American Association for Laboratory Accreditation

Clinical

Raising the Bar in Laboratory Quality...

Getting Started with ISO 15189 in Your Lab: Introduction to Resources, Training, Implementation, and Timelines for Earning Accreditation

Topics

- What is ISO 15189?
- What is Accreditation?
- Preparing for Assessment
- On-site Assessment Actions
- Corrective Action Process
- Mutual Recognitions

Management System

- A broad term that includes the laboratory's quality manual, work instructions, procedures, policies, systems, forms, external documents
- Helps ensure uniformity in processes, training and auditing actions

What *is* ISO 15189?

- Title - *Medical laboratories — Requirements for quality and competence*
  - Prepared by ISO Technical Committee ISO 212 – *Clinical laboratory testing and in vitro diagnostic test systems*
  - Originally published in 2003. Revised in 2007 and 2012.
  - Based upon:
    - ISO/IEC 17025 – General requirements for the competence of testing and calibration laboratories
    - ISO 9001 – Quality management system requirements

What *is* ISO 15189?

- Quality System Requirements
- Technical Requirements
- Laboratory Information System (LIS) Requirements
- The terminology used and processes were specifically written for medical testing laboratories

How do I obtain a copy of ISO 15189?

- Copyrighted ISO standard
- Available for purchase from:
  - www.iso.org
  - www.ansi.org
  - www.clsi.org

Use of ISO 15189

- Medical Laboratories base their management systems on this standard to demonstrate their technical competence

- Accreditation bodies use this standard as a tool to evaluate and confirm technical competence and management system compliance in order to grant accreditation to medical laboratories

Use of ISO 15189

- Accreditation bodies in all 27 EU countries adopted the standard for voluntary accreditation
- In some countries, it is the standard by which laboratories are reimbursed (ex. Australia, India & China)
- Growing use in US – compliments CLIA requirements nicely

What is Laboratory Accreditation?

Laboratory Accreditation

- Defined as a procedure by which an authoritative body* gives formal recognition that a *Conformity Assessment Body* fulfills specified requirements and is competent to carry out specific tasks.

*(e.g. A2LA)

  - *Conformity assessment body*: organization that fulfills specified requirements and is competent to carry out specific tasks and that can be the object of accreditation
    - i.e. Applicant Medical Laboratory

Accreditation Ten Second Tutorial

__Do__ing what you __say__ you are doing

And being able to __prove__ it!

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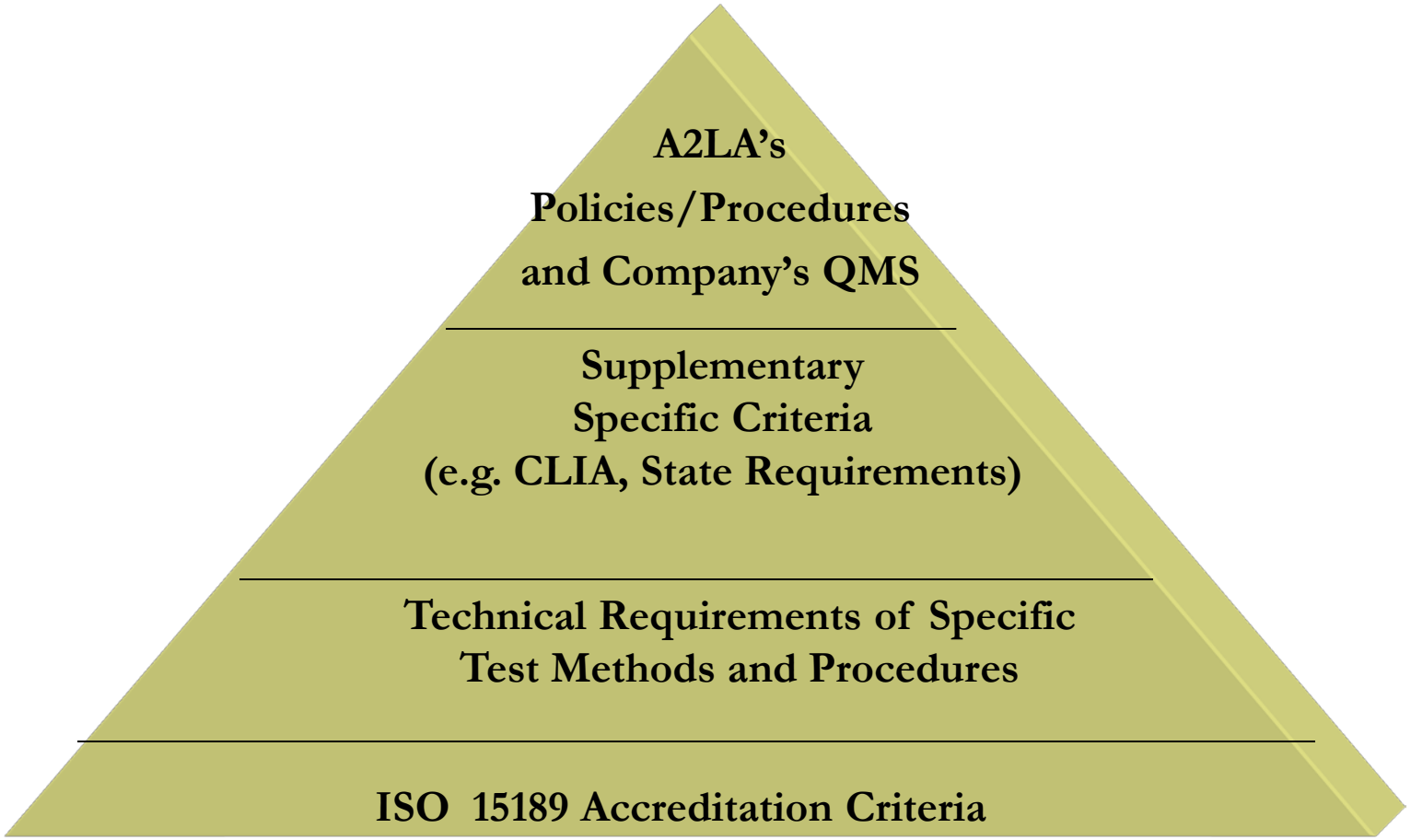
Three Critical Thoughts

