



ST101 Inspection Team Leader Workshop

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Laboratory Accreditation Program

Team Leader Essentials



Education by the Experts

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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.



LAP Inspection: Maintaining Balance



**Quality
Improvement**

Education

**Regulatory
Compliance**



Session Objectives

- Describe the philosophy of and recent changes to the CAP Laboratory Accreditation Program
- Use the Team Leader Inspection Planner to prepare for and conduct an inspection
- Apply the Team Leader Checklist to evaluate Lab Director qualifications and effectiveness
- Handle common situations that occur in pre-inspection and inspection settings

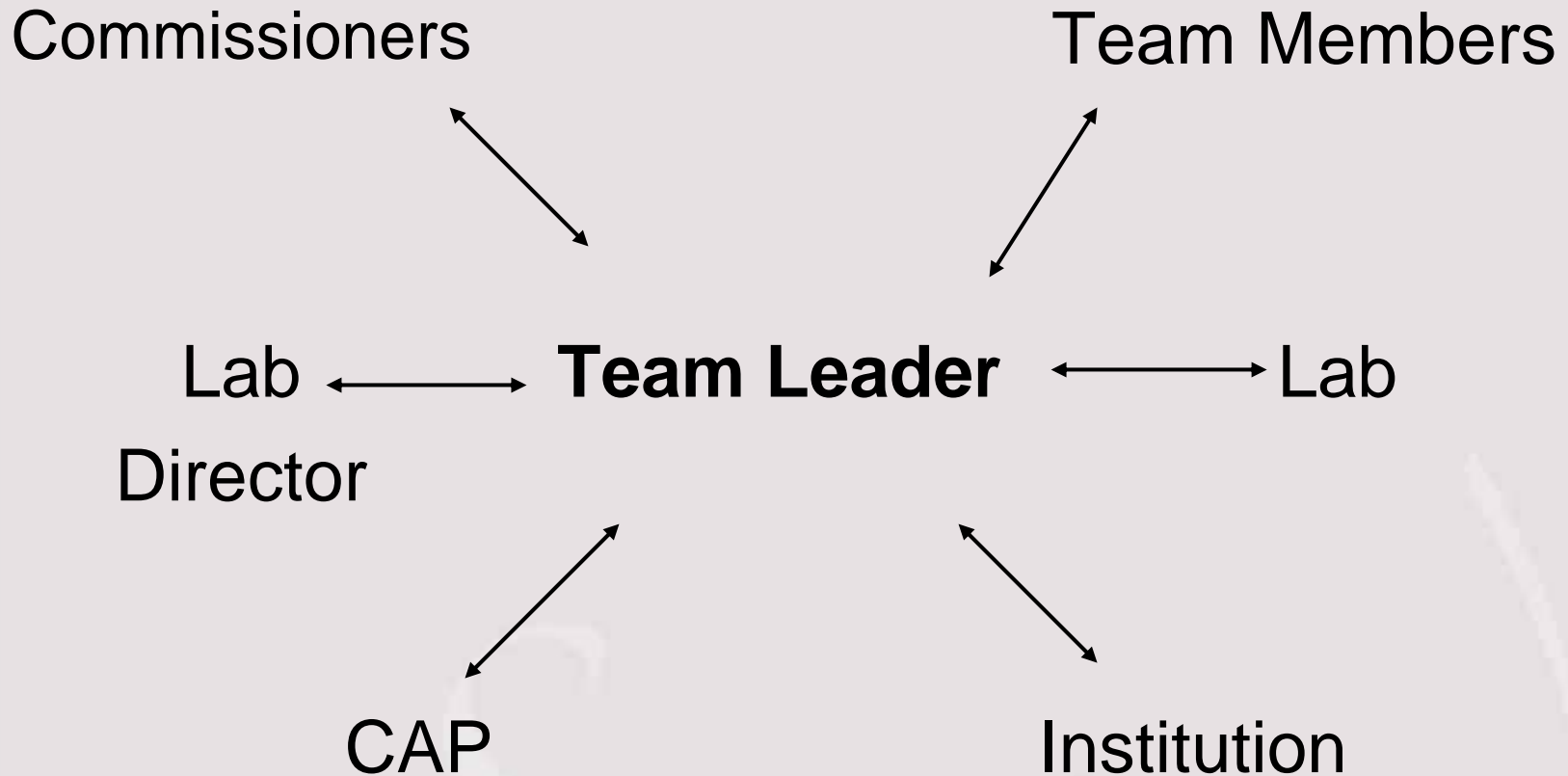


Questions to Answer

- Why do we need a Team Leader?
- What does the Team Leader do?
- What should the Team Leader inspect?
- What will happen if the Team Leader has not prepared:
 - Self?
 - Team?



Pivotal Role of Team Leader



NEW!

Starting Off...

- Team Leader contacted by College 6-12 months in advance
- Receives Assignment Acceptance Packet
 - Reviews:
 - Laboratory organization and workload
 - Availability of team
 - Recommended number of inspectors
 - Signs Conflict of Interest Form
 - Accepts assignment



Team Leader Essentials

- Activity #1 – Walk through Assignment Acceptance Packet



Would You Accept this Assignment?

- Why/Why not?
 - Size/complexity
 - Disciplines/specialties
 - Geographic location
 - Accreditation anniversary date
 - Conflict of interest
- Could someone else in your facility lead this team?



Team Leader Inspection Planner

1. Arrange the inspection
2. Review the packet
3. Distribute Team Member Packets
4. Prepare the Team
5. During the Inspection
6. Pre-summation
7. Summation
8. After the Inspection



Pre-Inspection



Time to Prepare



Education by the Experts

1. Arrange the Inspection

- For unannounced
 - Do NOT contact Lab Director(s) or staff
 - Select several possible inspection dates
 - Begin team selection
