

# New Directions in LAP



Robert R. Rickert, MD, FCAP  
Chair, Accreditation Committee  
Laboratory Accreditation Program

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- **Welcome the participants**
- **Introduce yourself**
  - Name
  - Role at CAP
  - Where you are from
  - Area of expertise

**Note to presenter: Suggested timing for this presentation is 20-30 minutes.**

## Learning Objectives

- Describe the most recent changes to the CAP Laboratory Accreditation Program
- Describe how laboratories can be prepared for unannounced inspections

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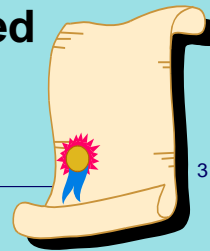
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**As a result of participating in this session, you will be able to:**

- Describe the recent changes to the CAP Laboratory Accreditation Program (LAP)
- Describe how laboratories can be prepared for unannounced inspections

## The LAP Mission

The CAP Laboratory Accreditation Program improves patient safety by advancing the quality of pathology and laboratory services through education, standard setting, and ensuring that laboratories meet or exceed regulatory requirements.



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- The mission of the CAP Laboratory Accreditation Program is:
  - To improve patient safety by advancing the quality of pathology and laboratory services through education, standard setting, and ensuring laboratories meet or exceed regulatory requirements.


CAP inspections promote this mission in two ways:

- Promote culture of quality patient care through
  - Quality control
  - Performance improvement
  - Proficiency testing (external quality assurance)
- Compliance with federal and other lab regulations (regulatory hat)
  - Labs must comply with CLIA
  - Meet CAP accreditation standards, which are at least as stringent as CLIA and sometimes more stringent

# Drivers for Change

- Regulatory
- Public environment
- Internal comprehensive review of program

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- **The CAP Accreditation Program is changing a bit, in response to real life**
- **The drivers for change are:**
  - Regulatory requirements
  - Public environment
  - Internal comprehensive review of the program
- **We want to:**
  - Keep it the best program it can be
  - Change it in a way that can improve it
  - Maintain the balance between education and regulation

# LAP Initiatives

- Enhance inspection consistency and effectiveness
- Strengthen procedures to monitor labs for sustained compliance
- Increase role of lab personnel in accreditation process
- Strengthen public confidence

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- **LAP adopted a series of initiatives based on its review of the program:**
  - Enhance inspection consistency and effectiveness
  - Strengthen procedures to monitor labs for sustained compliance
  - Increase the role of lab personnel in the accreditation process
  - Strengthen public confidence in the CAP accreditation process
- Each initiative will be discussed in more detail

## Enhanced Consistency and Effectiveness

- Inspection tools in checklists
- Mandatory training for all inspectors
- Standardized assignment process

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- **To enhance inspection consistency and effectiveness, LAP has:**
  - Included inspection tools in each checklist
  - Tightened the requirement for mandatory training for all inspectors
  - Standardized the assignment process

## Enhanced Inspection Tools

- **Provide written guidance to inspector within the checklist concerning:**
  - How to conduct the inspection
  - How to cite/write deficiencies
- **Best practices now available to all inspectors**
  - Focus more on observation and discussion with testing personnel

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- **Some laboratory inspectors have made it a practice to talk with bench level techs during an inspection,**
  - CAP is now formalizing that process so that it is incorporated into every inspection
  - One of the best ways to find out what's going on in the laboratory is to go up to someone performing testing at the bench
- **By observation and asking questions, an inspector can find information about:**
  - If they are performing the procedure as written
  - How the QC is working that day
  - When the last time the QC was out and what they did about it
  - How they perform PT
- **Only about one third of the inspection time should be spent reviewing documentation**

## **Mandatory Inspector Training**

- **All inspectors must complete training within two years prior to inspecting**
- **Monitoring for team leaders begins with assignments accepted after July 1, 2006**
- **Team leader's responsibility to ensure training of team members**
- **Update training every two years**

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- **All inspectors must complete training within the two years prior to inspecting**
- **LAP is monitoring this requirement for all team leaders who have accepted an assignment after July 1, 2006**
- **It is the team leader's responsibility to ensure team members are trained**
- **All inspectors will need to update training every two years**

## Team Leader Training Options

- **Comprehensive Online Team Leader Self-Study**
- **Full day Inspector Training Seminar**
  - With “Managing a Successful Inspection” breakout
- **Team Leader Workshop PLUS Team Leader Online Practice**

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**Three options for team leader training:**

**NOTE: the requirement is to complete 1 of the 3 options listed:**

### 1. Comprehensive Online Team Leader Self-Study

- Updated annually at the end of May
- Available 24/7
- Bookmarking feature to return to where you stopped

### 2. Full day Inspector Training Seminar (ITS)

- Must attend the “Managing a Successful Inspection” afternoon breakout at the ITS


