Transitioning to the Future of Medical Laboratory Quality Systems

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Topics

• The nature of the transition
• Trends in expectations for QMS
• ISO 15189 and CAP Laboratory Accreditation Program
• Methods to assess existing lab QMS
Reacting to Problems

Operations characterized by activities

This slide adapted from Baldrige 2011-12 Healthcare Criteria for Performance Excellence
Early Systematic Approaches

Beginning stages of repeatable processes

This slide adapted from Baldrige 2011-12 Healthcare Criteria for Performance Excellence
Aligned Approaches

Processes address key strategies and goals

Strategic and Operational Goals
Integrated Approaches

Collaborative improvement of processes

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Reacting to the Problem

Run with the hose and put out the fire

This slide adapted from Baldrige 2011-12 Healthcare Criteria for Performance Excellence
General Improvement Orientation

*Install more fire hoses*
Systematic Evaluation and Improvement

Evaluate which locations are most susceptible
Learning and Strategic Improvement

*Install heat sensors and sprinklers*
Organizational Analysis and Innovation

*Fireproof materials, water-based liquids*

This slide adapted from *Baldrige 2011-12 Healthcare Criteria for Performance Excellence*
Shifts in Thinking

- Transaction paradigm → System paradigm
- Procedure focus → Process focus
- Line item focus → Operations focus
Transaction focus
Single expired reagent

System focus
Inventory control system

<table>
<thead>
<tr>
<th>NO.</th>
<th>Item Name</th>
<th>Quantity in Stock</th>
<th>Re-Order Point</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Rewjklj jdaJK</td>
<td>000000</td>
<td>1111</td>
</tr>
<tr>
<td>2</td>
<td>Sawjsdelj jqa</td>
<td>000000</td>
<td>1111</td>
</tr>
<tr>
<td>3</td>
<td>Niwjkj jdal</td>
<td>000000</td>
<td>1111</td>
</tr>
<tr>
<td>4</td>
<td>Bywjkj jdfde</td>
<td>000000</td>
<td>1111</td>
</tr>
<tr>
<td>5</td>
<td>Rajkisaoi fklejw</td>
<td>000000</td>
<td>1111</td>
</tr>
</tbody>
</table>
# Shift in Focus

## Focus on procedures

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Rewjkll jdaJK</td>
</tr>
<tr>
<td>2</td>
<td>Sawjsdelj jqa</td>
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<tr>
<td>3</td>
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<td>4</td>
<td>Bwyjklj jdfde</td>
</tr>
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</tbody>
</table>

## Focus on process

![Diagram of process flow]
Two Paths to Profitability

Reduce costs (cut staff or budget for supplies and equipment)

- Lower cost per test
- Increase profitability

Reduce expenses from errors and waste

- Improve operations
- Increase profitability

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QMS Guidance – A Timeline

- **9001:1994**
  - QMS General Requirements
  - 2008 Update

- **17025:1999**
  - Requirements for Calibration and Testing Labs
  - 2005 Update

- **15189:2007**
  - Medical Labs—Requirements for quality and competence
  - 2012 Update

**Guidelines for QMS in Health Care**
- Many Updates

**Quality Management Education Modules**
- Detailed case examples
Evolution of Standards and Guidance

CLIA
- Test methods
- QC

CLSI
- Guidance documents for quality system

ISO
- International quality standard with accreditation process
Different Standards Focus On Different Perspectives

30,000 foot view: QMS, processes, systems, ISO 15189

500 foot view: Individual test procedures, individual results, various tasks
The concept of the process approach is so fundamental that one of the ISO 15189 reference standards shows this requirement as the first operational step in the standard.

