ONE LAB'S EXPERIENCE IN TAKING ISO 15189 FROM CONCEPT TO ACCREDITATION

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Presentation Outline

- Background/History Piedmont Medical Laboratories, (PML)
- Evolution of Quality Systems
- PML's Quest for a Quality Management System
  - Decision to Pursue ISO 15189
  - E-Suite Approval
  - Steps to Accreditation
  - Return on Investment
    - $Savings$/Benefits

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Out of Washington

Provisions in drafts of House and Senate Bills that impact the Lab Industries

Dropped	20% Co-Pay
On Hold	3% Lab Revenue Tax
Pending	1.1% Productivity Adjustment to Medicare Payments
Pending	1.7% Reduction in Future Medicare Fee Schedules
Pending	Pay for Performance Models

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Piedmont Medical Laboratory History

PML was formed as a Joint Venture for-profit independent Laboratory in 1991 by eight (8) hospitals and two Pathology P.C.s

PML's mission was to build business in the outreach market and perform core testing for it's hospital and pathology owners. PML's primary market is North Western Virginia and West Virginia servicing Physician offices, Hospitals, Long Term Care Facilities and Outpatient Clinics.

On July 31, 2009 PML was acquired by Clinical Pathology Laboratories "CPL" (Austin, Texas). CPL is a member of the Sonic HealthCare USA Network of Laboratories.

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PML Profile

- Full Service CAP and CAP/ISO 15189 Accredited Laboratory
- Performs approximately 1 million billable procedures
- Laboratory Disciplines:
  - Routine Chemistry and Hematology
  - Special Chemistry
  - Andrology
  - Blood Bank
  - Microbiology and Mycobacteriology
  - Molecular Pathology
- Staff approximately 100 FTEs
- Patient Service Centers – eleven (11)

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"Why is there never enough time to do it right...but always enough time to do it over?" -- Anonymous

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What is a Quality System?

A Definition of a Quality System:

"Management system to direct and control an organization with regard to quality"

Source: ISO 9000:2000 Quality Management Systems – Fundamentals and Vocabulary

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What is a Quality System?
(continued)

Description of a Quality System:

The Quality System includes the documents, records, personnel and activities used to generate your product or service.

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What is a Quality System?
(continued)

Basic philosophy of a Quality System:

Standardize. Standardize. Standardize.

and

Say what you do.

Do what you say.

Prove it.

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"Almost all quality improvement comes via simplification of design, manufacturing, layout, processes, and procedures."
--Tom Peters

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Past Quality Management Approaches

Benchmarking	Downsizing	Quality Circles
Breakthrough Management	Holistic Management	Value Analysis
Business Excellence Awards	Integrated Management	Reengineering
Business Partnerships	Just-In-Time	Value Engineering
Company-wide QC	Management by Objective	Reinventing Government
Concurrent Engineering	Managerial Breakthrough	Vendor (Supplier) Partnership
CQI	One-Minute Management	Rightsizing
Cost Reduction	Outsourcing	Voice of the Customer
Process management	Strategic Planning	Statistical Process Control
Profit Improvement	Total Quality Control	Zero Defects
Program Management	TQM	

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A Brief History of Quality Systems

- 1937: Pareto principle conceptualized by J.M.Juran.
- 1950s: Dr. Deming presented TQM and process control to Japanese engineers; TQM principles adopted by US auto companies in mid 1980s.
- Mid-1980s: JCAHO mandated quality indicators to ensure quality after cost-cutting DRGs were introduced.
- 1986: *The Juran Trilogy* was published.
- 1987: First edition of the ISO 9000 standard published. Based on a British quality system standard.
- 1991: The FDA published its Initial draft version of “Guideline for Quality Assurance in Blood Establishments”.
- 1994: AABB published its first quality program.

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A Brief History of Quality Systems (continued)

- 1995: Formal version of "Guideline for Quality Assurance in Blood Establishments" published by FDA.
- 1997: AABB reorganized their quality program into ten Quality System Essentials and published in an association bulletin.
- 1998: first US laboratory (Quest Diagnostics, Inc., Nichols Institute in California) achieved ISO registration based on the 1994 version of the ISO 9000 standard.
- 1999: AABB incorporated the ten Quality System Essentials into the 19th edition of *Standards for Blood Banks and Transfusion Services*.

