ISO15189

Taking Your Lab from Concept to Accreditation

Caroline Maurer, Program Director, College of American Pathologists, CAP 15189 Accreditation Program

Topics

- Overview of ISO/IEC 15189:2007
- The ISO 15189 concept of laboratory management
- Route to Implementation and Accreditation
- Overview of CAP 15189 Accreditation Program

ISO 15189:2007 Standard

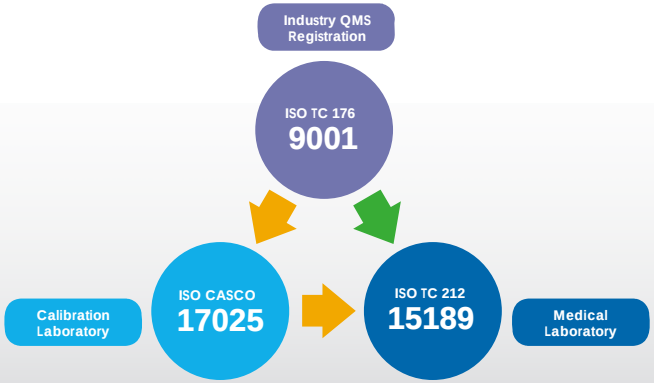
Medical laboratories – Particular requirements for quality and competence

- Written by Work Group 1 of TC 212

International standard for medical laboratories

- Standards are guidance documents to the state of the art in a specific discipline or technical area
- They do not have the force of law/regulation except in those countries that adopt the standards as requirements

ISO Evolution of Quality Management Standards



Relationship of CAP 15189 to CAP Accreditation

CAP 15189	CAP Accreditation

• Voluntary in U.S.
• Process methodology
• Scope goes beyond lab's internal activities
• Focus on prevention
  • Risk assessment
  • Understanding vulnerabilities
  • Apply effective measures
	• Based on CLIA (required in US)
	• Focus on technical procedures
	• Goal is valid current practices
	• Scope focused on lab

ISO 15189 Requirements

Management requirements

- 4. l Organization and management
- 4. 2 Quality management system
- 4. 3 Document control
- 4. 4 Review of contracts
- 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 nonconformities
- 4.l0 Corrective action
- 4.l l Preventive action
- 4.l2 Continual improvement
- 4.l3 Quality and technical records
- 4.l4 Internal audits
- 4.l5 Management review

Technical requirements

- 5.1 Personnel
- 5.2 Accommodation & environmental conditions
- 5.3 Laboratory equipment
- 5.4 Pre-examination procedures
- 5.5 Examination procedures
- 5.6 Assuring the quality of examination procedures
- 5.7 Post-examination process
- 5.8 Reporting results

Concept

Definitions

Quality	***Perception*** - Meeting customer expectations. ***Reality*** - The degree to which inherent (existing / assigned) characteristics fulfill requirements
Process	Activities transforming Inputs into Outputs
System	A set of interacting elements (Processes)
QMS	Processes designed to achieve and improve quality (Q Policy, Q Objective, Q Plan, QC, QA, QI)
CQI	Recurrent activity to increase the ability to fulfill quality requirements and enhance customer satisfaction
Competence	Demonstrated ability to apply knowledge/skills

Definitions (cont'd)

Conformity	Fulfillment of a requirement
Correction	Remedy of a detected nonconformity
CA	Eliminate the cause of nonconformity
PA	Eliminate cause of potential nonconformity
Effectiveness	Extent to which planned activities are realized and planned results achieved

QMS Elements

- Infrastructure (Facilities, Equipment, Tools, Support Services)
- Competent Management, Responsibilities, Accountabilities
- Quality Plan (Policies, Objectives, Standards, Document Control, Occurrence Management, etc.)
- Resources (Engaged Staff, Training, Procedures, Financials)
- Customer Focus (Internal / External Customers Satisfaction)
- Metrics (Measure Progress and Performance)
- Reviews (Monitor, Analyze, Adjust, Audit)
- Communication (Open / Transparent / 2-Ways / Engaging)
- Sustainability (Dynamic, Self-Policing Road-Map, CQI)

QMS activities fight inertia, maintain momentum

Quality and Cost Savings


Does ISO 9000 certification pay?

