



## Path to ISO 15189 Accreditation

**Benita I. Haines MT(ASCP)**

Quality Management, Compliance and  
Education Coordinator

Piedmont Medical Laboratory

September 25, 2008

© 2008 Piedmont Medical Laboratory. All rights reserved.



## 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

© 2008 Piedmont Medical Laboratory. All rights reserved.



## 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

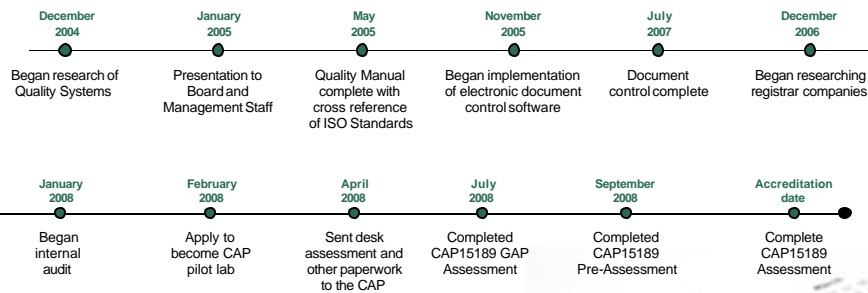


## PML Profile continued

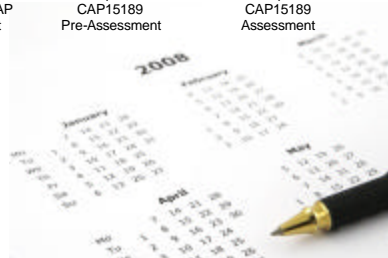
- ✍ A variety of value-added services are also provided
- ✍ PML staff is approximately 100 employees
- ✍ Patient service centers



## Timeline of ISO 15189 Accreditation



© 2008 Piedmont Medical Laboratory. All rights reserved.



## Quality System Decision

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

© 2008 Piedmont Medical Laboratory. All rights reserved.



## 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



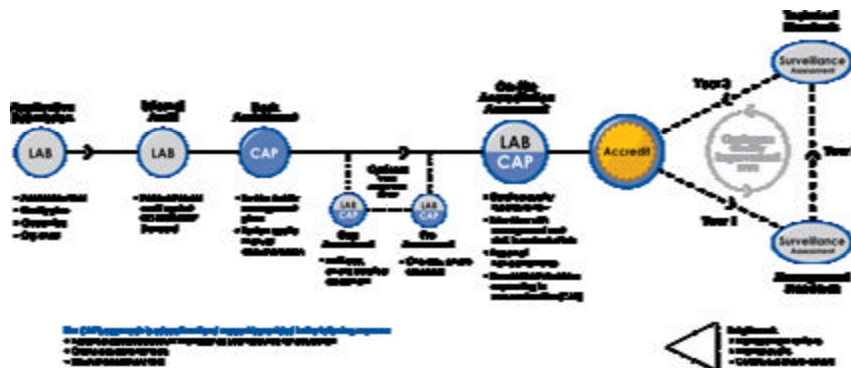
## Registrar

- ✍ Research
- ✍ Looking abroad
- ✍ Final decision/application



## CAP 15189 Overview

Laboratory accreditation to the ISO 15189:2007 Standard



© 2008 Piedmont Medical Laboratory. All rights reserved.



## 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

© 2008 Piedmont Medical Laboratory. All rights reserved.



## 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

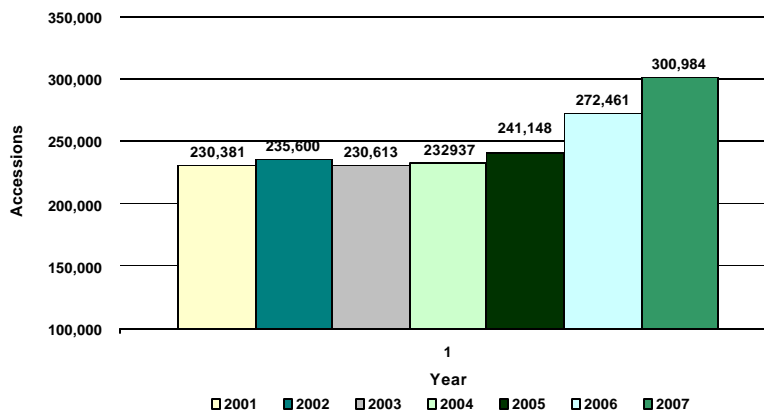
### Process improvement projects

- ? 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





## 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