 - Finalize date after reviewing Inspection Packet
- For initial, international, RLAP, FDT
 - Contact Lab Director(s)
 - Set inspection date



2. Review Inspection Packet

- Number and location of labs
- Lab organization
- Changes in number of checklists
- Changes in disciplines/specialties
 - Test menu and instrumentation
- Blackout dates
- Contact CAP with date



Team Leader Essentials

- Activity #2 – Walk Through Inspector's Inspection Packet



Inspection Team Size

(Hospital Lab, 100-250 beds;
250,000-1,000,000 tests/yr)

- One inspector for Lab General
- Two checklists per inspector unless:
 - Micro contains virology or fungal ID
 - Blood bank includes donor center
 - Chemistry includes both Tox and Spec Chem
- Common checklist match-ups:
 - Hem & UA; Micro & Immuno; Anatomic Path & Cytopath; Blood Gases and POC
 - Check lab's section organization; supervisors



Inspection Team Size

- Small laboratory
 - <100,000 tests/yr
 - 2-3 checklists per inspector
 - Limited services-one inspector
- Large laboratory
 - >1,000,000 tests/yr
 - 1 checklist per inspector
 - 1-2 inspector(s) for Lab General



Specialty Checklists

- Specially qualified inspectors for:
 - Cytogenetics
 - Flow Cytometry
 - Histocompatibility
 - Molecular Pathology
- Must use inspectors from list provided in packet



Team Leader Essentials

- Activity #3 - Finalizing Your Team



Activity #3: Discussion

- What are the differences between the information provided in the two packets?
- Did the information affect your team selection?
- Are there any additional factors to consider?



Team Members

- Have discipline-specific expertise
 - May use residents after they have completed the appropriate rotation
 - Residents may shadow on all local inspections
- Must be knowledgeable about the process and requirements (trained)
- Possess good communication skills
- Possess interpersonal skills



Tips for Team Selection

- Limit inspection duties of Team Leader to no more than one discipline-specific checklist
 - In addition to Team Leader Checklist
- Include specialty inspectors when appropriate
- Use people you know



NEW!