Process is listed first because if it is not done correctly the rest of the standard will make little sense.
Processes Are Like Puzzles

We need to put them together into a logical interconnecting flow in order to see the big picture.
The Process Management Approach

1. Starts with the organization’s own infrastructure – its own quality system
2. Recognizes that this quality system exists to meet the organization’s unique needs of its customers
3. Step back and examine the “backbone” processes of the organization
4. Processes are improved and documented
5. Processes that support the core process are studied, improved and documented
6. New processes are added (e.g., internal audit) that fill out the quality system in accordance with the ISO Standard
Process Approach

A way of looking at the management of quality to reduce errors

- The goal is to create an entire system whereby it is EASY to do the right thing, and DIFFICULT to do the wrong thing

- Recognize that most mistakes are not caused by people and procedures, but are instead frequently caused by process failures

- To prevent mistakes, the root cause (usually a process error) must be determined, and the process redefined.
What is a Process?

Inputs → Process / Value Added → Outputs
Analyzing Handoffs Helps Eliminate Mistakes and Inefficiencies
What is ISO?
ISO 15189:2007 Standard

*International standard for medical laboratories*

- Unique to medical testing laboratories
- Defines management and technical competency
- Takes attention and hard work.
- They do not have the force of law/regulation except in those countries that adopt the standards as requirements

*Medical laboratories – Particular requirements for quality and competence*

- Work Group 1 of TC 212 wrote requirements
- Is not document control on steroids.
ISO Quality Management System Standards:

- Different than most other standards
- A group of standards to logically describe how an effective QMS should operate.
- Defines expected results rather than the details of “how to get there”, results rather than tasks.
- Cannot be adequately evaluated by simply using a checklist.
ISO Quality Management System Standards:

• Intend that the user structure systems to identify when activities go right and when they go wrong.

• Intend that systems be structured to identify negative occurrences and trends, and have systems to address these issues, including escalation to appropriate parties for resolution.

• Have self policing mechanisms in place to monitor and manage.
ISO Quality Management System Standards:

- Are intended to be implemented by means of a process approach – the systematic identification and management of processes employed within an organization.

- Require that activities be performed consistently.

- Have systems in place to focus on effectiveness, risk mitigation solving problems and continually improving.

- Focus on designing a culture of prevention.
Self-Policing Includes Effective Processes For:

- Internal auditing
- Management review
- Corrective action/Preventive action
- Root cause analysis (focus on systems not individuals)
Core Processes

Preanalytic Processes
Analytic Processes
Postanalytic Processes

Support Processes
Support Processes

Training
Document Control
Records Management
Complaint Handling
Internal Audit

Management Review
Corrective Action
Customer Service Agreements
Advisory Services
Purchasing
Competency
Laboratory Processes

Pre-Analytical

Stage 1: Test Ordering
Stage 2: Specimen Collection
Stage 3: Specimen Transport
Stage 4: Specimen Receipt

Analytical

Stage 1: Testing
Stage 2: Result Review
Stage 3: Interpretation
## Specimen Collection Sub-Process

<table>
<thead>
<tr>
<th>Step</th>
<th>What</th>
<th>Who</th>
<th>Related Documents</th>
</tr>
</thead>
</table>
| 1    | Generate labels | - Lab secretary  
|      |                 | - Phlebotomist  
|      |                 | - Technologist  
|      |                 | - Ward clerk - ED | - PRE.349 Test Request and Ordering                              |
| 2    | Identify patient| - Phlebotomist  
|      |                 | - Technologist  
|      |                 | - Other appropriately trained healthcare staff | - PRE.385 Patient and Specimen ID  
|      |                 |                                           | - PRE.321 Laboratory Directory of Services  
|      |                 |                                           | - PRE.373 Specimens Requiring Chain-of-Custody |
ISO 15189 and CAP
Laboratory Accreditation Program
The College of American Pathologists, the leading organization of board-certified pathologists, serves patients, pathologists and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine.
The CAP’s Role and Mission: Committed to Excellence

- 630 expert pathologists and laboratory professionals representing the laboratory community’s interests on the CAP’s accreditation and proficiency testing resource committees.
Today, CAP’s Presence Spans the Globe