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A Brief History of Quality Systems (continued)

- 1999: NCCLS published *A Quality System Model for Health Care; Approved Guideline GP26-A,* based in large part on AABB Quality System Essentials.
- 2000: Revised ISO 9001:2000 standard replaced 1994 version.
- 2001: Europeans adopted ISO draft #15189 *Quality Management in the Medical Laboratory.*
- 2002: NCCLS published *A Quality System Model for Healthcare HS1-A.*
- 2003: *"Requirements Relating to Quality Systems and Certain Personnel Qualifications; Final Rule"* published 01/24/2003" http://www.phppo.cdc.gov/clia/regs/toc.asp.

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A Brief History of Quality Systems (continued)

- 2003: CAP published an educational program on Quality Assurance/Quality Control that covers the principles of quality systems and the major changes regarding quality systems in the January 24, 2003 CLIA regulations.
- 2003: NCCLS published *Application of a Quality System Model for Laboratory Services GP26-A2 (2nd edition).*
- 2003: CAP Lab General Checklist GEN.13806 requires an overall quality improvement plan based on NCCLS, ISO, AABB or JCAHO models or "the laboratory's own design".
- 2003: ISO 15189:2003 *Medical laboratories – particular requirements for quality and competence.* Includes much of the text of ISO 9001:2000. http://www.iso.ch/iso/en/commcentre/pressreleases/2003/Ref857.html
- 2007: ISO 15189:2007 – Updated to correlate with ISO 90001:2000 and ISO/IEC 17025:2005

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Current Quality Management Approaches: Systems

ISO 15189

ISO 9001

QS-9000 (automotive)

TQM/8 elements

Lean Enterprise

Malcolm Baldridge

Deming 14 Points/System of Profound Knowledge

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What are the Quality System Options for the Laboratory?

ISO 15189

AABB Model

NCCLS Model

ISO 9001:2000 Model

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Fact or Fable

To Err is Human?

Analysis shows “90% of operator errors are the direct cause of flawed systems.”

Author unknown

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Why have a Quality System?
(continued)

Relative Cost of Defects

Prevention: $1.00

The cost of detecting and preventing defects.

Correction: $10.00

The cost of correcting defects.

Failure: $100.00

Customer discovers defect.

Dissatisfaction and loss of business.

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Challenges in Establishing an ISO Quality System

- Entrenched corporate culture
- Resource requirements
- Time requirements for staff
- Expense of registration
- Lack of internal expertise
- Lack of knowledge about Laboratory Medicine/Healthcare among ISO consultants
- Lack of knowledge among laboratory peers, since few medical labs are ISO registered
- Document Control
  - Establishing a document control process
  - Ensuring that all documents conform to the document control process

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"People wish to produce quality; they wish to have pride in workmanship." -- W. Edwards Deming

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At Toyota World Headquarters the following Portraits are displayed

1. The Founder
2. Current Chairman
3. W. Edward Deming

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Why ISO Accreditation

Question:

"Why should we go to the trouble and expense of obtaining ISO 15189 accreditation
if it does not replace traditional accreditation?"

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Why ISO Accreditation?

Answer:

- Complement CAP accreditation
- Driven by a "Customer First Focus"
- Process approach emphasizing continual improvement
- Involves Staff at all levels all departments
- Establishes a common framework for coordination and communication between department. "Breakdown Barriers"
- Establishes internal trust and employee satisfaction/eliminates fear
- Creates consistency of purpose for improvement of product and service
- Formalizes, streamlines, and improves management systems processes, efficiencies, and effectiveness.

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Why ISO Accreditation? (Continued)

Answer: (Continued)

- Provides evidence of a safe environment for patients/customers
- Develops performance measures based on objectives and patient/customer requirements
- Monitors performance measures, health outcomes, and patient/customer satisfaction (internal and external)
- Institutes vigorous programs of education and retraining.
- The Medicare Medical Review Program now specifically recommends and/or requires that Medicare contractors becomes ISO certified or undergo an equivalent third party validation process.