3. Team Member Packet

- Team Member Packet
 - New lab section Synopsis Report
 - Activity (Test) Menu for applicable sections
 - Instrument and equipment list
 - PT Performance <100% Report
 - Team Member Evaluation form
- Checklist Packet
 - Previous ISR
 - Activity (Test) Menu for applicable sections
 - ISR Deficiency and Recommendation pages
 - Checklist(s)



3. Team Member Packet

- Add:
 - Inspection schedule-cover memo
 - Plane tickets
 - Hotel reservations
 - Sections of the Accreditation Manual



4. Team Member Preparation

- CAP inspection philosophy
- Inspection techniques
- Packet and checklist review
- Schedule and make travel arrangements
- Team Member training required within two years prior to inspection:
 - Inspector Training Seminars
 - Comprehensive Online Team Member Self-Study



Other CAP Resources

- Questions
 - accred@cap.org
 - 1-800-323-4040 (x6065)
- Resource Sheet
- LAP audioconferences



Travel Arrangements

- CAP Travel Desk **must** be used for:
 - Air travel purchase
 - More than 10 hotel nights
 - 1-800-323-4040 x7800
- Cost controls:
 - Tickets purchased well in advance
 - Modestly priced hotels
 - Meal expense maxima
 - Recommended number of inspectors



Team Leader Essentials

- Activity # 4 – Pre-Inspection Scenarios



Activity #4 – Scenario 1



Avoid an overnight stay if they take an early morning flight...begin the inspection at 10:00 am, and a late afternoon flight home that leaves at 5:30 pm. Good Idea?

- A. No, you should drive
- B. Yes, lab can complete its morning run
- C. No, fly in the night before



Activity #4 – Scenario 2



A week before the inspection, the inspector assigned to Histocompatibility has major surgery. What would you do?

- A. Reschedule inspection
- B. Inspect Histo later
- C. Find another inspector



Inspection



Positive Attitude



Education by the Experts

NEW!

One Hour Security Notice

- One hour prior to arrival
- Contact laboratory
 - Phone number in Team Leader letter
- Expedites security clearance
- Provides lab opportunity to confirm inspection team is authorized by CAP
- Also allows lab to gather key staff, expediting inspection process