### 3. Team Leader Workshop PLUS Team Leader Online Practice (must complete both )

- All three options offer the same content and are offered at no charge

# Inspector Selection & Assignment Project

- Expedite team selection and assignment
- Improve quality of inspections by selecting the best team
- Based on defined criteria:
  - Appropriate team size and composition
  - Trained and experienced inspection team
  - Timely assignments
  - Reduce the potential for real or perceived conflicts of interest

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**So, what is the Inspector Selection and Assignment Project, and how is it going to affect me?**

**The overall goal of this project is to enhance the selection of an inspection team by**

- ensuring appropriate team size and team composition, and
- ensuring timely assignments to better support on-time inspections
- minimizing conflicts of interest,

**Issues in the past have been**

- bringing too many or not enough inspectors,
- being asked to inspect a facility much larger than their own,
- not having qualified inspectors on a team, etc).

**The first piece (use in early 2007) is the assignment piece, which also includes monitoring of team leader training and conflicts of interest.**

**We will talk more about the Assignment Acceptance Packet during Team Leader Essentials.**

## **Strengthen Procedures to Monitor Labs**

- **Intensified scrutiny of PT**
- **More requests for off-cycle documentation**
- **More non-routine inspections**
- **Structured communication with CMS, JCAHO**

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- **Second initiative is to:**
  - **Strengthen procedures to monitor labs**
- **Some of these procedures include:**
  - **Intensified scrutiny of proficiency testing**
  - **More requests for off-cycle documentation**
  - **More non-routine inspections**
  - **More structured communications with CMS and JCAHO**

## Increase Role of Lab Personnel in Inspection

- **Inspectors will spend more time at bench**
  - Observe that practice matches policy
  - Talk with bench technologists
- **Increased communications within lab with unannounced inspections**
- **Pre-inspection video**

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### •The third initiative is:

To increase the role of lab personnel in the inspection process

- Historically, inspectors have dealt only with lab directors, managers and supervisors
- No longer true
- Now, inspectors will spend 2/3 of time
  - Observing practices
  - Talking with bench techs
- At unannounced inspections, key lab personnel may not be present
  - Important for all supervisors and bench techs to be able to demonstrate compliance
    - Know where documentation is located
    - Cross-training to explain processes
- An LAP video is now sent to the lab with its reapplication packet

# **Laboratory Accreditation Video**

- Mailed with reapplications beginning January 2006
- Explains CAP accreditation process
- Encourages active participation of all lab personnel
- Encourages interaction with inspectors
- Should be viewed by all lab employees

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### **The informational video:**

- **Designed to be shown to all lab employees to explain:**
  - **What accreditation is**
  - **Who CAP is**
  - **Why we inspect every 2 years**
  - **Purpose of accreditation – why we are there**
  - **What we will be looking for**
  - **Role of the lab in getting ready for inspection**
  
- **Encourages all lab personnel to participate in the inspection process**

**Strengthen Public Confidence**

- **Unannounced inspections**
- **Focus on patient safety goals**

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• **The fourth initiative is to:**

- **Strengthen the public’s confidence in CAP accreditation process**

• **Initiative is being accomplished through:**

- **Unannounced inspections**
- **Focus on patient safety goals**

**We’ll be talking about Patient Safety goals later, so let’s discuss the impact of unannounced inspections**

## Unannounced Inspections

- Have been used for non-routine inspection
- Are being performed for all CAP-inspected labs in US, Canada, Puerto Rico, except:
  - Initial inspection
  - Reproductive - RLAP
  - Forensic Drug Testing – FDT
- Not used for international labs

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- **Unannounced inspections are not new to CAP**
- **Have been performed for non-routine inspections**
  - For outside complaints
  - Problems with PT
  - Large number of deficiencies
- **Unannounced inspections are now being performed for all routine inspection in US, Canada and Puerto Rico,**
- **EXCEPT:**
  - Initial lab inspections (those new to LAP accreditation process)
  - Reproductive Laboratory Accreditation Prgm (RLAP)
  - Forensic Urine Testing Accreditation Prgm (FDT)
- **Unannounced inspections will NOT be performed for international labs**

## Unannounced Inspections What the Process Means

- Lab not notified of inspectors' identities
- No contact between inspector and lab
  - All communication through CAP
- Inspector chooses date
  - Notifies CAP *but does not notify lab*
- Coordinated inspections (e.g., AABB) also unannounced

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### What does “unannounced” really mean?