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Traditional US Business Model

- Quality is Expensive
- Defects are caused by workers
- Buy at lowest $cost$
- Fear and reward are proper way to motivate
- Play one supplier against another

The Deming Business Model

- Quality leads to lower $costs$
- Most defects are caused by the system(s)
- Buy from vendors committed to Quality
- Fear leads to disaster "stifling creativity"
- Work with your supplier, make a "win/win" scenario

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ISO 15189 – The ROI Story Selling ISO to the E-Suite, Making your Presentation

I. Engage Principle Decision Maker
- CEO; CFO; Lab Administrator/VP
- Solicit Support before Presentation

II. Present Business Model
- Objective/Purpose
- Investment/Resources required
- Expected Benefits/ROI

III. Sell Concept/Talking Points
- Background/History of Quality Initiatives, Quality Management, and continuous Process Improvement in US Manufacturing and Healthcare
- Why ISO 15189 Define ISO and the role of the International Organization for Standardization. Explain that ISO 15189 accreditation is a global confirmation of your lab's competence and commitment to Quality. ISO is the "Framework" and ongoing force for all Quality Management and Process Improvement initiatives.

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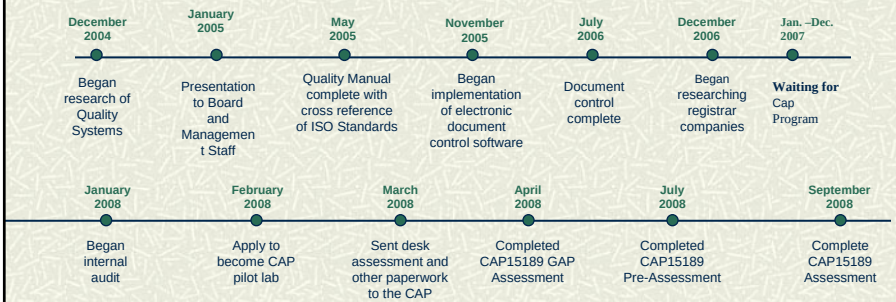
PML's Journey to ISO 15189 Accreditation



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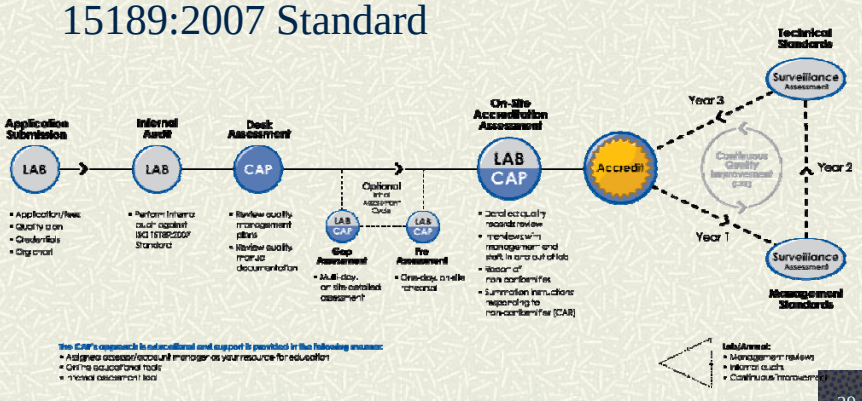
CAP 15189 Overview

Laboratory accreditation to the ISO 15189:2007 Standard



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25 Step Checklist to Establishing an ISO Quality System

1. Appoint a Quality Manager (Q. Mgr.) as the point person. Must have responsibility and authority for all aspects of implementation.
2. Immediate Q.Mgr. duties: select the implementation team comprised of management and staff; establish budget; develop written implementation plan.
3. Select a consultant.
4. Educate management and staff about the upcoming Quality System development.
5. Review, identify, select Accreditation Agency

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25 Step Checklist to Establish an ISO Quality System (continued)

6. Map the path of workflow and basic processes.
   - Serves as basis for establishing indicators and benchmarks.
7. Develop work instructions.
   - Standard format
   - Circulation list
   - Authorization process
8. Develop basic quality system manual:
   - ISO = The Quality Manual .
   - (NCCLS = Single manual organized into Quality System Essentials