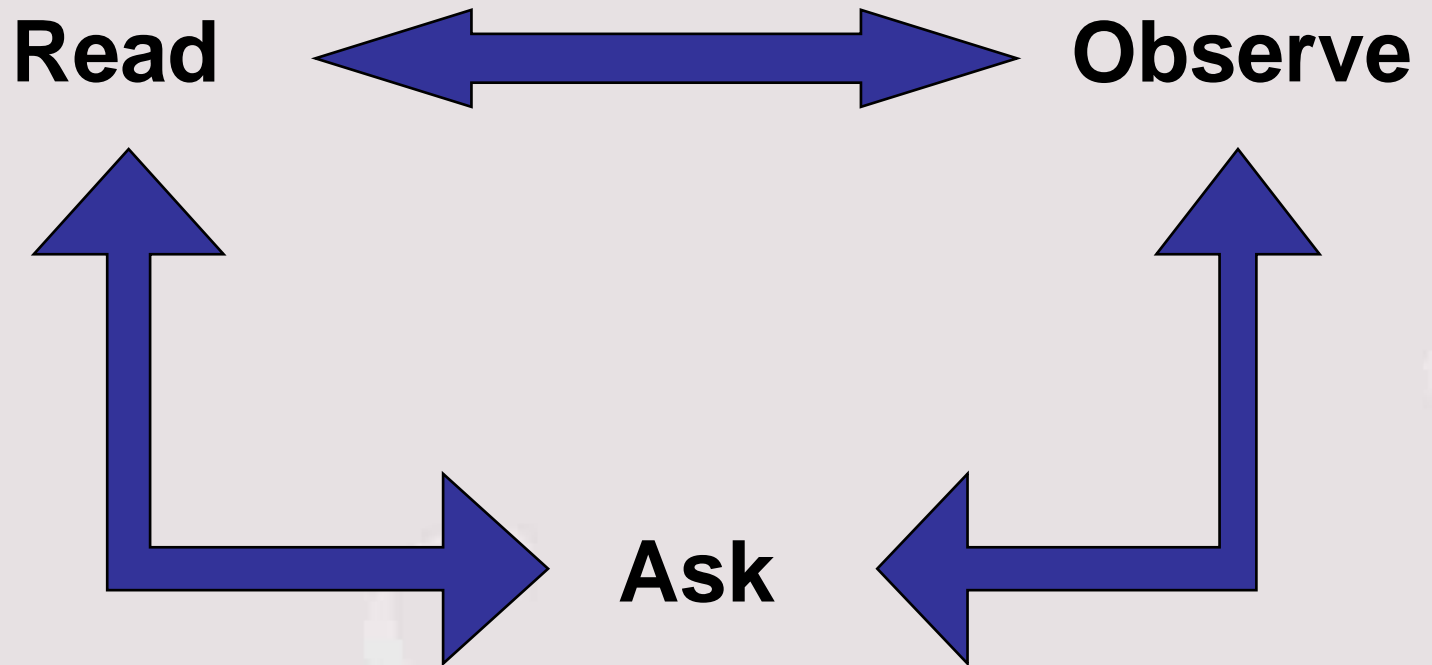
5. During the Inspection

- Arrive 7:30-8:00 AM
- Present letter from CAP (unannounced)
- Wear name tags and have personal ID
- Introduce team; set schedule
- Maintain contact with team
 - Working lunch
 - Brief meeting when section finished
 - Redirect inspectors as necessary
- **Call CAP with questions**
 - 1-800-323-4040 x6065



How to Get Information

Inspection Techniques



Inspection Approaches

- Effective Inspection Approaches
 - Follow the Specimen
 - Drill Down (in-depth analysis of select analysis)
 - Teach Me (pretend I am a new trainee)



Time Management

- For each 3 hours in a section:
 - 1 hour reading
 - 2 hours observing and asking
- Varies with expertise of inspector
- Tip: Keep inspecting while lab looks for documentation



Factors Affecting Time Management

- Preparation of lab
- Availability of key staff
- Workload of the lab that day
- Expertise of inspectors
- Number of problems discovered/depth of investigation required
- Unforeseen events



Team Leader Essentials

- Activity # 5 – Time Management



Activity #5 – Scenario 1



Inspection is proceeding very slowly...finding pertinent documents has been time-consuming. What should team members do?

- A. Confirm all documentation
- B. Accept verbal confirmation
- C. Cite deficiencies and remove them when documentation is found



Activity #5 – Scenario 2



Does not have appropriate virology checklist questions, still has Immunology to inspect

- A. Download checklist from the Web
- B. Call CAP for additional checklist
- C. Notify CAP after inspection



Activity #5 – Scenario 3



4:00 PM and five of the seven inspectors need another two hours; you have not talked with the lab director.

- A. Hold Summation based on the information you have.
- B. Continue to inspect; hold Summation when you have completed the inspection.
- C. Make arrangements to continue the inspection the following day.



Team Leader Checklist

- Assess Lab Director's:
 - Qualifications
 - Role and authority in the lab
 - Effectiveness
- Review Director's involvement in:
 - QM Program
 - Clinical consultations
 - Planning, development, etc.
 - Equipment and personnel decisions
 - Medical staff functions
- Evaluate lab's overall quality



Team Leader's Inspection

Sample Questions

- How is the QM Plan put together?
- What is the worst incident suffered by the laboratory last year?
- How does the laboratory satisfy the CAP patient safety goals?
- What is the most useful hospital committee that you serve on?
- What is the process for obtaining new instrumentation?