- **Laboratory will not know in advance:**
  - The exact date of its accreditation inspection
  - The name of their inspection team leader, team members or their institution
- **The inspection team leader and the inspected laboratory staff will not have any contact until the day of the inspection**
  - All contact will occur through the CAP

## How Does It Work?

- Inspector assignments ~1 year prior to Anniversary Date
- Reapplication 9 months prior to AD
- Inspection “window” begins 6 months prior to anniversary date
- Lab declares  $\leq 10$  “blackout” dates
  - Same dates for labs inspected together
  - May not be changed

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- Team leaders are being assigned more than 6 months in advance of the lab’s anniversary date
  - Goal is for all assignments to be made one year prior to lab’s anniversary date
- Inspection may occur in the 6 months prior to lab’s anniversary date
- In reapplication, lab may declare 10 black out dates which the inspection team must honor
  - If multiple labs are inspected by same team, each lab must indicate the same black out dates
  - Black out dates may not be changed once reapp is sent to CAP
  - Team must honor US national holidays

## Advantages for Inspectors

- **Earlier assignment - more time to prepare**
- **Easier for team leader to choose a convenient inspection date**
- **Current knowledge of inspection process still applicable**

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- **Due to the process changes required for unannounced inspections**

- **Team leaders are assigned earlier**

- **More time to prepare and gather team**

- **More time to complete training**

- **Inspection teams have more opportunity to select an inspection date that is convenient for them**

- **Understanding of the inspection process will continue to apply**

## Advantages for Lab

- **Lab focuses on continuous compliance**
  - Avoids “once-every-two years” syndrome
  - Less stressful for lab personnel
  - More consistent with best lab practices
- **Lab in state of constant readiness for inspection by any agency**
- **Current knowledge of laboratory quality programs still applicable**

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- **The advantages of unannounced inspections for the laboratory are:**
  - **Lab focuses on continuous compliance rather than “getting ready for the inspection”**
    - **Reduced stress for all lab personnel**
    - **Increased consistency of best lab practice**
      - **Produces a culture of quality**
  - **Lab is prepared for an inspection by any agency**
  - **Despite the change to unannounced inspections, what laboratorians know about establishing and maintaining quality in the lab will not change**

## What We've Learned - Labs

- Major anticipated issues not a problem
  - Availability of key staff
  - Access to documentation
  - Conference/work rooms/Meal planning
- Training of back-up staff essential
- Checklist “notebooks” very helpful
- No increase in number of deficiencies
  - But housekeeping and safety issues

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### Pilot studies and information from unannounced inspections so far show:

#### •Several anticipated logistical issues were not a major problem

- Availability of key staff:** labs relieved supervisors from bench work, reprioritized workloads, called in replacement bench techs as needed
- Access to documents** was not significantly impaired
  - Most documents could be located before the summation conference.
  - If not, and deficiencies were cited, in its deficiency response the lab can provide existing documents showing it was in compliance on inspection day. The deficiency can then be removed
- Conference room availability:** users readily released reserved rooms for Summation conference. Inspectors worked individually or shared available space throughout the day if one large room was not available
- Meal planning** – sandwiches were easily ordered in, or team used the onsite cafeteria. Many teams had a “working” lunch to communicate progress or discuss other issues.

#### •Training of supervisor back-up staff is essential

- Labs that created Checklist “notebooks” listing each checklist question and the location of supporting documentation added to efficiency
- Only increases in deficiencies were that the lab was not sparkling clean and some safety items, such as supplies blocking hallways/work spaces

## What We've Learned-Teams

- Team needs to prepare
- Team arrive 30-60 minutes earlier
  - Getting through security
  - Gives lab time to notify key staff and find documentation
- Team should bring photo ID/ security forms
- No increase in number of inspectors

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### Lessons learned regarding inspection teams are:

#### •Team needs to prepare

##### – MUST review inspector packet to know

- Blackout dates (The TL MUST WAIT FOR THE INSPECTOR PACKET to arrive before setting the actual inspection date)
- Days/hours of operation
- Organization chart
- Location of satellite labs, transportation issues

#### •Team should arrive 30-60 minutes earlier than for announced inspection. This extra time will be needed for:

- Security clearance (when required by lab)
- Presenting the CAP-supplied introduction letter that states you've been sent by CAP to perform an unannounced inspection
  - Team members must bring photo ID (and completed security forms when applicable)
- Locating key staff members
- Lab to quickly make available its policies and procedure manuals and other documentation
- Arrange for interviews of CEO, CMO and Lab Director

## Summary: Key Points

- CAP is pioneer in lab accreditation
- CAP is committed to raising the quality of lab testing
- Goal of the overall program initiatives is to be more:
  - Consistent
  - Objective
  - Efficient
  - Effective

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### To summarize:

- CAP has been a pioneer in laboratory accreditation since 1961
- CAP is committed to raising the quality of lab testing and improving patient safety, by
  - Advancing the quality of pathology and laboratory services through education, standard setting
  - Ensuring that laboratories meet or exceed regulatory requirements
- LAP has initiated several program changes which will ensure that laboratory inspections are:
  - Consistent
  - Objective
  - Efficient
  - Effective