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25 Step Checklist to Establish an ISO Quality System (continued)

9. Write the ISO Quality Manual to Include:
   - Description of Medical Laboratory/Services
   - Quality Management System (QMS)
   - Quality Policy
   - Quality Objectives
   - Document Control
   - Safety
   - List of Examination Procedures
   - Quality Assurance
   - Quality Control
   - Communications
   - Staff Education
   - Reporting Results
   - Remedial Actions and Handling Complaints
   - Research and Development
   - Laboratory Information Systems
   - Internal Audits
   - Role Quality Manager
   - Role Technical manager
   - Implement Plan ISO 15189

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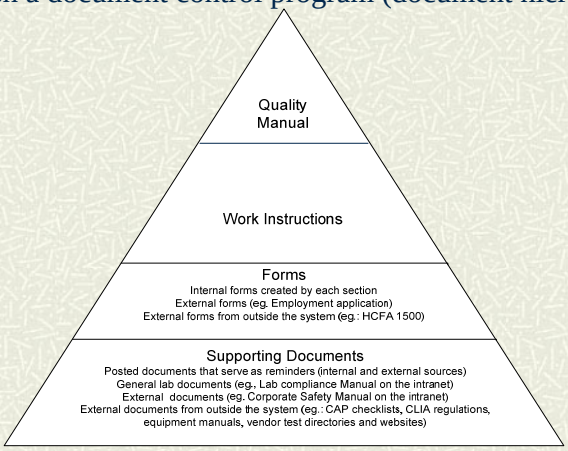
25 Step Checklist to Establish an ISO Quality System (continued)

10. Establish a document control program (document hierarchy).



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25 Step Checklist to Establish an ISO Quality System (continued)

11. Put all internally created forms in standard format.
    - Numbering/identification process for each form
    - Authorization process to ensure that only approved forms are used and obsolete forms are removed from circulation.
    - Requires intensive education of staff. Auditors will ask staff how they know if they are using the most current version.
12. Establish a records management program. Essential elements include:
    - Where records are stored, online and offsite
    - Retention period for both online and offsite records
    - Indexing for storage (alphabetical, numerical, etc)
    - Retrieval instructions
    - Importing documents on-line, training and implementation of document management software.

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25 Step Checklist to Establish an ISO Quality System (continued)

13. Educate staff regarding the Quality System and Document Management System.
14. Train internal auditors.
15. Make sure that there is at least one indicator or benchmark for each process and critical step.
16. Create production schedules to document key tasks and activities.
17. Select indicators or benchmarks to monitor key tasks, activities and processes.

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25 Step Checklist to Establish an ISO Quality System (continued)

18. Submit Application to CAP

- Undergo an internal audit against ISO 15189 2007 Standards after quality system has been in effect for at least three to six months.
- Make corrections and adjustments to the quality system based on the findings of the internal audit.
- Desk Assessment by CAP of Lab's Quality Management Plans and Quality Manual Documentation.

22. (Optional) LAB/CAP Gap Assessment (multi-day on-site)
23. (Optional) LAB/CAP Pre Assessment (one-day on-site)
24. CAP Accreditation Assessment (3-days on-site)
25. CAP/ISO 15189 Accreditation.

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The ROI

What was the Outcome on PML's Investment in Quality?

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The PML Experience and ROI

Financial Investment	Year 1	Year 2	Year 3
Consulting	$28,500	$3,100	$1,500
Documentation Software	$23,800	$4,500	$3,750
Accreditation Fees	-	-	$16,845
Staff Time [2]	TBD[3]	TBD	TBD
Quality Managers Time	$45,000	$45,000	$45,000
Sub Total	$97,300	$52,600	$119,695

Estimated Investment ISO Program	$269,595
Quality Managers Costs	(135,000)
Estimated Investment w/o Quality Mgrs. Time	$134,595

1. Accreditation Fees years two and three of CAP's ISO program are $13,145/year respectively
2. Four Staff members obtained Black Belts via Tuition Reimbursement
3. To be Determined – Staff can be viewed as Fixed or Variable Assets ($Costs)

