An Assessor's Perspective: Lessons Learned from Labs Implementing ISO 15189

Greg Cooper CLS, MHA
W. Gregory Cooper LLC
Denton, TX

Certification Versus Accreditation

- Certification
  - **VERIFIES** that all requirements of the Standard have been met.
    - Does the laboratory have a quality manual? (Yes/No)
    - Is there evidence that quality control is practiced? (Yes/No)
    - Does the laboratory have a quality manual? (Yes/No)
    - Are technical procedures easily accessible by testing personnel? (Yes/No)
    - Does the laboratory have an internal audit program in place? (Yes/No)
    - Is there evidence of Management review of Internal Audits? (Yes/No)
    - EN ISO 15189-2007 has 259 requirements
      - Must and Shall

Certification (Audit) Versus Accreditation (Assessment)

- Accreditation
  - **VERIFIES** that all requirements have been met
  - MORE IMPORTANTLY **MUST ASSESS** the competence of the laboratory to perform specific tasks
    - Effectiveness of policies
    - Inter relationship of processes
    - Clarity and appropriateness of procedures
    - Competency of staff and the organization

CLIA Versus ISO Requirements– One Assessor's Opinion

	CLIA	ISO
QMS	+/-	5+
Technical	4+	5+

An ISO Based System

- Horizontal not vertical system
  - Horizontal means all staff, from phlebotomists and clerks to the lab director, are involved in creating, developing and implementing the system
  - Vertical means that Management and supervision create, implement and monitor the system
    - Frontline staff merely follow.
  - Often US labs approach accreditation more from the vertical than horizontal perspective

An ISO Based Accreditation System

- Driven by the Scope of Accreditation
  - Identifies all testing that occurs by name, matrix, and method
    - Prepared by the laboratory
    - Submitted to the accreditor prior to the assessment
      - Used for desk audit
      - Used to architect the assessment
  - Accreditation is test, matrix, method specific

An assessor's observations

- Labs accredited under ISO from this assessor's experience have embraced the horizontal approach

ISO QMS for Medical Laboratories

- Core components that must be present in the QMS (foundational)
  - Laboratory must be legally identifiable
    - Organizational chart
  - Quality Manual
    - Includes quality policy, organizational objectives and scope
    - Explains how quality system processes interact

ISO QMS for Medical Laboratories

- Core components that must be present in the QMS
  - A person identified as the Quality Manager
    - Part time/full time
  - Technical and administrative policies that are supported by technical and administrative processes and procedures
    - Policies specify intent and direction
    - Processes transform the policy into action and confer accountability
    - Procedures describe “how to” perform a specific task

An assessor’s observations

- Quality Manual seems to be a challenge so far
  - Lack of organization, purpose and direction
    - Represents a missed opportunity for the lab to characterize itself
- Organizations are committing to a full time Quality Manager

ISO QMS for Medical Laboratories

- Core components that must be present in the QMS
  - Process for internal audits
    - Must be done regularly
    - Must lead to process improvements
    - Must be independent and non judgmental
    - Can be an external audit
  - Process for control of non-conforming product
    - Bad patient test results
    - Reagents/consumables that do not pass acceptance tests
    - Expired reagents/consumables
    - Reagents/consumables damaged by external causes
  - Process for continual improvement
  - Process for corrective action
  - Process for preventive action

ISO QMS for Medical Laboratories

- Core components that must be present in the QMS
  - Document control system
    - Readily accessible to staff
    - Current
    - Approved
    - Includes Reference materials
  - Records management system
    - Design, use , storage and retention

An assessor's observations

- Document and record control seems to be a challenge so far
  - Document numbering
  - Master list
  - Obsolescence procedure

ISO QMS for Medical Laboratories

- Management Review
  - Complete system at least annually
  - Demonstrates Management commitment
  - Should lead to Management action where necessary
  - Must be documented

ISO Technical Components for Medical Laboratories

- Core components that must be present
  - Personnel
    - Job descriptions
    - Qualifications and duties
    - Adequate numbers of personnel
    - Responsibilities of the lab director
    - Responsibilities for LIS manager and staff
    - Critical employees

ISO Technical Components for Medical Laboratories

- Core components that must be present
  - Training process
    - Staff training, remedial training
    - Competency assessment
    - Continuing education
      - Relates to competency and currency in the field
  - Occupational safety and health

An assessor's observations

- Labs seem to be on top of personnel/training requirements so far
- Labs sponsor internal programs, recruit industry programs, encourage use of online programs, monitor CE compliance
- ISO assessors will be looking for analysis of safety incidents
  - Root cause
  - Corrective action
  - Preventive action

