QMS in the ISO World:
ISO 9001 and ISO 15189 - Certification and Accreditation

Quality Confab

3 November, 2010

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Presentation topics

- ISO 9001 vs 15189 – “In a nutshell”
- Conformity Assessment in ISO
  - As implemented by ILAC and IAF
- The Standard for Accreditation Bodies
- Implementation of ISO 15189 in ILAC
- Difference: Accreditation for US medical labs and for every other lab in the world
- International use of ISO and trust in ILAC member accreditation bodies

Certification and Accreditation

- **Certification** states that an organization conducts its activities under a QMS that complies with ISO 9001
- The organization's products or services are produced under a system where consistency and continuous improvement can be expected

Certification and Accreditation

- **Accreditation** states that an organization conducts its activities under a QMS that complies with ISO 9001 *and it is competent to conduct certain conformity assessment activities*
- The organization's products or services are produced under a system where consistency and continuous improvement can be expected *and where competence has been demonstrated*

By ISO / ILAC / IAF agreement

- Testing, Medical, and Calibration Laboratories are to be *accredited* to ISO 15189 or ISO/IEC 17025
- Laboratories should ***not*** seek to have their QMS *certified* as complying with ISO 9001
  - Only exception is when lab is part of larger organization and is covered in a certified QMS

2 Minute Explanation

- Medical Laboratories are a type of "Conformity Assessment Body" (CAB)
- Conformity Assessment Bodies are to be accredited for competence: part of this competence is technical and part is the operation of a QMS
  - Per ISO/IEC 17011
  - Per ISO/ILAC/IAF MOU

Conformity Assessment Bodies

- Types of CABs:
  - Testing laboratories
  - Calibration Laboratories
  - Certification Bodies (e.g., QMS certifiers)
  - Inspection Bodies
  - Proficiency Testing Providers
  - Reference Material Producers
- Note: An accreditation body is *not* a CAB

ISO Conformity Assessment Committee (CASCO)

- In ISO: all Conformity Assessment activities are the responsibility of CASCO
  - Many prior activities in TC's are extended under ISO acceptance, but the standards must comply with ISO Directives
  - TC176 (ISO 9000) TC212 (ISO 15189) are notable TCs with "priors"... but their Standards must comply with ISO Directives

ISO CASCO Policies

- In ISO all Conformity Assessment activities are the responsibility of CASCO
  - For ANY ISO Standard – from any TC – if there are requirements for QMS, those must be consistent with ISO 9001
  - Any TC Standard with requirements for laboratories must comply with ISO/IEC 17025
    - Any requirements for laboratories can not be in conflict with ISO/IEC 17025

What's CASCO?

- CASCO is really complicated, political, and boring, which keeps medical types away.
- It develops standards for the following:
  - Certification bodies (ISO 9000, ISO 13485)
  - Inspection bodies
  - Medical, testing, and calibration laboratories
  - Personnel certification bodies
- CASCO Standards apply to many international trade & business agreements

Who uses CASCO Standards?

- World Trade Organization treaty on Technical Barriers to Trade, references compliance with ISO CASCO standards.
- Global Trade involving products, personnel, testing, calibration, or certified QMS systems.
- CASCO Standards are EU Regulations for any product or service crossing borders

Conformity Assessment Standards and Medical Laboratories

- Every country is different – more so than for any other area of laboratory testing
- In many countries, the ILAC member accreditation body is responsible for accreditation, always in cooperation with national technical organizations
  - Almost all European countries; China; Japan; Australia, Hong Kong, Singapore, Thailand, Australia, Philippines, New Zealand, India

Conformity Assessment Standards and Medical Laboratories

- In some countries the Ministry of Health (however named) has control, or shares control with the accreditation agency
- Often the MoH is strongly influenced by professional medical societies, and may allow professional accreditations rather than independent assessments.
  - USA, Canada, Mexico, Brazil, UAE

ISO CASCO and ILAC

- ISO has MOU with ILAC
- ILAC has MOU with most international organizations for medical laboratories
  - JCTLM (Joint Committee on Traceability in Laboratory Medicine)
  - WHO (World Health Organization)
  - IFCC (International Federation for Clinical Chemistry) – signed June, 2010
  - WADA (World Anti-Doping Authority)

ISO CASCO and ILAC

- ILAC has MOU with other international organizations for laboratories
  - BIPM (International Bureau of Weights and Measures)
  - OIML (International Organization for Legal Metrology)
  - IEC (International Electrotechnical Commission)
  - UN (United Nations)

ISO CASCO: Other

- CASCO Policies adopted by many private accrediting bodies
  - Use ISO 9001 combined with professional Technical Requirements from relevant Industries
- DNV Healthcare
  - Approved by CMS for Hospitals

ILAC Accreditations

- Accreditations for Trade, Health, Industry
  - 69 Full Member accreditation bodies
    - 57 countries
    - Usually national agency (government)
  - 60,000+ laboratories
  - Growing numbers of PT providers, Inspection Bodies, Reference Material Producers
  - 19 Affiliate Members (intend to join)
  - 20 Associate Members (observing)
    - CAP