US study analyses financial performance data

- Potential cost savings by avoiding problems through preventive actions
- Corrections to problems are evaluated for effectiveness, reduces rework and risks
- Build in a culture of quality
- Customer First Focus
- Stimulates Innovation
- Improves Staff Morale

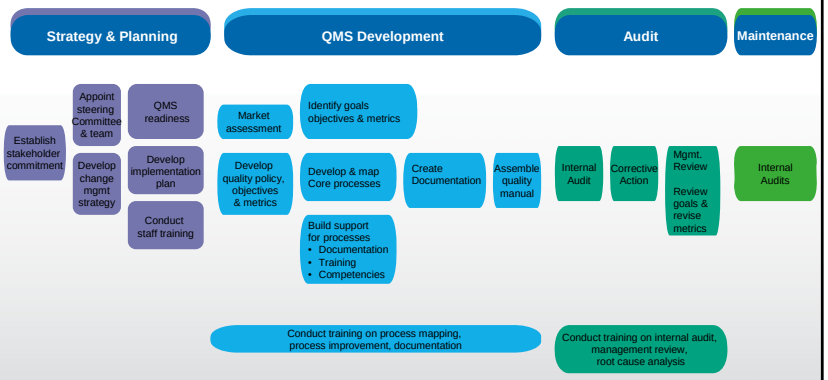
Understanding the Benefits

Examples from pilot laboratories

- Optimized operational performance - increased workload (44%) with reduced Technical Staff (3 MTs through attrition)
- Streamlined order entry procedure - reduced overtime
- Improved control of inventory, eliminated cost of overnight shipping due to emergency orders approximately 4000.00 a year
- Client satisfaction scores have increased
- Courier Route Optimization
- Reduced paperwork - implemented an electronic document control system, which eliminated all of the manuals that were kept in each department
- Implemented scanning technology which will eventually reduce storage of requisitions and the accompanying paperwork
- Reduced cost per test

Implementation

Implementation Roadmap



Implementation

- **Step 1 - Stakeholder Commitment**

  Involvement of key leadership across organization to understand business proposition and gain commitment

  - **Step 2 - Identify Team**

  Appoint QMS manager or otherwise named to lead/champion, consider appropriate skills, personality and authority

Implementation

- **Step 3 - Appointment of Steering Committee**

  Responsible for oversight of implementation progress

  Meet at regular intervals throughout to monitor progress

- **Step 4-Conduct Initial QMS Readiness and Education**

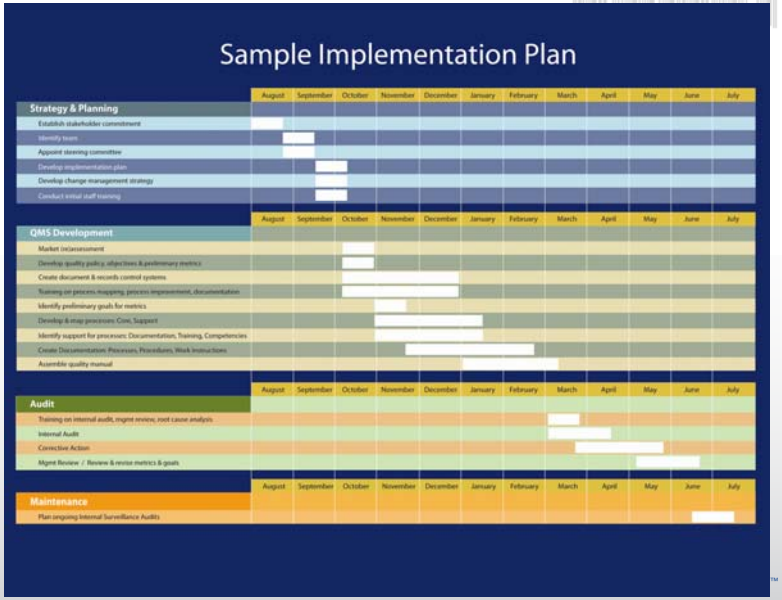
  Raise awareness about QMS and ISO requirements