When Director Functions have been Delegated

- Person(s) and delegated functions must be documented
- Director must stay informed
- Director must ensure that function is performed appropriately
- Director retains overall responsibility for function



Interviews

- Chief Executive Officer
 - Unique aspects of CAP inspection
 - Relationship between lab and hospital
 - Plans for facility/services expansion?
 - Show appreciation for support
- Chief of Medical Staff
 - Scope, quality, timeliness of services
 - Participation in medical staff functions



Alternate Interviews

- RLAP
 - Medical Director of practice, staff physician
 - Medical practice Administrator
- FDT
 - Scientific Director, if different from Director
- Hospital-based
 - QA Manager for the institution



Questions to Ask CEO

- How do the pathologists/lab staff participate in hospital-wide committees?
- How effective are they in working with medical/administrative staffs?
- Does the lab meet the expectations of the administration?
- Are you planning any expansion of services that would affect the lab?



Questions to Ask CMO

- How would you evaluate the scope, quality and timeliness of lab services?
- Do the turn-around-times meet the needs of the patients and staff?
- How does the Lab Director participate in medical staff functions, such as committees, teaching conferences, etc.?
- Is the Lab Director available when needed?



Interview No-Nos

- Belittling lab or personnel
 - Do report systemic problems
 - Do maintain perspective
- Offering services to CEO or discussing finances
- Recruiting personnel
- Sympathizing with complaints about CAP or other organizations



Would You Discuss?

- Director's contract
- Quality of reference lab services
- Cost of CAP inspections
- Number of lab staff on night shift
- Expansion of OP services affecting lab
- Lack of cooperation between lab and nursing
- How to get nursing to label specimens



Team Leader Essentials

- Activity #6 – Team Leader Checklist



Activity #6 – Scenario



You ask how the lab director is involved with the QM system. He calls the lab manager who produces a copy of the QM plan.

- A. Cite a deficiency
- B. Write a recommendation
- C. Thank him for showing you the documentation



6. Pre-Summation

- Team meeting – sets the tone
- Answer Team Members' questions
- Review Deficiencies and Recommendations pages for citations
 - Systemic problems; consistency
- Remind Team Members to:
 - Complete pages before Summation
 - Write legibly; signature, credentials, date



Systemic Problems

LAB GEN:

- Method performance specs
- Personnel
- Computers
- QM
- Patient Safety Goals

ALL CHECKLISTS:

- PT
- QC
- Procedure Manuals
- Reagents
- Instruments/
equipment
- Reports



Immediate Jeopardy

- Situation requiring immediate corrective actions
- Non-compliance has already caused, is causing, or is likely to cause serious injury or harm
- Concern for health or safety of lab staff or general public



When to Cite a Deficiency

- No policy/procedure
- Policy not being followed
- Incomplete documentation
- Lab's processes not contributing to quality



How to Cite a Deficiency

- Use appropriate pink sheet
 - Checklist and section unit
- Clearly write checklist number and phase of question
- Provide reason for deficiency
 - Why is the lab not in compliance
 - Provide specifics e.g., dates, analytes, etc
 - Do not rewrite the question



When to Give a Recommendation

- Suggestions for improvement
- Compliance is not an issue
- Need not be related to specific checklist question



Team Leader Essentials

- Activity #7 – Pre-Summation Conference



Activity #7 – Scenario 1



Some inspectors cited space deficiencies, some gave recommendations, others did nothing.

- A. Too late to change the ISR
- B. Remove all the deficiencies and recommendations
- C. Review for consistency and notify supervisors of changes



Activity #7 – Scenario 2



No documentation of deficiencies found during self-inspection; only faxed statement

- A. Cite a deficiency
- B. Write a recommendation
- C. Do nothing



Activity #7 – Scenario 3



Reporting of troubleshooting and corrective actions on worksheets and reagent logs makes it difficult to find info.

- A. Cite a deficiency
- B. Write a recommendation
- C. Do nothing



Activity #7 – Scenario 4



Molecular Pathology refrigerator missing occasional temperatures in 2 years; QC records show no problems; corrective actions complete.

