

- 
- 
- 
- 
- 
- 
- 
- 
- 
- 

# ISO 15189:2007

## Medical laboratories — Particular requirements for quality and competence



## Using PT Data in the Assessment Process

Presented to A2LA Assessor Conclave  
April 3, 2009



- 
- 
- 

# Presentation Overview

- How is PT used in the laboratory?
- 15189 Requirements
- A2LA Requirements
- Using PT as a tool for assessment



- 
- 
- 

## How is PT Used in the Laboratory?

- Proficiency Testing is used to assess the ability of a laboratory to accurately perform testing.
- Used as a requirement toward accreditation
- Used as a requirement in meeting regulatory compliance
- Used as education within the laboratory



- 
- 
- 

## How Is PT Used During an Assessment?

- Is the laboratory meeting the regulatory and accreditation requirements for PT?
- Does laboratory management review PT results?
- Does the laboratory have and use a corrective action (CA) process?
- Is that CA process effective?



- 
- 
- 

## How Is PT Used During an Assessment?

- As a thread to “pull” to check for systemic compliance.
  - Instrument calibration/verification
  - Staff qualification and training
  - Document control
  - Vendor evaluation
  - Quality control



- 
- 
- 

## ISO 15189: 2007 5.6.4

- The laboratory shall participate in interlaboratory comparisons such as those organized by external quality assessment schemes
- Laboratory management shall monitor the results of external quality assessment and participate in the implementation of corrective actions when control criteria are not fulfilled..
- Interlaboratory comparison programmes shall be in substantial agreement with ISO/IEC Guide 43-1.
- External quality assessment programmes should, as far as possible, provide clinically relevant challenges that mimic patient samples and have the effect of checking the entire examination process, including pre- and post-examination procedures.



# A2LA Requirements for PT

## R306 – GENERAL REQUIREMENTS: PROFICIENCY TESTING ISO 15189 MEDICAL TESTING LABORATORIES

- Requires the use of a PT provider that is approved by CMS
- Forbids sending PT samples to other laboratories
- Requires that PT samples be integrated into normal patient workload
- Requires participation in accordance with Subpart H of 42 CFR 493
- Requires a written PT plan covering all aspects of PT testing.



# A2LA Requirements for PT

## R306 – GENERAL REQUIREMENTS: PROFICIENCY TESTING ISO 15189 MEDICAL TESTING LABORATORIES

- Requires that all methods be covered by PT, including back-up methods.
- Requires that PT results are reviewed by management
- Requires that incorrect results be subjected to the laboratories corrective action process
- Requires the laboratory to submit the summary results to A2LA



- 
- 
- 

## Using PT as a tool for assessment

- Review PT data provided with assessment package for open issues, trends or problem areas.
  - Note any PT results, corrective actions or other documentation that you specifically wish to look at on site.



- 
- 
- 

# Using PT as a tool for assessment

- Once you are on site
  - Ask the laboratory for the documents that were identified in your desk audit
  - Ask for any PT results that were not yet submitted to A2LA
    - (Record this review on the PT Matrix)



- 
- 
- 

# Using PT as a tool for assessment

- Review the PT Data for
  - Coverage of scope
  - PT Failures
    - Evaluate results for the same analyte that are available before and after the date of the PT failure.
  - Completeness of any corrective action
    - Has the CA plan been fully implemented?(4.10)
    - Has the laboratory put monitoring in place to assess the effect of the CA?(4.10.3)
    - Is there evidence that the CA has been effective? (4.10.3)



- 
- 
- 

# Using PT as a tool for assessment

- Where to from here?
  - Use the PT results to ID staff for record review
    - Have they undergone training on this procedure? (4.1.5 g)
    - Are their credentials consistent with the QM personnel policy?(4.1.5 d)
  - Corrective Action Responses
    - Follow the labs CA process?(4.9.1)
    - Fully implemented?
    - Monitored?(4.10.3)
    - Effective?(4.10.3)
    - Entered in Labs Error/Issues process?(4.10)
    - Has any training been completed and documented?(4.1.5 g)



- 
- 
- 

# Using PT as a tool for assessment

- Where to from here?
  - Are PT processes evaluated during internal audits?(4.10.4)(4.14)
  - Is PT performance summarized during the management review?(4.10.4)(4.15)

