ISO 15189 –
The Next Step in Laboratory Quality

Presented by:

Chloe Scott, MLS(ASCP)^CM, CQA(ASQ)
BioQ Solutions, LLC
chloe@bioqsolutions.com

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Agenda

- History of laboratory quality systems
- Why is ISO 15189 the next step?
- History of ISO 15189
- ISO 15189 Requirements
- Accreditation/Certification options
Quality Systems in the Laboratory - The History

• FDA and blood banking - mid ‘90s
  – FDA Guidance
  – AABB Standards
• Harmonization with ISO 9001 late ‘90s
• CLIA
  – CAP
  – Joint Commission
  – COLA
WHY is ISO the next step?

8 Quality Management Principles *
1. Customer Focus
2. Leadership
3. Involvement of people
4. Process approach
5. System approach to management
6. Continual improvement
7. Factual approach to decision making
8. Mutually beneficial supplier relationships

* ISO 9000:2005 Quality management systems – Fundamentals and vocabulary
WHY is ISO the next step?

• CAP 15189
  – In addition to current laboratory accreditation program (LAP)
• DNV
  – Hospitals
  – ISO based
• TJC
  – Future program
History of ISO 15189

- **ISO 17025:1999 (2012),** General requirements for the competence of testing and calibration laboratories
- **ISO 15189:2003 (2012),** Medical laboratories – requirements for quality and competence
ISO 15189:2012

• 15 Management Requirements (Section 4)

• 10 Technical Requirements (Section 5)
ISO 15189 Requirements

4.0 Management Requirements
• Organization & Management Responsibility
• Quality Management System
• Document Control
• Service Agreements
• Examination by referral laboratories
• External services & supplies
• Advisory services
• Resolution of complaints
• Identification and control of nonconformities
• Corrective action
• Preventative action
• Continual improvement
• Control of records
• Evaluations and audits
• Management Review

5.0 Technical Requirements
• Personnel
• Accommodation & environmental conditions
• Laboratory equipment, reagents & consumables
• Pre-examination processes
• Examination processes
• Ensuring quality of examination results
• Post-examination processes
• Reporting of results
• Release of results
• Laboratory information management
ISO 15189 Requirements

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Definitions

• Examination = “set of operations having the object of determining the value or characteristics of a property”
  – set of operations = procedure(s)
  – value or characteristics of a property = result

• Examination = Test or assay
  – Level of analyte such as sodium, red blood cells, or prothrombin
  – Analysis for bacterial identification
  – Anatomic evaluation of tissue from a biopsy
Phases of Examination

• Pre-Examination Phase (Pre-Analytical)
  – Order
  – Patient identification
  – Specimen collection

• Examination Phase (Analytical)
  – Perform analysis
  – Quality Control

• Post-Examination Phase (Post-Analytical)
  – Result evaluation and interpretation
  – Result report
  – Specimen storage
  – Specimen disposal
4.1 Organization and Management Responsibilities

- Medical laboratory services ... designed to meet the needs of patients and all clinical personnel responsible for patient care
- Ethical conduct
- Laboratory director
  - ‘maintain the ultimate responsibility for the overall operation and administration of the laboratory’
- Quality policy
- Communication
- Quality manager
  - Ensure the promotion of awareness of users’ needs and requirements throughout the lab
4.2 Quality Management System

• Policies, processes, procedures (PPP) documented and communicated
• QMS includes, but is not limited to, internal quality control and interlaboratory comparison programs
• Quality Policy
• Quality Manual
4.3 Document Control

- Procedures to control all types of documents and information
- Define retention periods
- Documents uniquely identified
- Procedures need to ensure:
  - Documents reviewed and approved prior to use
  - Document master list maintained
  - Only current versions available for use
  - Obsolete documents are removed from point of use
  - Periodic review is performed and revisions made when needed
  - A method for manual amendments
  - Controlled changes for documents maintained in computerized systems
4.4 Service Agreements

• If lab enters into an agreement to provide medical laboratory services, establish and maintain procedures for review of agreements to ensure:
  – Requirements are defined, documented and understood
  – The lab has the capability and resources to meet the requirements
  – Procedures selected are able to meet contractual requirements and clinical needs