- A. Cite a deficiency
- B. Write a recommendation
- C. Do nothing



Activity #7 – Scenario 5



3 refrigerators in Transfusion Medicine; only one with complete temp records. Policy only covers blood storage refrigerator. Had written a deficiency; should she change it?

- A. Do not change it
- B. Change it to a recommendation
- C. Remove the deficiency



Activity #7 – Scenario 6



Lab monitors all four CAP Patient Safety Goals in QM Plan; no evaluation/actions taken; no improvement.

- A. Cite a deficiency
- B. Write a recommendation
- C. Do nothing



7. Summation Conference

- Presentation of inspection findings
 - State information clearly
 - Be supportive, not punitive
 - Exchange views; avoid arguments
 - Report what you learned/liked
 - Update ISR for any last minute corrections (corrected on site, documentation found)
- Explain deficiency response process
 - Reminder: 30 days to respond
- Obtain Lab Director's signature
- Leave copy of deficiencies/ recommendations



Team Leader Essentials

- Activity #8 – Summation Conference



Activity #8 – Scenario 1



Several unacceptable PT results not evaluated. At Summation, chief tech gives you copy of results indicating review done day of inspection.

- A. Keep it unchanged
- B. Mark it corrected-onsite
- C. Remove the deficiency



Activity #8 – Scenario 2



QC is performed as described in technical procedure. Corrective actions complete; reviews performed; no policy describing QC program. At Summation, director gives you policy that was misfiled.

- A. Keep it unchanged
- B. Mark it corrected-onsite
- C. Remove the deficiency



Activity #8 – Scenario 3



QC is performed as described in technical procedure. Corrective actions complete; reviews performed monthly; no policy describing QC program. At Summation, director gives you policy that was misfiled, but policy changed from weekly review to monthly review with today's date.

- Keep it unchanged
- Mark it corrected-onsite
- Remove the deficiency



Activity #8 – Scenario 4



Several deficiencies cited because records could not be located. Just prior to the Summation, you receive a binder with method validations for two new instruments, reviewed and approved prior to the beginning of testing.

- A. Keep them unchanged
- B. Mark them corrected-onsite
- C. Remove the deficiencies



Activity #8 – Scenario 5



Final procedures reviewed prior to Summation; had been previous deficiency; 23-month interval for annual review.

- A. Keep them unchanged
- B. Mark them corrected-onsite
- C. Remove the deficiencies



Post-inspection



Don't rush out



8. After the Inspection

- Complete Part A of ISR:
 - Inspector's Comments should reflect inspection findings, overall impressions
 - Pages signed with credentials noted
- Return ISR to CAP Central Office
 - Within 24 hours
- Collect and send to CAP:
 - Evaluation forms
 - Reimbursement forms and receipts
- Discard (shred) remaining paperwork



Summary

- Why do we need a Team Leader?
- What does the Team Leader do?
- What should the Team Leader inspect?
- What will happen if the Team Leader has not prepared?



Thank You



Questions
and
Answers

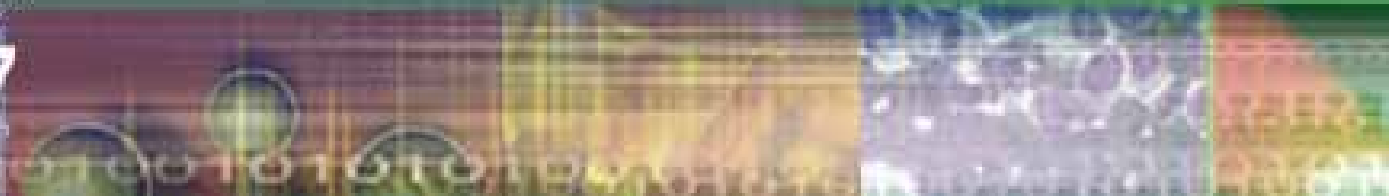


Success

**Thank you for
participating!**

Please complete the course
evaluation before you leave.

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