- Works with distributors in select markets throughout the world
- Accredits laboratories in 45 countries
- Provides EQA/PT to laboratories in more than 90 countries
- Headquarters: Chicago, Illinois
- Employs ~600 people with two main offices (Chicago and Washington, DC)
CAP’s Contribution

CAP was a significant contributor to the development of the original ISO 15189 Standard released in 2003, and CAP members continue to actively participate on the technical committee for the standard.
CAP 15189 Rests on the Foundation of the Laboratory Accreditation Program
Building on the Gold Standard – Additional QMS Requirements for ISO 15189

- Demonstrated understanding of processes (process mapping)
- Expansion of quality policy into quality objectives and metrics
- Quality manual
- Rigorous root cause and internal audit programs
- Periodic review of the QMS (management review)
- Demonstrated continuous improvement
CAP Accreditation & CAP 15189SM Are Complementary

**CAP Accreditation**
- Exceeds CLIA (required in United States)
- Provides Continuous Compliance
- Focuses on technical procedures and activities for test accuracy and quality improvement
- Monitors laboratory performance against the CAP checklists

**CAP15189SM**
- Remains voluntary in United States
- Provides Preventive Action
- Focuses on business processes and systems integration for continual improvement and risk mitigation
- Monitors laboratory QMS effectiveness to the ISO 15189 standard

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**ISO15189**

**Advantages**

- Broad clinical market relevance – promotes global harmonization
- Requirements less prescriptive
- Enables transition from quality assurance to management
- Provides a structure to build and sustain the Quality Management System
- Emphasis on monitoring effectiveness, and prevention of errors
- Offers external assessment and validation
- Tighter document and change control
- Promotes efficiencies through improved integration of processes and design of systems
  - Framework to hardwire Lean, Six Sigma and other quality initiatives

**Disadvantages**

- Standard is subject to interpretation
- Requirements not as technically prescriptive allowing variation in how testing is performed
- Limited global experience, relatively new standard
- Wide global variation in entities providing ISO 15189 services
  - Accreditation organization credibility and comprehensiveness of services vary
- Anatomic pathology not specifically included in 15189
CAP’s Approach to ISO 15189

- No mandatory timeline
  - All assessments are announced with a defined agenda
  - Schedules and site visits are coordinated and based on when the client is ready

- Three-Year Accreditation Cycle
- Evaluates intent, implementation, and effectiveness
- CAP staff assessors with specialized training
- Educational approach
CAP 15189 Accreditation Process

- Application Submission
- Internal Audit
- Desk Assessment
- Gap Assessment
- Accreditation Assessment
- Accreditation Decision
- Surveillance 1 (Management)
- Surveillance 2 (Technical)
- Optional Pre Assessment
Example: Medical Reimbursement Pressures

Reduce Costs
- Reduce Errors
- Corrected reports/retesting
  - Less reagent, labor, run time, redraws

Don’t be satisfied with less than 100% performance. Setting your goals lower means you will turn off your alarms.
Focus on Improvement Versus…

Cultivate laboratory services that:

- Emphasize a philosophy of prevention
- Promote continual review of corrective actions and outcomes
- Support effective communication within the laboratory process, among facility, and customers
Does ISO 9000 certification pay?

- Saves cost through prevention
- Reduces problems, stress, rework
- Stimulates innovation
- Improves staff morale
- Improves reimbursement
- Increases confidence in services
Potential Errors

Don’t try to implement another organization’s “proven system.” Customize it, make it your own. It will be obvious if the system is not yours.

Don’t try to implement the standard following the structure and sequence in which it is written. The document is written in such a way that it conveniently and logically categorizes the necessary information. The intent is that you structure your own processes.
CAP 15189 Educational and Informational Offerings

On-Line Courses

- 15189 Walkthrough
- QMS Implementation Roadmap
- Root Cause Analysis
- Internal Auditing
- Document Control
- Quality Manual Development
- Management Review

Non-Accreditation QMS Gap Assessments

Now with CE credit!
Contact

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