• Maintain records of reviews
• Inform customer of any deviations from contract
4.5 Examination by Referral Laboratories

- Procedure for evaluating and selecting referral labs and consultants who provide second opinions
- Lab management responsible for selection and monitoring performance and competence
- Maintain register of all referral labs used, all samples referred
- Retain record of lab report in patient record and lab permanent files
4.6 External Services and Supplies

• Policies and procedures for selection and use of the items that affect quality service:
  – Purchased external services
  – Equipment
  – Consumable supplies

• Maintain approved suppliers list

• Verify, before use, that equipment and consumables comply with specifications or requirements

• Inventory control for supplies

• Monitor the performance of suppliers
4.7 Advisory Services

Establish arrangements for communicating to users on:

• Choice of examinations and use of services
• Individual clinical cases
• Professional judgments on interpretation
• Promoting effective utilization of services
• Consulting on scientific and logistic matters
4.8 Resolution of Complaints

• Procedure for resolution of complaints or other provided feedback
• Maintain records of complaints with associated investigations and corrective action(s)
4.9 Identification and Control of Nonconformities

- Procedure to identify and manage nonconformities in any aspect of the QMS
  - Responsibilities and authorities for handling
  - Define immediate actions to be taken
  - Consider medical significance and inform clinician when appropriate
  - Results of nonconforming examinations should be recalled, if necessary
  - Records reviewed at regular intervals by management to detect trends and initiate preventive action
4.10 Corrective Action
   — reactive

4.11 Preventive Action
   — proactive
4.12 Continual Improvement

• Continually improve effectiveness of the QMS
  – Management reviews
  – Develop action plans for improvement; document implementation

• Ensure laboratory participates in continual improvement activities that includes patient outcomes

• Communicate improvement plans and goal to staff
4.13 Control of Records

• Establish procedure for record identification, collection, indexing, access, storage, maintenance, and disposal
• Legible
• Readily retrievable
• Provide suitable environment for storage
4.14 Evaluation and Audits

• Verify operations comply with
  – needs and requirements of users
  – QMS
  – Continually improve effectiveness of QMS

• Utilize:
  – User feedback
  – Staff suggestions
  – Internal audit
  – Risk management
  – Quality indicators
  – External reviews
4.15 Management Review

- Management shall review lab’s QMS and all of its medical services
- Review results incorporated into a plan with action items
- Typically once every 12 months, shorter if QMS is new
- Monitor and evaluate quality and appropriateness of lab’s contribution to patient care
- Management ensure corrective actions completed
5.1 Personnel

• Have an organizational plan, personnel policies and job descriptions that define qualifications and duties for all personnel

• Maintain records of relevant education and professional qualifications, training and experience, and competence of all personnel

• Lab directed by a person(s) with executive responsibility and competence
5.1 Personnel (2)

- Responsibilities of lab director/designee
  - Professional
  - Scientific
  - Consultative or advisory
  - Organizational, administrative and educational matters
  - Have appropriate training and background to be able to discharge duties
5.1 Personnel (3)

• Personnel shall have training specific to QA and quality management for services they provide.

• Continuing education available to personnel involved in managerial and technical processes.

• Competency assessments following training and periodically.

• All staff take part in regular professional development or other professional liaison activities.
5.2 Accommodation and Environmental Conditions

- Adequate space for workload to be performed without compromising quality of work, QC procedures, safety or patient care services
- Designed for efficiency of operation
- Protect patients, employees and visitors from recognized hazards
5.2 Accommodation and Environmental Conditions (2)

- Lab design suitable for tasks being carried out
  - Energy sources, lighting, ventilation
  - Water, waste and refuse disposal, environmental conditions
- Procedures for checking that the environment does not adversely affect performance
  - Sterility, dust
  - Electromagnetic interference, radiation
  - Humidity, temperature
  - Electrical supply, sound and vibration levels
5.2 Accommodation and Environmental Conditions (3)

• Effective separation between lab sections with incompatible activities (prevent cross-contamination)

• Controlled access areas

• Adequate storage space and conditions

• Work areas clean and well maintained

• Storage and disposal of dangerous materials per relevant regulations
5.3 Laboratory Equipment, Reagents, and Consumables

Equipment

• Equipment includes HW and SW or instruments, measuring systems, and laboratory information systems.

