

## Laboratory Quality Impacts Patients and the Economy

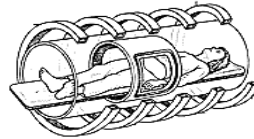


*SG Cowen Securities:*

- 3% of the healthcare dollar is spent on clinical laboratory testing
- 70% of healthcare spending is impacted by clinical test results

## Quality Management Systems

- ▶ The QMS embodies the policies, procedures and processes that address the vital components of a business or organization.
- ▶ Having a QMS gives an organization the ability to measure performance and quality of the business as a whole.



- ▶ Measurement leads to identification of areas that are weak and need improvement.
- ▶ Customers recognize that the organization has put a high commitment on quality.

## Benefits of a Quality Management System

- ▶ Customer satisfaction that results from
- ▶ Accurate and timely services through
- ▶ Continuous process improvement which also
- ▶ Improves productivity and reduces operational costs and
- ▶ Ensures compliance with regulatory requirements as well.

## What is ISO

- ▶ International Organization for Standardization
- ▶ Formed in 1946  
“to facilitate the international coordination and unification of industrial standards”
- ▶ Voluntary – in the USA  
– Non governmental
- ▶ ISO is the acronym for the International Organization for Standardization – in any language.



## Why ISO

- ▶ A philosophy of prevention rather than reaction.
- ▶ Continuous review of all the critical process points, corrective actions and outcomes.
- ▶ Consistent communication with staff, suppliers and customers.
- ▶ Efficient control of critical documents and records.
- ▶ Total quality awareness by all employees.
- ▶ Executive management responsibility and support.

## The ISO 15189 QMS

ISO 15189 forces you to look at the lab as a system with a set of processes that are interrelated.

Those processes are made up of procedures and resources.

They all work together towards the goals of the lab.

Objectives are reached by design, not over time by fortuitous fate.

## The look of the ISO 15189 QMS

It's not a cookie cutter approach.

Because every organization is unique, no two QMSs are identical.

ISO 15189 provides a flexible framework for labs of all sizes and complexity.

Tailor the implementation and maintenance of the system to your lab.



## ISO is voluntary

But... Often governments decide to adopt ISO standards especially those concerned with health, safety and the environment.

## **The Product of the Effort**

After implementing ISO 15189, the immediate take away is a durable, well-founded quality management that can be built on and improved

A system that consistently delivers quality service to the doctor and patient and thereby increases customer satisfaction.

Service output becomes predictable and processes, therefore, can be continually improved.

A quality management system that works for you

## **CAP vs ISO 15189**

- ▶ CAP accreditation integrates technical procedures and activities for quality improvement.
- ▶ ISO 15189 integrates all systems' processes for continual improvement and risk reduction.

## Who Participates in Quality?



## The Essential Provision

A commitment to quality  
From the senior management  
Down through the entire organization



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 Relationship
- The Eight Quality Management Principles*

## Basic Necessities for a Good Program

- Functioning Management Review
- Ongoing Internal Audits
- Standardized Corrective Action Plans
- Mechanism for Handling Complaints
- Document Control Process

## How We Started

- ▶ Proposed ISO 15189 accreditation to our Senior Vice-President and Operations Vice-President
- ▶ Obtained the standards
- ▶ A gap analysis was performed to determine what needed to be in place in order to apply.
- ▶ Set a deadline for application submission.
- ▶ Training – ASQ training class on implementing ISO 9001 (no classes for ISO 15189 available).

## How We Started

- ▶ Added a Chief auditor and a trainer (both existing employees).
  - Chief auditor became a Certified Auditor.
- ▶ Tasks, timelines, and deadlines were established to close the gaps.

## The Gaps

- ▶ Quality Management System Manual
  - Needed to be created it's different than a QA manual.
  - Includes all the elements of the product/service cycle.
  - Development of our quality statement.
  - Describes:
    - What we do
    - Why we do it
    - Our commitment to doing it right the first time

*“Our Priority is our patient ,  
our commitment is to Quality”*

## The Gaps



- ▶ The process gap:
  - All technical manuals complete and in Master Control  
(no sticky note process steps).
  - Standardize non-technical manuals .(phlebotomy, accessioning, logistics etc.)
  - Develop a procedure manual for sales.



## The Gaps



- ▶ Training gap:
  - Revamped technical competencies based on CLSI standards.
  - Created non-technical competencies modifying CLSI standards as a guide (all departments)
  
- ▶ Auditing gap:
  - Created technical and non-technical audit tools.
  - All departments audited every 6 months.

## *Driving to the Finish Line*

- ▶ Employee education
  - Powerpoint presented to all employees.
    - Discovery: even after presentation employees really did not have a grasp of what we were trying to do differently than other “flavor of the month” programs.
  
  - Education has to be continuous
    - Banners, posters, screensavers
    - Weekly “Umbrella Talks”
    - Five minute quality talks
  - Supervisor “Communicating on communication” training.

## *Driving to the Finish Line*

- ▶ Created an employee communication system
  - Back to Basics (BtB)
    - Division Concern on line communication
  - Division Operating Council (DOC)
  - Process Improvement suggestion form
  
- ▶ Continual quality improvement system
  - Root cause analysis procedure
  - PDCA Cycle for improvement projects
    - Plan Do Check Act

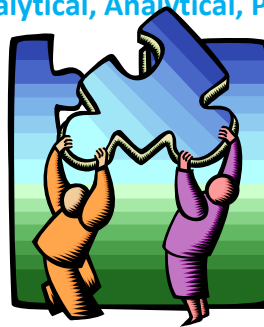
## Sweat Equity

- ▶ Create the system from within.
  
- ▶ Standardize the system in your own way.
  
- ▶ Copy what works.
  
- ▶ Don't get hung up on things that aren't working, be flexible to change during change.
  
- ▶ You find unexpected talents in the organization

*“When you hire a pair of hands,  
you get a brain for free.”*

## Quality Improvement Process

- Improvement Initiative
  - Service, Pre-analytical, Analytical, Post-analytical



- Plan it
- Try it
- Measure it  
for effectiveness
- Implement it

## Early Successes



- A BtB submitted about Glucose tolerance labels led to a reduction in overtime of 20 hours per pay period. TAT was improved.
- A lean exercise in Histology led to the re-allocation of 1 FTE. TAT was improved.
- A fishbone exercise in Cytology led to the re-allocation of 1 FTE. TAT was improved.

## Early Successes



- A quality team effort has led to a significant reduction in QNSs in the Tampa Lab. It has also reduced the labor used to address QNS issues by 1 FTE.

**More Recently...**

**ZERO!!!**

**... Clerical errors on  
CAP surveys for 2011**

## **What do our customers say?**

- ▶ **From our latest quarterly client satisfaction survey:**
  - Ratings are markedly higher for ability to resolve problems relative to 12 months ago.
  - The “very satisfied” category has risen by 29% over the same period.

**THE FOUNDATION**

Quality Management System

**THE JOURNEY**

**TO SUPERIOR TOTAL QUALITY**

**THE CULTURE**

Customer Driven  
Quality Focused  
Process Oriented

**THE GOAL**

Center of Excellence  
for Patient Care &  
Customer Service

