The Future Role of Laboratory Inspections and Accreditation

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Future Role?
The “Inspector”

It’s only my strong, negative attitude that keeps me going. I will get you too!
ISO 15189 Accreditation and CLIA Certification

Accreditation
ISO 15189

CLIA Certification
(CAP, TJC, COLA “accreditation”)
ISO (International Organization for Standardization) states:

- Accreditation is a “procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks”
- Key words:
  - **Authoritative body** means a 3rd party organization granted to accredit medical labs according to widely recognized International Standards
  - **Competent** means lab has to comply with “universal” quality requirements, AND [demonstrate]
  - **Specific tasks** that means to demonstrate specific analytical and medical competences

[Link to ISO website for further reading](https://cdb.iso.org/cdb/termentry/display.action?entry=185007&language=1)
ISO States:

Certification is a procedure...[where] a third-party attestation (i.e., issue of a statement) that specified requirements related to products, processes, systems or persons have been fulfilled (adapted from ISO/IEC 17000, 2005, Definitions 5.2 and 5.5).

Key words:
- Attestation (issue of a statement)
- Specific requirements
- Fulfilled

Certification or Accreditation

- In the U.S., the term “accreditation” is used also for laboratory licensing procedures and for certification of conformance to procedures and processes, e.g., CLIA.

- Examples of this difference in application of terms are the College of American Pathologists (CAP) and Joint Commission (TJC), which “accredit” clinical laboratory testing.

- According to ISO’s definitions, CAP and TJC would be certification not accreditation programs.

Is it Certification or Accreditation?

Confused?
Goal: ISO 15189 Accreditation AND CLIA Certification:

Quality test results for quality patient care

Patient Care
ISO Accreditation or CLIA Certification: (for quality purposes)

You say "either" and I say "either"
You say "neither" I say "neither"
"Either" "either", "neither" "neither"

You say "potato," I say "patattah"
You say "tomato", I say “tomata”

(for this discussion)
Oh, let's call the whole thing off!
ISO 15189 Accreditation and CLIA Certification: The “Devil is in the Details”
ISO 15189 Accreditation: The Laboratory World (outside US)
ISO, from the Greek *isos*, meaning "equal"

- ISO is a network of national standards institutes
  - 161 countries (1 member /country); secretariat in Geneva

- ISO develops cooperation and international standardization

- ISO facilitates exchange of goods and services
  - 18 500 *International Standards on many subjects*
  - 1100 new ISO standards are published every year
ISO15189 (2007)*

Medical Laboratories – Particular requirements for quality and competence

*Will be updated in 2012
ISO 15189 – Specifically Developed for Medical Laboratories

Consists of elements from:
- ISO 9001 - Quality management systems
- ISO 17025 - General requirements for the competence of testing and calibration laboratories

David Burnett, Consultant in quality and accreditation systems. AACC, 7/26/11
Developed by ISO/TC 212:
(33 member countries + observers)

* Argentina (IRAM)
* Australia (SAI)
* Austria (ON)
* Belgium (IBN)
* Brazil (ABNT)
* Canada (SCC)
* Chile (INN)
* China (SAC)
* Czech Republic (CSNI)
* Denmark (DS)
* Finland (SFS)
* France (AFNOR)
* Germany (DIN)
* Iran (ISIRI)
* Ireland (NSAI)
* Israel (SII)
* Italy (UNI)
* Jamaica (JBS)
* Japan (JISC)
* Korea, Republic of (KATS)
* Mexico (DGM)
* The Netherlands (NEN)
* New Zealand (SNZ)
* Norway (SN)
* Portugal (IPQ)
* Singapore (SPRING SG)
* Spain (AENOR)
* Sweden (SIS)
* Switzerland (SNV)
* Turkey (TSE)
* Trinidad and Tobago (TAT)
* United Kingdom (BSI)
* United States (ANSI)
ISO/TC 212 Expertise:

- Background of participants
  - Pathologists
  - Biochemists
  - Technologists
  - Industrial scientists
  - Auditors etc

- Interests
  - Medical laboratories
  - Professional bodies
  - Industry
  - Accreditation bodies
Requirements of ISO 15189...