ISO Technical Components for Medical Laboratories

- Requirements unique to medical/testing/calibration laboratories
  - Equipment
    - Verification of performance
      - Method comparison
      - Linearity
      - Imprecision and Bias
    - Calibration of devices and ancillary equipment
      - Calibration of mercury thermometers, digital hygrometers, pipettes, balances, and timers
        - traceability
    - Identification
    - Maintenance
    - Monitoring Environmental conditions: temperature and humidity

An assessor's observations

- Labs are really good on the technical aspects relating to analytical device
  - Need to verify auto dilution
- Not so good on ancillary equipment
  - Verifiable and traceable calibration
  - Understanding need for monitoring
    - Humidity requirements for Olympus mainframe analyzer

ISO Technical Components for Medical Laboratories

- Requirements unique to medical/testing/calibration laboratories
  - Pre-analytical (ISO Pre-examination)
    - Request forms
    - Specimen collection, processing and handling

An assessor's observations

- Need to pay closer attention to remote/ off-site (phlebotomy) services.
  - How they operate
  - Policies
  - Processes and procedures in place
  - Patient instructions and privacy concerns
- Remote/off-site services can be potential sources of failure.

ISO Technical Components for Medical Laboratories

- Requirements unique to medical/testing/calibration laboratories
  - Analytical (ISO Examination)
    - Technical procedures appropriate and validated for intended use
    - Uncertainty of Measurement
      - No internationally approved formula
      - Cumulative standard deviation for now
    - Traceability (See equipment)
      - Analytical methods
        - Evidence supplied by manufacturer
    - Quality Control
      - Assure quality of patient test results
    - External quality assessment

An assessor's observations

- Looking for evidence of compliance
- In event of QC and PT failures looking for evidence of
  - Root cause – more than just a simple answer
  - Corrective action
  - Preventive action

ISO Technical Components for Medical Laboratories

- Requirements unique to medical/testing/calibration laboratories
  - Post-Analytical (ISO Post-examination)
    - Review of results
  - Report of results

An assessor's observations

- Looking for audit trails related to results
- Looking for evidence that original results are retained when corrected reports issued
- Looking for accountability for results
  - ISO pays special attention to the role of the LIS

How to Organize the QMS

- No right way
  - Be creative
- Some suggestions
  - Map laboratory processes as you know them to be
    - Divide the processes into discrete blocks based on laboratory organization or activity
    - Use a cross section of staff
    - Use the map to determine compliance/non-compliance with the requirements of the accrediting organization or the Standard

How to Organize the QMS

- Build the QMS to fit organizational needs
- Link policies, processes and procedures to requirements.
  - Look for gaps
- Process maps are not a part of the QMS
  - But good to give assessors so they can better understand the organization and how it works
  - Provides labs greater insight into operations
  - Identifies potential points of failure

How to Organize the QMS

- A suggestion
  - Have four manuals that comprise and describe the QMS[1]
    - System Manual
    - Administrative Procedure Manual
    - Operations Manual
    - Reference Documentation Manual

[1]John Orthaber, Get Your Ducks in a Row: A step-by-step guide to implementing an ISO 9001 quality management system, Quality Progress, American Society of Quality, October 2010, pp 40-46

System Manual

- Background information and how the system works
  - Management oversight and relationships
  - Organization chart
    - Quality Manager
- Quality policy, organizational objectives
- Key policies as they relate to specific processes or activities within the organization
- Legal identity

Administrative Procedure Manual

- Policies and procedures managing the following processes
  - Management review
  - Human resources/personnel
  - Document control
  - Quality and technical records
  - Internal audits
  - Resolution of complaints
  - Corrective and preventive actions
  - Continual improvement
  - Contract review
  - External services and supplies

Operations Manual

- Policies and procedures managing the following processes
  - Facilities and environmental conditions
  - Equipment validation, verification,
  - Control of non-conformities
  - Pre-examination
  - Examination/quality control
  - Post examination
  - Reporting of results

Reference Documentation Manual

- Technical references
- Maintenance records
- Records of internal audits and corrective action
- Records of preventive action
- Complaint records and resolutions

Accrediting Organizations

- May interpret (further define) ISO Standard requirements for their membership.
  - 5.6.1 The laboratory shall design internal quality control systems that verify the attainment of the intended quality of results.
    - Pretty general
  - Could be defined as:
    - Laboratories shall test quality control materials each day the test is performed. OR
    - Laboratories shall test two concentrations of quality control materials each day the test is performed. OR
    - Electronic controls are insufficient to assure quality of the test results so the laboratory must supplement these controls by testing liquid quality control materials.