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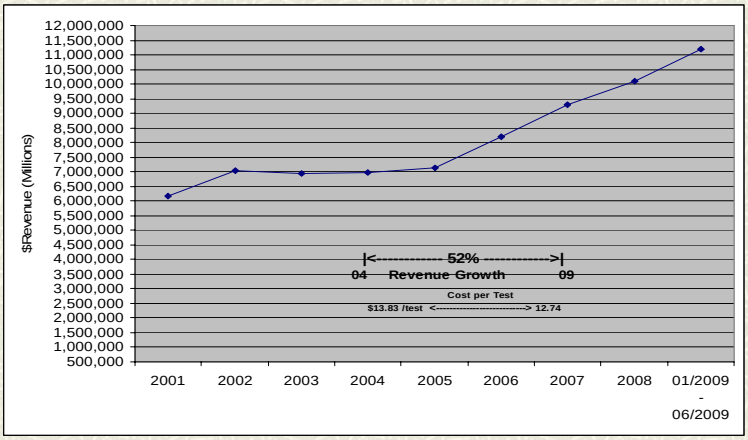
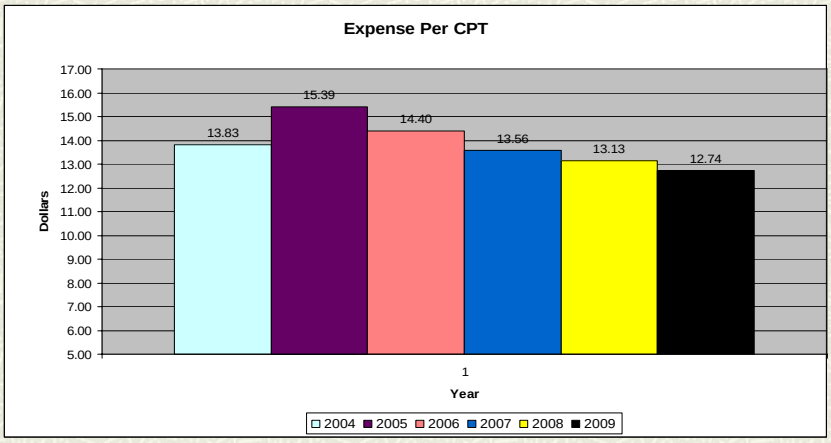
PML Revenue



Expense per CPT



The PML Experience and ROI (continued)

$ Cost reduction ($savings) per CPT year four $1.09**

SAVE $3.00 for every $1.00 Invested

**The Lion Share of Savings is attributed to organizing PML's Process Improvement initiatives under the CAP/ISO 15189 Standards

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Key Benefits of Organizing Your laboratory under the ISO 15189 Quality Program

- Facilitates Building a Quality culture amongst your Staff
- Creates Customer First Focus
- Stimulates Innovation
- Improves Staff Morale
- Promotes continuous process improvement, reducing waste and lowering costs
- Assists in Business Development and Growth with the appropriate PR and Marketing campaign
- Improves Documentation, improves tracking and problem resolution

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Benefits of ISO Quality Program (continued)

- Generated numerous Department improvement Projects (DIPs)

Courier Route Optimization	Lean processing
Document scanning	Call management
Auto verification	Broadcast Fax
Requisition Scanning	Requisition design
	Revenue cycle improvement

- Increased workload (44%) with reduced Technical Staff (3 MTs through attrition)

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Ultimate ROI for PML??

"The Development of a Quality Culture Amongst the PML Staff"

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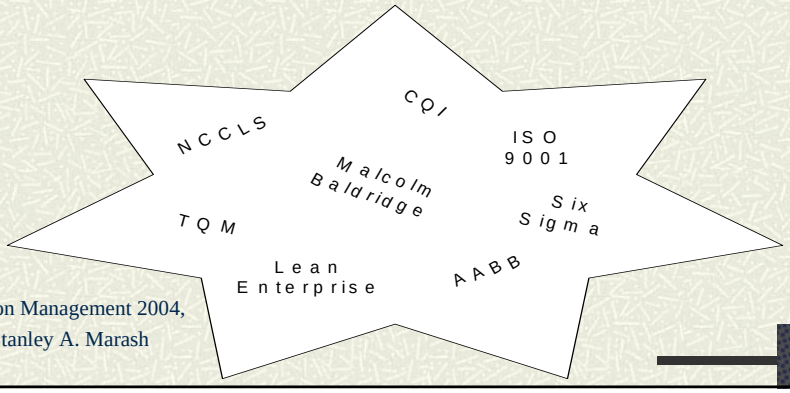
Future Holds??