4. Management requirements
4.1 Organisation and management responsibility
4.2 Quality management system
4.3 Document control
4.4 Service agreements
4.5 Examination by referral laboratories
4.6 External services and supplies
4.7 Advisory services
4.8 Resolution of complaints
4.9 Identification and control of non-conformities
4.10 Corrective action
4.11 Preventive action
4.12 Continual improvement
4.13 Control of records
4.14 Evaluation and internal audits
4.15 Management review

5. Technical requirements
5.1 Personnel
5.2 Accommodation and environmental conditions
5.3 Laboratory equipment, reagents and consumables
5.4 Pre-examination processes
5.5 Examination processes
5.6 Ensuring quality of examination results
5.7 Post examination processes
5.8 Reporting results
5.9 Information systems
Sector specific aspects of ISO 15189

- Defines competences of laboratory director
- Focuses on patient outcome without downgrading the need for measurement accuracy
- Emphasizes not only the quality of measurements but total service of a medical laboratory (consultation, turn around time, cost effectiveness, etc.)

David Burnett, Consultant in quality and accreditation systems. AACC, 7/26/11
Sector specific aspects of ISO 15189

- Uses language and terms familiar in the profession
- Highlights important features of pre and post investigational (examination) issues
- Covers ALL medical laboratory testing regardless of location
- Addresses ethics and information needs of the medical laboratory

David Burnett, Consultant in quality and accreditation systems. AACC, 7/26/11
Editorial

Towards quality specifications in extra-analytical phases of laboratory activity

Healthcare delivery organizations around the world are focusing considerable attention on the definition and use of quality indicators to identify health care improvement opportunities, to measure the efficacy of specific interventions, and to provide a quantitative link between quality of care and cost effectiveness. Using quality indicators for performance and outcome measurement is a way of measuring, monitoring and improving the quality of care and services. Laboratory data are an integral part of the physicians’ decision-making process and, according to current evidence presented at the CDC meeting “Making the Laboratory a Key Partner in Patient Safety” in Atlanta, they influence 70% of medical diagnoses (1). Therefore, the reduction of laboratory errors and the improvement of quality in medical laboratories play a significant role in programs for assessing and improving quality in health care.

The availability of the definitive edition of the new International Standard “Medical laboratories. Particular requirements for quality and competence” (2), released in February 2003, does not appear to have been followed by a debate on the acceptance of this new International Standard for harmonizing existing accreditation programs worldwide and for further detailing quality indicators.

The value of the new International Standard is irrefutable. Medical laboratories are the first medical discipline for which a specific International Standard has been elaborated and delivered, linking the needs of quality management systems, according to the ISO 9001:2000 series, with technical requirements that determine competence in clinical laboratories.

The authors have reviewed available scientific evidence and have made a thorough search in the literature (Medline) for quality indicators and related specifications. According to current recommendations, when standards are not established, and this is our case, they must be based on preliminary data collection where benchmarks are available. The authors base their proposal on data in the literature and on state-of-the-art evidence obtained, in particular, in Q-Probes and Q-Tracks studies of the College of American Pathologists and, based on their findings, report a series of indicators related to the three main processes and sub-processes of laboratory activity. For example, the pre-analytical phase includes indicators related to requesting laboratory tests and collecting, transporting and receiving samples. Moreover, the study details the quality specifications, or limits of acceptability, for each indicator.

The pre-analytic phase, error and risk specifications, however, that currently in this well-informed discipline are not yet measurable, and the debate of this two, few reliable standards, it requires medi-cal evidence by means of a meta-analysis of existing studies. Second, the heterogeneity of data retrieved, due to differences in study designs, types of laboratories, geographical settings, and number and statistical treatment of data compromises the scientific validity of quality specifications for each and every
Quality management system (QMS)

- ...a set of interrelated or interacting elements that organizations use to direct and control how quality policies are implemented and quality objectives are achieved

www.praxiom.com/iso-definition.htm
ISO 15189 and QUALITY MANAGEMENT SYSTEM

Management of Responsibility

Management of Resources

Control, evaluation and improvement

Testing process
- Pre-analytical
- Intra-analytical
- Post-analytical

REQUEST
clinical request

REPORT
clinical information

PATIENT

CLINICIAN

Mario Plebani, MD, Depart Lab Medicine, University-Hospital, Padova-Italy
ISO 15189's Philosophy

Do the “right” thing; have a framework

- Laboratory determines what is appropriate
- Laboratory develops a quality management system to assure everything is “right”
- Laboratory follows it
ISO 15189 Accreditation
(voluntary & mandatory)
ISO 15189 - Internationally Recognized Standard

(B) Used by Accreditation body to make an objective assessment of a laboratory

(A) Used by a laboratory for Self assessment (and in preparation for assessment by an accreditation body)

MEDICAL LABORATORY

Internationally recognized Accreditation Body

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ISO 15189 & Voluntary Accreditation

(B) Used by Accreditation body to make an objective assessment of a laboratory

(A) Used by a laboratory for Self Assessment (and in preparation for assessment by an accreditation body)

