Path to ISO 15189 Accreditation

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Presentation Objectives

- Decision to pursue ISO 15189
- How PML implemented the standard
- Registrar information
- Preparing for internal audits
- Preparing for gap assessment, pre-assessment and the assessment
- Benefits PML gained during implementation
PML Profile

- Full service CAP accredited reference laboratory established in 1991
- Performs approximately 1 million billable test procedures annually
- Testing platform includes
  - Chemistry and hematology
  - Limited andrology
  - Limited blood bank
  - Microbiology and limited mycobacteriology
  - Molecular Pathology

PML Profile continued

- A variety of value-added services are also provided
- PML staff is approximately 100 employees
- Patient service centers
Timeline of ISO 15189 Accreditation

January 2004 - Began research of Quality Systems
January 2005 - Presentation to Board and Management Staff
November 2005 - Began implementation of electronic document control software
December 2006 - Document control complete

January 2008 - Began researching registrar companies
February 2008 - Began internal audit
April 2008 - Send desk assessment and other paperwork to the CAP
July 2008 - Completed CAP15189 GAP Assessment
September 2008 - Completed CAP15189 Pre-Assessment

December 2008 - Accreditation date

Quality System Decision

- December 2004 began quest of a quality
- Review of quality systems
- PML chooses to pursue ISO 15189
Implementing ISO 15189

- Presentation to PML Board of Directors and PML management team
- Presentation and education to general staff
- Hiring a consultant
- Quality Manual – creation and education

Implementing ISO 15189

- Document control
  - Manual vs. Electronic
  - Vendor search
  - Proposal to Board
Implementing ISO 15189

- Importing documents, training, and implementation of paradigm
- Departmental education for paradigm users
- Training and education of general staff of the ISO 15189 standard and TR 22869

Registrar

- Research
- Looking abroad
- Final decision/application
CAP 15189 Overview

- Laboratory accreditation to the ISO 15189:2007 Standard

Internal Audit Preparation

- Consultant
- Volunteers to become internal auditors
- Creation of internal audit forms
- Division of the standard for quarterly audits to be reported to management staff
Desk Assessment

- Preparation
- Submission

Spreadsheet example

| 5.8.3.b | The identification of the laboratory that issued the report. | - | x | x |
| 5.8.3.c | Unique identification and location of the patient, where possible, and destination of the report. | - | x | x |
| 5.8.3.d | Name or other unique identifier of the requester and the requester’s address. | ActiveNet / Compliance Plan | x | x |
| 5.8.3.e | Date and time of primary sample collection, when available and relevant to patient care, and time of receipt by the laboratory. | 1. ActiveNet / Customer Service 2. Quality Manual: QSE 06 | x | x |
| 5.8.3.f | Date and time of release of report, which, if not on the report, shall be readily accessible when needed. | Quality Manual | x | x |
| 5.8.3.g | Source and system (or primary sample type). | Quality Manual: QSE 06 Process Control | x | x |
Gap Assessment

- Elective
- Preparation
- 3 day assessment
- Summation
- Post gap assessment

Pre-Assessment

- Elective
- Preparation
- 1 day assessment
- Summation
- Post pre-assessment
Assessment

- Preparation
- 3 day assessment
- Summation
- Post assessment

Benefits from Implementing ISO 15189

- Standardized work
- Reduced waste
- Improved tracking
- Improved staff morale
- Comparison with international laboratories – learn best practices
Benefits from Implementing ISO 15189

- Process improvement projects
  - Courier re-routing
  - Scanning requisition and patient results
  - Auto-verification
  - Requisition design
  - Lean processing department – first in, first out, specimen integrity
  - Broadcast fax

- Increased work load by 25%; lost 2 medical technologists to attrition

Accessions per year

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Benefits from Implementing ISO 15189

- Increase criteria for participation with contracts

Items that worked for PML

- Gaining support from executive and upper management
- Creating a cross referenced quality manual
- Full time quality management position
- Addition of quality management to all job descriptions
- Education for all staff – continuing
Items that worked for PML

- Choosing the right registrar
- Continual education with ISO standard and process improvement
- Electing to perform the gap assessment and the pre-assessment
- Celebrating the success

Items PML would do differently

- Deploying ISO and Lean simultaneously
- Trained quality coordinator as a certified ISO internal auditor
- Deploy ISO first then implement Lean