Why ISO-15189 is Soon to Change Lab Operations and Public Perceptions of Quality

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Goals of This Presentation

- Understand the origins of ISO
- Differentiate between ISO 15189 and LAP
- Understand how the public perceives quality now and in the future.
What is ISO?

- The International Organization for Standardization is a worldwide federation of national standards bodies from over 140 countries.
- Established in 1947.
- ISO is derived from the Greek “Isos” meaning “equal”.
- Because “International Organization for Standardization” would have different acronyms (IOS in English, ION in French, etc). ISO was chosen as an all-purpose name.

Mission of ISO

- The mission of ISO is to promote the development of standardization and related activities in the world with a view to facilitate the international exchange of goods and services, and to develop cooperation in the spheres of intellectual, scientific, technological and economic activity. This work results in international agreements published as International Standards.
How Does ISO Develop Standards

- Standards are developed in response to clearly established need.
  - Standards are developed by Technical Committees (TC) who verify the “global relevance” of the proposed item.
    - Technical Committees are composed of experts from the sectors who have asked for the standards and who would put them to use.
    - Proposals to establish a new TC are submitted to all ISO national member bodies.
    - Experts are chosen by the ISO national member body for the country concerned.
    - TC creates a “consensus draft document” for voting by all member bodies.

Health Care Related Standards

- ISO has a number of health care related standards:
  - Medical Sciences/Healthcare Facilities
    - ISO 11991:1995 – Airway Management
    - ISO 51939:2005 – Practice for blood irradiation dosimetry
  - Medical Equipment (General)
    - ISO 13485:2003 QMS for Medical Devices
    - ISO 15223:2007 Labeling for Medical Devices
    - ISO 15225 – Nomenclature system for medical devices for regulatory data exchange
• Pharmaceutical Standards
  - ISO 11418:2005 – Containers for pharmaceutical preparations

• Laboratory Medicine
  - ISO 7713:1985 – Disposable serological pipettes
  - ISO 12771:1997 – Disposable plastic serological pipettes

Medical Laboratory Specific
  - ISO 15190:2003 – Requirements for Safety
  - ISO 22367:2008 – Reduction of error through risk management and continual improvement
  - ISO 15189:2007 – Requirements for quality and competence

ISO-15189 Accreditation

➢ What is Accreditation to ISO 15189:2007?
  This is an accreditation program & quality management system that focuses on the continuum of care directly connected with improved patient safety and risk reduction. It outlines standards for quality and competence particular to medical laboratories.

➢ How does it differ from certification?
  Certification only looks at a general quality system management where as accreditation also looks at the specific quality & technical competence required.
Accreditation focuses on creating laboratory competency.

Laboratories can be checked and certified for their conformance to international quality management system standards using ISO-9001 but it will not indicate anything about their technical competence or its ability to provide accurate and reliable test data.

What Does ISO 15189 Look At?

- Customer satisfaction & quality of care.
- Quality management of test and calibration data
- Validity and appropriateness of test methods
- Traceability of measurements and calibration to national standards
- Technical competence of staff
- Testing environment
- Suitability, calibration & maintenance of test equipment.
- Sampling, handling and transportation of test items.
CAP ISO 15189 Philosophy

“At the core of the ISO 15189:2007 program is the development of processes that drive quality systems improvements. It is an educational approach based on criteria and procedures that identify best practices & develop technical competence, thus assuring Laboratory consumers that the tests, calibration, or data supplied by the lab are accurate and reliable.”

What Is The Difference Between ISO-15189 and LAP?

- The CAP Laboratory Accreditation Program (LAP) is a CLIA deemed program.
- Compliance with CLIA is a legal requirement, a government MANDATE.
- ISO is voluntary and is a GLOBAL standard with a different scope.
Additional Differences

- ISO uses professional assessors
- ISO assessments are announced and scheduled with the laboratory and CAP.
- ISO is a three (3) year cycle- LAP & CLIA are on a two (2) year cycle.
- ISO allows a variable time for initial accreditation based on laboratory readiness.
- ISO has optional assessments to prepare for accreditation.

