 15189 is helping to bring about a more standardized quality approach that is worldwide.
- The lab quality community is growing.
- The internet and social networking changes how knowledge is shared.

Thank You!

- **Robert L. Michel**
  rmichel@darkreport.com

- For more about ISO 15189:
  - *www.darkdaily.com*
  - *www.labqualityconfab.com*