MEDICAL LABORATORY

(C) Accreditation Body assesses lab and grants accreditation if it is in compliance with the chosen standard. **Voluntary accreditation**

Internationally recognized Accreditation Body

David Burnett, AACC – Atlanta, 7/26/11
ISO 15189 Accreditation Process

- Validates technical procedures
- Validates competence of director and laboratory to carry out scope of practice
- Validates compliance with the laboratory’s stated quality management system (QMS)
  - Endorses the QMS of audited laboratory

Diagram:
- Technical Requirements
- Management Requirements
  - Quality Assurance
    - (Doing the "right" thing and assuring it is done right)
  - Third party assessment
    - Accreditation
ISO 15189 & Mandatory Accreditation

(B) Used by Accreditation body to make an objective assessment of a laboratory

(A) Used by a laboratory for SELF ASSESSMENT (and in preparation for assessment by an accreditation body)

MEDICAL LABORATORY

(C) Accreditation Body assesses lab and grants accreditation if it is in compliance with the chosen standard. Voluntary accreditation

Internationally recognised Accreditation Body

Regulatory Mandate

D. Burnett, Consultant in quality and accreditation systems. AACC, 7/26/11
ISO 15189 & Mandatory Accreditation

(A) Used by a laboratory for **SELF ASSESSMENT** (and in preparation for assessment by an accreditation body)

MEDICAL LABORATORY

(B) Used by Accreditation body to make an objective assessment of a laboratory

(C) Accreditation Body assesses lab and grants accreditation if it is in compliance with the chosen standard. **Voluntary accreditation**

Internationally recognised Accreditation Body

(D) Government or regulator mandates accreditation to a chosen standard, as part of regulatory framework for medical labs

Regulatory Mandate

(E) Accreditation Body informs Government or designated regulator of the accreditation status of medical lab
International Accreditation Organization

- INTERNATIONAL
- REGIONAL
- NATIONAL

Mandated by the EC to provide Accreditation services

PLUS

Accreditation bodies of 34 ‘European’ countries

David Burnett, Consultant in quality and accreditation systems. AACC, 7/26/11
International Laboratory Accreditation (ILAC)

- Develop/harmonize lab and inspection accreditation practices
- Promote lab and inspection accreditation to industry, governments, regulators and consumers
- Assist and support developing accreditation systems
- Provide global recognition of labs and inspection facilities via the ILAC Arrangement, thus
  - facilitating acceptance of test, inspection and calibration data accompanying goods across national borders

Worldwide acceptance comes from worldwide acceptance of accreditation bodies (in conformance with ISO 17011)

David Burnett, Consultant in quality and accreditation systems. AACC, 7/26/11
CLIA Certification
(Clinical Laboratory Improvement Amendments)

All U.S. clinical testing must be under CLIA (www.cms.gov/CLIA/)

This means you too!
CLIA’s History

- CLIA’1967 (A=Act) regulated ~12,000 (large) labs
- CLIA’1988 regulates ~226,000 U.S. labs (06/11)
  - Signed into law in 1988
    - Enacted due to inaccurate Pap test results
    - Government’s way to ensure quality
  - Regulations to meet law written by FDA, CDC and CMS
  - Regulations are site neutral
    - Same for every test site, e.g., shopping centers to intensive care units
CLIA Regulations

- Based on test complexity or difficulty to perform - e.g. training, knowledge, interpretation
  + What constitutes “lab” testing?”
    × Yes – Results for diagnosis, monitoring, treatment
    × No – Research only (no diagnosis), forensics, paternity

- Test complexity levels
  + Waived
  + Non-waived methods
    × Moderate complexity
      ✗ PPMP (professional performed microscopy procedures)
        × Only for a select group of practitioners
        × Specimen collected as part of physical exam
    × High complexity - Remaining test methods
Tests in Waived Category*

- The list keeps on growing!
  - 1992 only 8 tests
  - 2011 over 100 analytes and 1000 methodologies

- For a methodology/instrument to qualify for waived status, test must be:
  - Simple
  - Accurate
  - No reasonable risk of harm to patient
  - (also approved for home-use)
    - Purchased over the counter

65% of labs are waived!