How Widespread is ISO-15189?

- It is an internationally recognized standard and in some countries, it is the standard by which laboratories are reimbursed.
- There are ISO 15189 accredited labs around the world, including the US, Canada, Asia, Europe, South America and the Caribbean.
How Does A Lab Get ISO-15189 Accredited?

- Go to the CAP website and gather info.
- Get buy-in from key stakeholders.
- Obtain an official copy of the ISO 15189:2007 standards
  - From www.ISO.org or www.ANSI.org
- Assign the appropriate roles to key staff.
- Do the self assessment.
  - Review and update your QMS.
  - Document your findings.

Getting ISO Accredited

- Perform root cause analysis and corrective actions as necessary.
- Use sources such as CLSI for your QSEs, etc.
- Update your process flow charts

- Re Do your self assessment
- Complete the application and submit.
  - Do a GAP assessment – very valuable - done by assessors. Worth the money.
  - The CAP will guide you thru the rest.

Get ready for a lot of work!
WHY ISO??

- It is an internationally recognized standard that is based on best practices and goes all the way back to Deming. It is an evidence based standard.
- ISO is part of a journey or the natural progression of quality.
  - Process Improvement Programs such as Lean, 6 Sigma, Process Excellence, etc. help prepare you for the ISO journey.

ISO raises the "quality bar" in laboratory medicine.

- At a time when the standards are being lowered to the lowest common denominator and practices are deteriorating, ISO raises the quality bar.
  - Think of CLIA as concentrating on how to do a test and stratifying competency (i.e. waived testing, eQC, lower personnel standards, moderate complexity, high complexity, lack of certification requirements and an overall politicalization of laboratory testing.
  - ISO concentrates on both QUALITY and technical COMPETENCE based on GLOBAL standards and values.
Does It Make A Difference?

Ask yourself this:

- How good is “good enough”?
- Are you comfortable with being “average”?
- How many testing errors are acceptable?
- How does your Lab compare to “world class”?
- Are you satisfied with mediocre quality?

Is ISO Worth The Effort?

- Why does manufacturing tout the ISO-9001 certification standards?
- Why is there suddenly such a focus on quality and pay for performance?
- How do you prove you have quality worth paying for?
  - How long before labs negotiate with payors citing ISO 15189 accreditation to justify higher reimbursement rates?
Does ISO certification Pay?

- In a July 2002 article published in ISO Management Systems, an international group (US and Spain) found:
  - An analysis over a 10 year period of companies in 3 different business sectors found that
    - ISO 9001 certified companies led to improved financial performance measured by Return on Assets.
    - Firms that failed to seek certification showed substantial deteriorations in ROA, productivity and sales; while certified firms avoided such declines.

Tobin's Q (a ratio of the market value of the outstanding financial claims on the firm to the current replacement costs of the assets) values > 1 mean that the firm is extracting more value from its assets than it would from selling them.

- ISO certified companies have consistently higher Tobin's Q values and after certification they tend to rise to a higher level as compared to a control group of non-ISO companies.
Who Will Be Pursuing ISO 15189?

- Going forward ISO-15189 accreditation will be a distinguishing factor in the field.
  - Quest and LabCorp will be pursuing
  - Genzyme and other specialty referral labs too.
  - Do not be surprised to see other “quality top tier” labs pursuing ISO
    - ARUP, Cleveland Clinic, Sonic Healthcare, Tri-Core, Henry Ford Health, Etc.

McKennon Experience

- Immediate impact on grant funding- the Avera Research Department cited the Hospital Lab accreditation in grant applications for clinical trials and found it led to quick acceptance.
- A modest marketing effort has had excellent results with community as well as Corporate Accounts.
Lessons Learned

- IT ISN’T EASY!!!
- It helps to have done Lean or other process improvement system.
- No matter how thorough you think you are, there are always surprises.
- The public is aware of ISO and what it means.

Questions??

Thank you!!