Implementation

- **Step 5- Develop Implementation Plan**

  Consider scope of activities and potential timelines

  - ✓ budget
  - ✓ resources, any other major initiatives that may compete for same resources,
  - ✓ education for staff, introductory and on-going
  - ✓ current state of QMS already in place and preliminary gaps
  - ✓ document control system, manual or automated



Implementation

- **Step 6-Change Management Strategy and Communications**

Change management strategy and effective communications are a vital key to success

Set a schedule for organized communications and the modes to deliver the news

- ✓ new letters, story boards, steering status reports,
- ✓ cross divisional meetings and laboratory department meetings
- ✓ two way communication in a safe environment

Implementation

- **Step 7- Market Assessment**

  Define the patient population, organizations, individuals, your laboratory and healthcare organization serves.

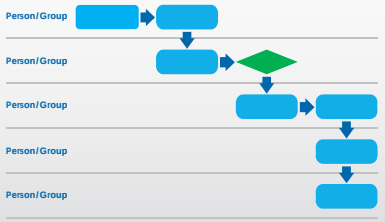
Step 8-Develop Quality Policy, Objectives and Preliminary Metrics

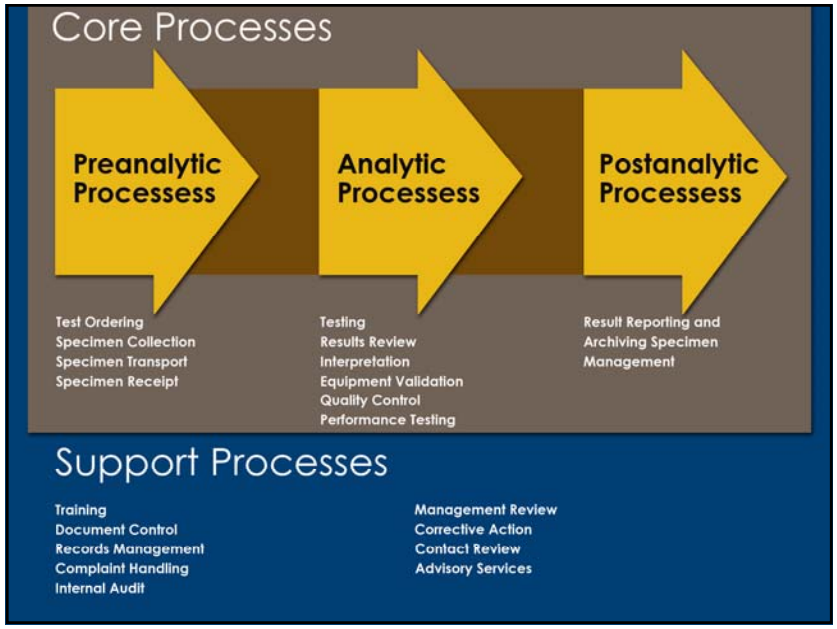
Identify the goals which you would like to achieve through a QMS

Implementation

- **Step 9-Map Core Processes**

  Document your core processes, consider the interactions between departments, handoffs and the what, where and why of current state.





Implementation

- **Step 10-Identify Preliminary Goals for Metrics**

  By mapping processes you will gain insight into improvements and ways you can measure if you are effectively meeting your objectives.