Who to Turn To

- Look for an accrediting organization that:
  - Focuses on process
    - Not just how the laboratory meets the specified requirements
  - Allows for or provides pre-assessment
    - Very important to first time ISO 15189 applicants
  - Uses technically qualified assessors not auditors
    - Important that assessors be able to understand the nuances of each laboratory specialty
  - Uses assessors with ISO experience
    - Provides unique insight for a meaningful assessment
  - Regularly trains/re-trains assessors
    - Assures competency and currency
  - Oversees and evaluates assessor performance
    - An ISO 17011 requirement
    - A CQI process

Who to Turn To

- Look for an accrediting organization that:
  - Is recognized to ISO 17011
    - Assures an unbiased, qualified and competent assessment
    - Sets requirements for
      - Assessor competence, selection and training
      - Access to and use of professional expertise
      - Pre-review of Quality System documentation
      - Pre-assessment, assessment and post assessment activities
      - Making accreditation decisions
      - Safeguarding the confidentiality of clients
      - Monitoring assessor performance to establish training needs
  - Preferably is a signatory to the ILAC MRA
    - Confirms that the accreditation body is competent to assess testing laboratories.
    - Maintains membership in Mutual Recognition Agreements
      - Allows other members to recognize each other's accreditation
    - Constitutes a move toward international harmonization

ILAC Accrediting Organizations

- International Laboratory Accreditation Cooperation
  - Started in 1977 and chartered in 1996 to establish a network of mutual recognition agreements among accreditation bodies.
    - Aim of developing international cooperation for facilitating trade by promotion of the acceptance of accredited test and calibration results.
- On 2 November 2000, 36 laboratory accreditation bodies, full members of the International Laboratory Accreditation Cooperation (ILAC), from 28 economies worldwide signed an arrangement in Washington, DC to promote the acceptance of technical test and calibration data for exported goods.
- As of October 2011 there are 71 international signatories

ILAC Accrediting Organizations

- ILAC accrediting organizations are recognized by peer evaluation and must meet the requirements of ISO 17011 to participate in Mutual Recognition Agreements (MRAs)
  - ILAC accrediting organizations must have, implement and maintain a typical ISO Quality Management System (QMS)

One American Accrediting Organization Offering ISO 15189 Accreditation Meeting ALL of These Requirements

- American Association for Laboratory Accreditation (A2LA)
  - www.a2la.org +1-301-644-3248

US Signatories to the ILAC Arrangement as of October, 2011

- **American Association for Laboratory Accreditation (A2LA) (2000)**
- National Voluntary Laboratory Accreditation Program (NVLAP) (2000)
- International Accreditation Service, Inc(IAS) (2000)
- ANSI-ASQ National Accreditation Board *doing business as ACLASS (2006)*
- Laboratory Accreditation Bureau (L-A-B) (2007)
- Perry Johnson Laboratory Accreditation, Inc. (2008)
- American Society of Crime Laboratory Directors/Laboratory Accreditation Board(ASCLD/LAB) (2009)
- AIHA Laboratory Accreditation Program, LLC (AIHA-LAP, LLC) (2010)
- Forensic Quality Services (FQS) (2010)

Comments of US labs accredited under ISO by A2LA

- Much more comprehensive, more intense, more introspective
- Gained valuable insights into operations

Conclusions

- Accreditation of medical laboratories is good for public health and safety
  - We owe this to our patients
- Accreditation to an international standard such as ISO 15189 is necessary in a mobile society
  - The standard of care should not vary
- ISO accreditation does not guarantee test results are accurate 100% of the time
  - It merely provides a framework for quality
  - It confers competence to perform specific examinations listed on a scope of accreditation

References

- Greg Cooper and Trudy Gillions, Producing Reliable Test Results in the Medical Laboratory: Using a Quality System Approach and ISO 15189 to Assure the Quality of Laboratory Examination Procedures, Bio-Rad Laboratories, 2007

- John Orthaber, Get Your Ducks in a Row: A step-by-step guide to implementing an ISO 9001 quality management system, Quality Progress, American Society of Quality, October 2010, pp 40-46

Contact Information

Greg Cooper CLS, MHA
W. Gregory Cooper LLC
8801 Grandview Dr.
Denton Texas 76207
Cell: +1-972-983-1946
Internet: labguy46@gmail.com

Ms. Roxanne Robinson COO
Mr. Larnell Simpson, Medical Program Manager
American Association for Laboratory Accreditation
5301 Buckeystown Pike, Suite 350
Frederick, Maryland 21704-8373
Phone:+1-301 644 3208
Internet: www.a2la.org