• Procedures for:
  – Selection, purchasing and management of equipment.
  – Acceptance testing
  – Instructions for use, safety, and maintenance
  – Calibration and metrological traceability
  – Adverse incident reporting

• Equipment records
5.3 Laboratory Equipment, Reagents, and Consumables (2)

Reagents and consumables

• Reception and storage
• Acceptance testing
• Inventory management
• Instructions for use
• Adverse incident reporting
• Records
5.4 Pre-Examination Processes

• Information for Patients and Users
  – Location and hours
  – Services offered
  – Instructions for order completion, prep of patient, patient collected samples, transportation of samples
  – Sample acceptability criteria
  – Factors affecting examination or interpretation
  – Personnel information policy
  – Complaint procedure
5.4 Pre-Examination Processes (2)

- Request form information sufficiently identifies the patient and authorized requester
- Request form (paper or electronic) should include:
  - Patient ID
  - Authorized requester
  - Type of primary sample/anatomic site of origin
  - Examination requested
  - Relevant clinical information
  - Date and time of sample collection
  - Date and time of receipt of samples in lab
5.4 Pre-Examination Processes (3)

- **Primary sample** collection and handling procedure
- Sample transportation
  - Procedure for monitoring
- Sample reception
  - Ensure sample traceability *(sub-samples)*
  - Acceptance criteria
  - Accessioning
- Pre-examination handling, prep, and storage
5.5 Examination Processes

• Selection, verification, and validation of examination procedures
  – Measurement uncertainty of measured quantity values
  – Biological reference intervals or clinical decision values

• Documentation of examination procedures
5.5 Examination Processes (2)

- All procedures documented and available to the staff at the relevant workstation
  - Card files/job aids acceptable but must be under document control
- Procedures based on manufacturer’s instructions
  - Can be included in procedure by reference
  - Need to be under document control
5.5 Examination Processes (3)

- Reference ranges should be reviewed periodically.
- When procedures are changed, changes should be communicated in writing to lab services users if they significantly impact results or their interpretation.
5.6 Ensuring Quality of Examination Results

• Internal quality control system
• Determine possible impacts that can affect the quality of results
• Calibration and verification
• Participation in interlaboratory comparisons.
  – Evaluate laboratory performance
  – If not available, develop a method to determine procedure acceptability
• Take action for unacceptable outcomes
• Comparability of examination results
5.7 Post-Examination Processes

• Authorized personnel review results per clinical information and release the results
  – Automatic selection and reporting (autoverification)
• Storage, retention and disposal of samples procedures
• Dispose of samples per appropriate waste management
5.8 Reporting of Results

• Process to notify requester if result delayed that may impact patient care
• Ensure reports are received by the appropriate users within an agreed timeframe
• Use terminology per appropriate medical specialty organizations
• Include comment if specimen was unsuitable or could compromise results
5.9 Release of results

• Procedures need to indicate
  – Who can release results and to whom
  – Inclusion of potential compromise of result
  – Ensure only authorized recipients receive results

• Develop alert/critical values
  – Report critical and alert immediately per protocol.
  – Document action(s) taken.

• Revised Reports
  – Clearly indicate revision
  – Original report information remains in record
5.10 Laboratory Information Management

- Procedure to ensure patient information confidentiality
- Define responsibilities for user, maintenance, and modification
- **Validated by the supplier and verified for functionality by laboratory**
- Protected from unauthorized access
- Safeguarded against tampering or loss
- Environmental conditions
- Data protection
- Contingency plan
Why ISO?

• Ongoing commitment to meeting the expectations of the healthcare providers and patients that utilize laboratories services
• Management must maintain an active role
• Better assessment of ongoing compliance with QMS requirements
• The business benefits from efficiencies and effectiveness
Accreditation/Certification Options

- CAP 15189
  - Done in addition to current CAP LAP accreditation
- ISO 15189
  - Certifying body American Association for Laboratory Accreditation (A2LA)
- Three year assessment cycle
  - Year 1 - Partial
  - Year 2 - Partial
  - Year 3 - Full
References

- ISO 15189:2012 Medical laboratories – Requirements for quality and competence
- ISO 9000:2005 Quality management systems – Fundamentals and vocabulary
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It's QUESTION TIME!!