- **Step 11-Consider Gaps and Needed Support for Process Improvements**

  Consider the resources, roles, specific training and competency

Implementation

- **Step 12-Create Document System:**

Considerations

Develop a system that keeps your procedures easily accessible, current, using intranets, social media constructs (blogs, wikis, SharePoint), software, or new knowledge management systems.

- **Step 13-Create & Implement Document and Records Control**

Set realistic timelines with prioritization for converting existing documents to the new system, orientation training for staff and ongoing training and competency assessment for on-going use.

Implementation

- **Step 14-Assemble Quality Manual**

Ensure the Quality Manual is easily accessible to staff, electronic on-line manuals are better for ease of distribution and maintenance. The effective date of implementation should also be decided.

Implementation

- **Step 15-Internal Audit:**

  Typically three to four months after the documentation has been written, trained auditors should carry out internal audits covering all activities for the QMS to establish a baseline.

Implementation

- **Step 16- Corrective Action:**

  Management should take corrective action on the audit findings without delay.

Root Cause Analysis

ISO 15189
4.9 Identification and Control of Nonconformities

4.9.2 If it is determined that nonconforming examinations could recur or that there is doubt about the laboratory's compliance with its own policies or procedures as given in the quality manual, procedures to identify, document and eliminate the **root cause(s)** shall be promptly implemented (see 4.11).

The 5 Whys

- **History**
  - Developed by Toyota Founder Kiichiro Toyoda's father Sakichi
- **Quality Models**
  - Used by Six Sigma
  - *Toyota Production System* (TPS)
  - Deming *Plan Do Check Act* (PDCA) cycle
  - Ishikawa ("fishbone") root-cause analysis
- **Application and Benefits**
  - Five iterations of asking why is generally sufficient to get to a root cause
  - Key is to encourage troubleshooting and avoid assumptions
  - Learn the nature of the problem as well as its solution

Problem example

- Observed problem not the solution: not "doctors call for the results rather than looking in the computer" but "how can we eliminate phone calls to the lab".
- Scope: easy to make too large. Avoid using for a "just do it."
- What guidance would you suggest for initiating a root cause?

Results are sometimes delayed from being reported
Why? Techs forget to report the results
Why? Tech responsible multi-task
Why? Often times, the tech loads the sample and walks away to perform other duties
Why? Day tech is also responsible for blood bank support
Why? TS tech is responsible in the evening
Why? Cell tech is responsible at night
Why? Sometimes anyone who has time
Why? Inconsistent visual cue to indicate a test is in progress
Why? Some techs place the label on the instrument as a visual cue before placing the label on the log book
Why? Some techs do not place the label on instrument

A3 Corrective Action Tool

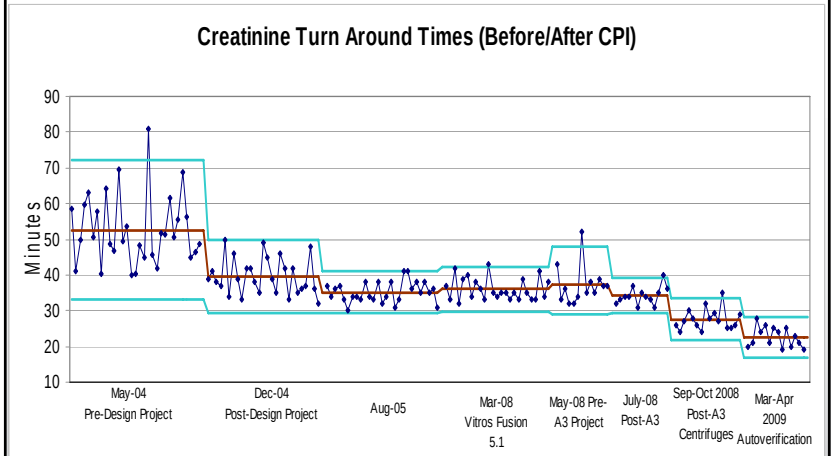
- Used by Toyota
- Relates to getting the thinking documented on an A3 sheet of paper (11 x 17 inches)
- Limits the scope of the problem / solution

- Can be used for
  - Problem solving
  - Status check
  - Proposals

- Usability
  - Practical method easy to learn (but not the thinking)

Preventive Action and Near Misses

Example: Different centrifuges remove bottle neck in core chemistry



Implementation

- **Step 17-Management Review**

Minimum annual review to review effectiveness of system.