<table>
<thead>
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<tr>
<th>CLIA EXEMPT STATES</th>
<th>Number of Labs</th>
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<td>3,336</td>
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2011 ASCP Annual Meeting
CLIA Requirements for Waived Tests (covers 65% of testing sights)

Why is waived testing so loved; Let me count the ways:
- Have a CLIA certificate
- Follow manufacturer’s directions
  + Do quality control only as required by manufacturer
- NO testing personnel requirements
- NO proficiency testing (external quality assessment)
- NO method validation necessary
- NO documentation requirements
- NO quality assessment requirements
- NO CLIA inspection for compliance, unless…
CLIA Requirements for Nonwaived Tests (35% of testing sights)
493--Lab Requirements: 2/28/92–1/24/03
(http://wwwn.cdc.gov/clia/regs/toc.aspx)

Subpart A--General Provisions (§493.1 - .25)
Subpart B--Certificate of Waiver (§493.35 - .39)
Subpart C--Registration Certificate, Certificate for
Provider-performed Microscopy Procedures, and
Certificate of Compliance (§493.43 - .53)
Subpart D--Certificate of Accreditation (§493.55 - .63)
Subpart E--Accreditation by a Private, Nonprofit
Accreditation Organization or Exemption Under an
Approved State Laboratory Program (§493.551 - .575)
Subpart F--General Administration (§493.602 - 649)
Subpart G [Reserved]
Subpart H--Participation in Proficiency Testing for
Laboratories Performing Nonwaived Testing
(§493.801 - .807); (§493.821 - .865)
Subpart I--Proficiency Testing Programs for
Nonwaived Testing (§493.901 - .905)
Proficiency Testing Programs by Specialty and
Subspecialty (§493.909 - .959)
Subpart J--Facility Administration for Nonwaived
Testing (§493.1100 - .1105)

Subpart K--Quality Systems for Nonwaived Testing
(§493.1200 - §.1227)
General Laboratory Systems (§493.1230 - .1239)
Preanalytic Systems (§493.1240 - .1240)
Analytic Systems (§493.1250 - .1289)
Post Analytic Systems (§493.1290 - .1299)
Subpart L [Reserved]
Subpart M--Personnel for Nonwaived Testing
(§493.1351)
Labs Performing Provider-Performed Microscopy
(PPM) Procedures (§493.1353 - .1365)
Labs Performing Moderate Complexity Testing
(§493.1403 - .1425)
Labs Performing High Complexity Testing
(§493.1441 - .1495)
Subparts N-O [Reserved]
Subparts P [Reserved]
Subpart Q--Inspection (§493.1771 - .1780)
Subpart R--Enforcement Procedures (§493.1800 - .1850)
Subpart S [Reserved]
Subpart T--Consultations (§493.2001)
Subpart K--Quality Systems
(called QS, but really technical requirements)

- §§493.1241 - 493.1249 – Pre-analytical requirements
- §§493.1251 - 493.1289 – Analytical requirements
  + Procedure Manual
  + Test systems, equipment, instruments, reagents, materials, supplies
  + Establishment and verification of performance specifications
  + Maintenance and function checks
  + Calibration and calibration verification
  + Comparison of test results
  + Corrective actions
  + Test records
  + Assessment
- §§493.1290 - 493.1299 – Post-analytical requirements
CLIA vs ISO 15189 QMS

Management of Responsibility

Management of Resources

Control, evaluation and improvement

CLIA

Testing process

Pre-analytical

Intra-analytical

Post-analytical

CLINICIAN

PATIENT

REQUEST

clinical request

REPORT

clinical information

2011 ASCP Annual Meeting
CLIA’s Philosophy

Prescriptive: must “do” CLIA’s minimum

- Do “xyz” as specified in CLIA and quality results SHOULD be the outcome

(CLIA sets minimum standards for all laboratories to follow and with biannual inspections determine if laboratories are achieving at least those standards)

Note: Minimum often becomes maximum
CLIA and QC mandates

§493.1256 Standard: Control Procedures
(d) 1) perform QC as defined in …specialty and subspecialty requirements (§493.1261-493.1278)
   2) …perform QC using the number and frequency specified by the manufacturer or established by the laboratory …
   3) At least once each day patient specimens are assayed or examined perform the following for
      (i) Each quantitative procedure - 2 QC of different concentrations
      (ii) Each qualitative procedure - negative and positive QC

http://www.cms.gov/CLIA/
ISO 15189 and QC mandates

- 5.6.1 The laboratory shall design internal quality control systems that verify the attainment of the intended quality of results

It is important that the control system provide staff members with clear and easily understood information on which to base technical and medical decisions.
In U.S., CLIA Still Rules:
Paraphrasing J. Yost, director, CMS’ division of Lab Services comments on ISO 15189*

- ISO 15189 accreditation will not satisfy CLIA requirements
  + However, U.S. labs are encouraged to take a QMS approach
  + Labs using CLSI QM documents and ISO standards claim they now work smarter, not harder, and produce higher quality work as a result