- Does the laboratory "**say**" what they do?
  - Are there written documents (policies, procedures, arrangements) that meet the requirements of ISO 15189?
- Does the laboratory "**do**" what they say?
  - Are they in compliance with their own quality system, test methods and ISO 15189?
- Can the laboratory "**prove**" it with their records?
  - Ranging from having training records to standards preparation to work books to patient reports to audit reports and everything in between?

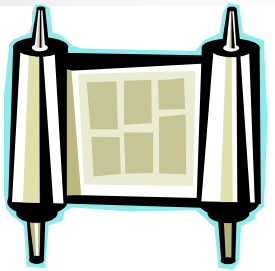
Accreditation Requirements



Some Terms Defined

- **Shall** = imperative
- **Should** = strong recommendation
- **Policy** = rules – the "what"
- **Procedure** = step-by-step – the "how"
- **Documents** = the "what" and "how"
- **Quality System** = written policies, procedures, arrangements, etc. (all of the documents)
- **Record** = history (the "proof")

"Documents"



ISO 15189 defines these terms as written "documents" and in this context they describe how work IS to be done:

- Policy
- Procedure
- Instruction
- System
- Plan
- Define
- Specify
- Pre-defined
- Pre-determined
- Arrangement

"Records"

ISO 15189 defines these terms as "records" and *in this context they serve as historical evidence of how work WAS done:*

- Record
- List
- Register
- Formulate
- Validate
- Evaluate
- In Writing
- Monitor
- Feedback

Deficiency (Nonconformity)

- A departure from or an instance of noncompliance with a condition or criterion for accreditation:
  - ISO 15189
  - Method
  - Specific Program Requirement(s)
  - Policies & Procedures

"Weasel Words"

- "Where practicable"
- "Where necessary"
- "Including but not limited to"
- "Where appropriate"
- "Where possible"
- "Whenever reasonable"
- "If relevant" "Where relevant"

"Weasel word" doctrine

Who's right when there is a difference of opinion between the lab and the assessor?

- Unless the assessor has non-refutable objective evidence of the technical validity of enforcement of weasel words, the lab is always right.
- A weasel word is also enforced if another document (regulation, program requirement, etc.) supersedes the weasel word

Shall plus…

- Shall include – Whatever is listed after "shall include," must be in the procedure or record…unless it is accompanied by a weasel

- Shall ensure – The objective evidence (outcome) must show that the stated goal listed in the standard has been met.

Preparing for Assessment

Resources

- A2LA Public and In-House ISO 15189 Training
  - http://www.a2la.org/training/index.cfm
- ILAC Guidance Document – ILAC-G26:07/2012 "Guidance for the Implementation of Medical Laboratory Accreditation System"
  - Available for free from www.ILAC.org
- A2LA ISO 15189 Checklist
  - Must sign ISO 15189 ownership confirmation form

Preparing…

- Study and understand requirements
- Make a list of every procedure/document required
- GAP analysis of your Laboratory and the ISO 15189 standard
- Assign tasks and achievable deadlines
- Spread the workload

Preparing…

- Involve the technical staff in ensuring the lab's compliance
- Review all technical procedures and quality manual with technical staff
- Perform thorough internal audits (4.14)
- Perform Management review (4.15)

What is needed to start?