Fusing Performance
Excellence models, with Six Sigma
And Quality Management System



Fusion Management 2004,
Dr. Stanley A. Marash

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"Loyal Customers Drive
Higher Profits"

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"Even if you're on the right track, you'll get run over if you just sit there." -- Will Rogers

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Key Definitions

- Accreditation – Procedure by which an authoritive body gives formal recognition that a body or person is competent to carry out specific tasks or certification by the certification body.
- Certification – The state of being certified that one has fulfilled the requirements of and may practice in a field of discipline.
- ISO: International Organization for Standardization based in Geneva, Switzerland
- NCCLS: The National Committee for Clinical Laboratory Standards
- Path of Workflow – "Sequential processes in pre-analytic, analytic and post-analytic clinical laboratory activities that transform a physician's order into laboratory information". (NCCLS GP26-A2)
- Quality: Conformance to expectations or the "Degree to which a set of inherent characteristics fulfills requirements". (ISO9000:2000 Quality Management Systems – Fundamentals and Vocabulary)

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Key Definitions

- Registration – Organization's certification is recorded in auditor's register.
- Quality System Essentials – "Coordinated management activities to direct and control an organization with regard to quality. NOTE: ISO 9000:2000 uses the term 'Quality Management' to describe these activities." (NCCLS GP26-A2)
- Product: Result of any process. Examples: Service call, specimen, test result.
- Policy: What you plan to do. Plans, intentions and direction.
- Process: How it happens. Tasks and activities that transform policies into action.
- Procedure: How to do it. Specific work instructions.

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ISO References

- To obtain a copy of the ISO standard: http://www.ansi.org
- Rob Kantner. *The ISO 9000 Answer Book.* John Wiley & Sons. 2000.
- Introduction to ISO http://www.iso.ch/iso/en/aboutiso/introduction/index.html
- ISO 9000 Overview http://www.iso.ch/iso/en/iso9000-14000/iso9000/iso9000index.html
- The ISO 9000 Family http://www.iso.ch/iso/en/CatalogueListPage.CatalogueList?ICS1=3&ICS2=120&ICS3=10
- TC 176 Interoretations of the ISO 9001:2000 Standard http://www.tc176.org/Interpre.asp
- ISO Auditing Practices Group http://isotc176sc2.elysium-ltd.net/APG_index.html

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Quality System References

- ISO #15189:2003 “Quality Management in the Medical Laboratory”, adopted by Europe in 2001. http://www.iso.ch or http://www.nccls.org
- AABB “Standards for Blood Banking and Transfusion Services”. http://www.aabb.org
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- NCCLS GP26-A2 “Application of a Quality System Model for Laboratory Services”. http://www.nccls.org
- NCCLS HS01-A “A Quality System Model for Healthcare”. Applies to any healthcare organization.

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- The Benchmark Exchange http://www.benchnet.com/
- National Association for Healthcare Quality. Journal and certification. $115 for individual membership. http://www.nahq.org
- Deming Institute http://www.deming.org/
- Deming Electronic Network http://deming.eng.clemson.edu/pub/den/
- Juran Institute http://www.juran.com
- The Quality Network http://www.quality.co.uk/

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Other Quality References (continued)

- American College of Medical Quality. Mostly physicians, but also includes other healthcare professionals. http://www.acmq.org
- Agency for Healthcare Research and Quality. http://www.ahcpr.gov
- Quality Magazine. Free subscription. Online buyer's guide (shows that there are currently 39 vendors of quality management software). http://www.qualitymag.com
- ASQ and Healthcare Quality. http://www.asq.org/healthcare
- Quality Digest. Free subscription. http://www.qualitydigest.com

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