Ideally after each internal audit, the top management should review the effectiveness of the system.

Schedule based on needs assessment

Implementation

- **Step 18-Internal Surveillance Audits**

After initial corrections have been applied from your first audit you will want to do another full audit of the system to establish progress and on-going frequency required for each area.

Consider external assessment findings

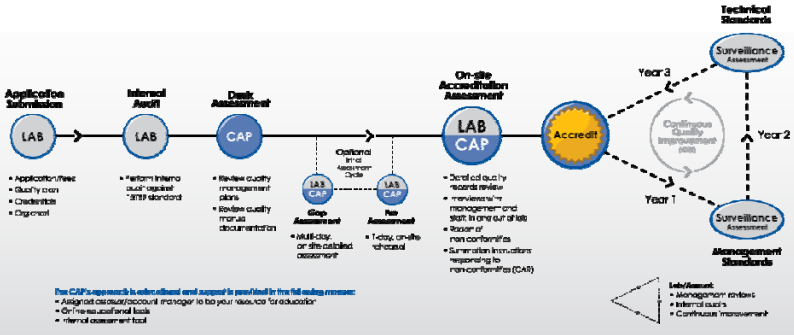
QMS Implementation Phases

- **Strategy and Planning**
  - Establish a Positive Mind Set & Support Education
  - Set the Standard
  - Stay in Touch with Process
- **Generate and Follow a Realistic Plan**
- **Select the Right Person to Lead**
  - However Quality is Everyone's Responsibility
  - Involve the Right People as Agents of Change and to Sustain
- **Develop a Strong ISO Knowledge Base within the Organization**
- **Promote and model process analysis, and process improvement**
  - Create documentation and Quality Manual
- **Implement the ISO Continual Improvement Process**
  - Root cause analysis
  - Preventive Action
  - Management Review

Accreditation

CAP 15189 Process Overview

Laboratory accreditation to the 15189:2007 Standard



Every number is a life.™

Application Completion Checklist

Email the following requested quality management documentation to cap15189@cap.org.

- ☐ Quality Manual (see ISO 15189 for details on quality manual requirements)
- ☐ Updated organization chart with key personnel
- ☐ Credentials (CV's) of key personnel (medical and administrative directors, and quality manager - however named).
- ☐ Description of participation in external quality assessment schemes or proficiency testing programs for all tests and evidence of participation over the preceding two years

Procedures for:

- ☐ Internal audits (clause 4.14)
- ☐ Management review (clause 4.15)
- ☐ Document control (clause 4.3)
- ☐ Examination by referral laboratories (clause 4.5)
- ☐ Quality and technical records (clause 4.13)
- ☐ Management of occurrences - Resolution of complaints (clause 4.8), Identification of nonconformities (clause 4.9), corrective and preventive actions (clauses 4.10 and 4.11)

Every number is a life.™

If available at time of application:

- Internal audit records (required to schedule accreditation assessment)
- Management review records
- Process maps/flow charts for:
  - Pre-examination Process (orders, collection of specimens, transportation, acceptance/rejection, processing, traceability)
  - Examination Process (validated test methods, calibrated equipment and reagents, work instructions/ procedures, specifications, reference intervals, QC, Proficiency Testing)
  - Post-Examination Process (systematic review of results, control charting/trending, storage and disposal of specimens, result reporting, and reporting of critical results)
- Records and analysis of quality Indicators

Questions?

Contact Information

- Email: cap15189@cap.org
- Website: www.cap.org/cap15189
- Phone: 1-800-323-4040 option1