- Application
- Quality Manual
- Quality and technical SOPs and Work Instructions
- Completed ISO 15189 Assessor Checklist
- Equipment List & Technical Staff Matrix
- Scope: Test w/ corresponding method IDs
- Proficiency Testing (PT): Enrollment & Successful PT
- Evidence of purchase of ISO 15189

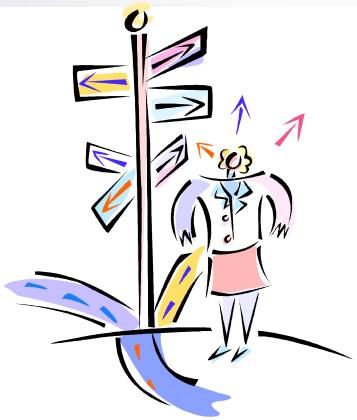
Issues Requiring an Early Start…

- Estimates of Measurement Uncertainty
  - Develop procedures, ID contributing factors
  - Training on performing calculations
- Traceability of Calibrations
  - Thermometers, balances, centrifuges, hygrometers, etc.
- A2LA's Metrological Traceability (P905) and Measurement Uncertainty (P903) documents are great resources

The Application

- Specific information on your laboratory
- Provide the technical staff matrix
- Application date
  - Attests to when laboratory is ready for assessment
  - Send in the accreditation fee

Quality Manual



- Lays out Quality System roadmap
  - No set format required
  - Level of detail based on structure / function of the laboratory and its' needs
    - Clause 4.2.2.2 lists the elements that *absolutely* need documentation here:
      - Examples:
        - Quality policy
        - Roles and responsibilities of laboratory management

Scope of Accreditation

Identifies precisely what the laboratory is accredited for:

Includes a listing of test methods or test technologies, products or materials on which the testing is done, the anniversary date and location of testing facility.

- Must be confirmed by the assessor
- Does not need to include all of lab's capabilities
  - Unlike CLIA, you can get accredited for a "limited" scope of activities

On-site Assessment Actions

Assessor Prior Review

- Review Quality Manual, Lab procedures
  - Do they contain required policies and procedures
  - Review test methods
- Review of past PT results
  - Scope Coverage
  - Look for outliers, evidence of "concern"
- Report on potential areas of noncompliance (ISO 15189 only program)
  - Allows labs to make "minor" fixes in advance
  - Warning if "major" problems exist

What is assessed?

- Management system…
  - Review of ISO 15189 / A2LA Requirements
    - Documents, Records, Interviews
    - Say, Do, Prove
- Review of PT results for competency

What is assessed?

- Management system…
  - Management / administrative activities, such as:
    - Purchasing of consumable materials
    - Management of calibration system
    - Contracts / Client interactions
    - Document control and Change
    - Training records
  - Strict adherence to documented procedures

What is assessed?

- Technical
  - Scientific judgment
    - Performance of test
    - Sampling activities
    - Preparation of reagents
    - Results / data analysis
  - Strict adherence as well as technical correctness
  - Audit must be conducted by those familiar with technology

Watch Performance of Activity

- Confirm that technicians are following procedures
- Judge technical skill
- Gain information about training and supervision
- Detect status of the equipment
- Confirm answers

After the assessor leaves…

- Leaves a deficiency report detailing non-conformances
- Initial corrective action response required within 30 days
- As a new applicant, must resolve deficiencies within 90 days of the date of the exit briefing, or may be subjected to a follow-up assessment
- Corrective action with objective evidence is reviewed by A2LA staff; additional information is requested, if needed
- The Accreditation Council is balloted
- Accreditation is granted when all issues are resolved with objective evidence

Accreditation Timeline

- Initial accreditation effort takes an average of 5-8 months
- Two year anniversary date
- On-site surveillance after 1st year of accreditation (A2LA)
- On-site renewal every 2 years
- On going proficiency testing participation
- Annual Submission of Internal Audits and Management Review (A2LA)

Who accredits the accreditor in the ISO world?

- A2LA is a full signatory to the International Laboratory Accreditation Cooperation (ILAC)
- A2LA operates in compliance with ISO/IEC 17011
- Every 4 years A2LA's ISO 15189 accreditation program undergoes a peer evaluation by fellow ILAC signatories from around the world

ILAC recognition for the accreditation of medical testing laboratories to ISO 15189 means that your laboratory's ISO 15189 accreditation through A2LA will be accepted internationally

A2LA Clinical Accreditation Program Options

- ISO 15189 only
- CLIA only
- Platinum Choice (CLIA + ISO 15189)

For Further Information

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