ILAC Agreements

- Mutual Recognition Agreement (MRA) among Accreditation Regions and their member bodies:
  - APLAC (Asia Pacific) – 32 ABs (21 countries)
  - EA (Europe) – 30 EU member ABs
  - IAAC (Inter-American) – 30 ABs (22 countrys)
  - Unaffiliated (Africa, Middle East, and Central Asia) ~ 6 countries

ILAC MRA

- Mutual Recognition of Accreditation requires common reference:
  - ISO/IEC 17011: General requirements for accreditation bodies accrediting conformity assessment bodies
  - ILAC (and Regional) Policies
    - Proficiency Testing, Traceability
- Requires an On-site Assessment for conformity with 17011 and ILAC Policies, every 4 years, or when Scope expands

ISO/IEC 17011 - Key Requirements for Accreditors

- Operate a Quality Management System
  - Meets ISO 9001
- Demonstrate Strict Impartiality
  - No apparent Conflict of Interest
  - *Cannot run PT as a commercial activity*
- Train and Monitor Competent Assessors
  - *Trained* to assess, *tested* and *monitored*
- Involvement of all major stakeholders

Differences in ILAC… "unannounced" inspections

- Currently in the US for CLIA "unannounced inspections" are required in order to check that the CLIA requirements are being followed every day
- In the ILAC paradigm assessments are always planned and announced, because a trained assessor can easily tell whether the QMS is operating every day

What's The Difference?

- Unannounced inspections are a symptom of the problem, they are not a solution
- This can happen in ILAC, but only in extraordinary circumstances (complaint).
- Assessments are disruptive and the laboratory needs to plan accordingly.
  - Adjust workload
  - Assure key personnel are available

In the ILAC Model
The expertise is in the Assessor

- In US for CLIA, the expertise is in the checklist – accreditors devote enormous resources writing the details in the checklist; CMS spends enormous resources reviewing them
  - Puts the expertise into the checklist
  - Should be Guidelines for Practice

What's The Difference?

- Problem – this takes a lot of time and is never current. It also isn't necessary - a competent assessor knows it.
- Current practices are robust for incompetent assessors, but restrict the ability of an expert assessor to interpret the requirements for a local condition.
  - Limits the need to train the Assessor

What's The Difference?

- In ILAC Accreditations we rely on the expertise of the assessor and his/her knowledge about testing within a QMS
  - Train only experts with 10 years experience and good communication skills
  - 5 day training (15% washout rate)
  - Monitor 1st assessment and every 3 years, track all evaluations (10-20% washout)
  - Overall 25-35% washout of experts

What's The Difference?

- ***Assessing*** is a skill – it cannot be assumed to come with technical expertise in a field of testing
  - Put the Expertise into the assessor, not into the checklist
- Difficult concept in US Medical community

In the ILAC Model
The role of QMS

- In ILAC (ISO 17011), the QMS is the foundation on which all other testing activities occur, and is a fundamental part of all technical assessments
- Not an add-on module

Summary ILAC and ISO 17011 vs CMS/CLIA

- Operate a QMS “It takes one to know one”
- Put the expertise into the Assessor
- No PT as commercial activity
- Include all Stakeholders
- Competence in accreditation verified by Peer Accrediting Bodies

Trust in the ILAC MOU

- US CPSC – labs accredited to ISO/IEC 17025 with appropriate methods in Scope, for acceptance of products for children and for other consumer goods (lead paint, phthlates in plastic, cadmium, etc.)
- US Congress (proposed) for Food Safety
- US DoD for Environmental testing

Trust in ISO 17025

- US EPA for environmental laboratories in drinking water and in The NELAC Institute standards – formal basis for the Standards for all regulated environmental testing in 14 States, and informally in at least 23 more States

Trust in ISO/ILAC and A2LA

- USDA Food Safety Inspection Service
  - All 3 regional laboratories and 1 national lab
- US FDA Office of Regulatory Affairs
  - All 12 regional laboratories
- US DoD Veterinary Food Analysis
- US DHS Transportation Security Lab
- US DHS Critical Reagent Program for Bio-defense Laboratories, RM, PT
  - Includes 52 mobile WMD labs US Nat Guard

Trust in ISO/ILAC and A2LA

- Both USADA (US Anti-Doping Authority)
  - Both Labs: UCLA and Utah
- Seven State Agricultural Laboratories

Corporations trusting A2LA and ILAC recognition

- Agilent Technologies
- Alcoa
- BASF
- DuPont
- Dow Chemical
- Exxon Mobile
- General Motors
- Harley Davidson
- Herman Miller
- Hitachi
- Honeywell
- Intel
- Johnson Controls
- Lexmark
- Lockheed Martin
- Motorola
- Northrop Grumman
- Philip Morris
- Pratt and Whitney
- 3M

Conclusions

- Under ISO/ILAC/IAF agreement, laboratories are to be accredited, not certified to ISO 9001
- ISO standards for laboratory accreditation are widely accepted for trade and health matters
- ISO/IEC 17011 is the essential common base for accreditation using ISO standards
- ILAC provides assurance of compliance with ISO/IEC 17011 and application of ISO 15189
  - In all countries, all areas of testing (**), calibration, inspection, PT, and reference materials

**…except US medical testing

Conclusions

- A2LA is an Influence Leader in ILAC
- You already trust A2LA accreditation in key areas of public health

- Check us out!

  www.a2la.org

Thank You