- CLIA covers more than 200,000 labs
  + Smaller or less sophisticated organizations would have a hard time applying something as comprehensive as ISO 15189

- ISO 15189 requirements, written for many countries, are too general and, sometimes, not as stringent or specific as CLIA’s
  + ISO 15189 requires the lab to have a competent director; CLIA specifies education, training, experience AND responsibilities

CLIA U.S. Certification

- CLIA Regulations used by a laboratory in preparation for compliance inspection by an agent of CMS (U.S. government)

MEDICAL LABORATORY

- Inspection for Compliance by CMS’ Agent

- CLIA Certification Mandated by Government
College of American Pathologists (CAP) and Accreditation in US

... (one) inspected by a private not-for-profit accrediting organization, [that is one]:

• approved by the Centers for Medicare and Medicaid Services (CMS)

• [has] requirements deemed as equivalent to or more stringent than CMS's regulatory requirements

• inspects a laboratory in lieu of CMS

### CLIA UPDATE – June 2011
Division of Laboratory Services
Centers for Medicare & Medicaid Services

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### CERTIFICATE OF ACCREDITATION BY ORGANIZATION (Non-Exempt only)

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<td>COLA</td>
<td>6,623</td>
</tr>
<tr>
<td>College of American Pathologists</td>
<td>5,602</td>
</tr>
<tr>
<td>The Joint Commission</td>
<td>2,431</td>
</tr>
<tr>
<td>American Osteopathic Association</td>
<td>110</td>
</tr>
<tr>
<td>AABB</td>
<td>219</td>
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<tr>
<td>American Society for Histocompatibility and Immunogenetics</td>
<td>124</td>
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Laboratories voluntarily seeking “accreditation” follow CMS approved requirements that are at least as stringent as CLIA’s.

CLIA Regulations used by a laboratory in preparation for compliance inspection by an agent of CMS (U.S. government).

MEDICAL LABORATORY

Inspection for “Accreditation by CMS’ Approved Agent

Inspection for Compliance by CMS’ Agent

CLIA Certification Mandated by Government

2011 ASCP Annual Meeting
Future Role?
Meaning of U.S. CLIA Certification

Certification... third party gives...

Written assurance
Conforms [to]
Specific requirements

Conforms to CLIA’s Requirements
Role of U.S. Mandated CLIA Certification

- 79,675 out of 225,746 testing sites must meet and adhere to minimum requirements developed by U.S. government agencies to test specimens
  - Focus on quality practices including quality improvement
  - (Waived testing sites must do only waived testing and follow manufacturers’ requirements)
- Can receive Medicare and Medicaid payments
- Can analyze samples from other laboratories
- Are subject to biannual inspection for compliance and must respond to deficiencies, if found
Role of CLIA Certification

- Assures third-party payers (and government) that sites at least meet minimum quality requirements
- Allows government to address
  - Public expectations for testing only conducted by CLIA certified sites
  - Concerns on escalating costs
  - Concerns on excessive and esoteric testing
  - Demand for test and cost accountability
- Provides a mechanism for government to disseminate changes in testing requirements
Role of ISO 15189 Accreditation
ISO 15189 Provides International Recognition of Quality

- Requirements based on *internationally developed and accepted quality practices*
  - Allows test sites to adopt and be measured against *high quality, professional standards*
  - Provides a *uniform framework*

- Provide global recognition of labs and inspection facilities via the ILAC Arrangement
  - Allows for *mutual evaluation and acceptance* of data from accredited labs
    - Comparable data between testing sites
    - Acceptance of data worldwide
ISO 15189 Provides International Recognition of Quality

- **Recognition** for quality efforts
  - Allows for independent acknowledgement of competency to carry out specific tasks (ISO 15189)
  - Gives worldwide acknowledgement

- **Proof** of quality by “outside experts”
  - Provides credibility for increased customer confidence (doctors, patients, public)
  - Enhances national and international reputation
  - Provides a credible marketing tool

- **Promotion** of quality efforts
  - Meets organizations’ expectations
  - Builds staff morale
  - Encourages continual quality improvement
In CONCLUSION, the Future is…

'It is in the interests of patients, of society, and of governments that clinical laboratories operate at high standards of professional and technical competence…

…and it is in the interests of competent laboratories that their competence is verified through a process of inspection, comparison against appropriate standards, as a confirmation of their good standing’

D. Burnett, Consultant in quality and accreditation systems. AACC, 7/26/11
ISO 15189 Accreditation and CLIA Certification

Bright and Sunny