The CAP Inspection Process

So you've accepted an inspection assignment…

- Inspector's Inspection Packet sent from CAP 3 – 6 months prior to lab's anniversary date
- Inspection must occur within 3 month window of anniversary date
  - Ensure inspector training for all team members is up-to-date

The Inspection Packet Cometh

- Open the packet as soon as it arrives.
- Review the Activity Menu (type and complexity of testing per section unit) and instrumentation list
- Use these and the Inspection Assignment Worksheet by Laboratory form to determine the number and type of inspectors needed
- Contact Assigning Commissioner for assistance if needed
- Contact CAP Inspection Assignment Specialist (847-832-7313) if you need assistance in locating appropriate inspectors, especially specialty inspectors: e.g. chemistry

Laboratory Inspection Packet

- Activity menu
- Organizational chart
- Variant PT report
- Previous deficiencies
- Inspector Summation Report
- Deficiency and Recommendation pages
- Checklists

Preparing for the Inspection

- Schedule the inspection as soon as possible after receiving notice.
  - Work with the lab to find a mutually agreeable date
  - Must be done within three months prior to anniversary
  - Work with Tracy Bousquet at CAP if issues arise when scheduling
    - 800-323-4040 ext. 7313
- Arrange travel through the CAP Travel Desk
  - 800-323-4040 ext. 7800

Preparing for the Inspection

- Be sure that the Team Leader and any Team Members have completed inspection training, either in a “live” training seminar or online.

- www.cap.org > Learning > Laboratory Professionals Learning Programs > Inspection Team Leader Training

Preparing for the Inspection

- Review assigned checklists
- Read Laboratory Accreditation Manual
- Take advantage of training options
- Inspector Self-Study (on-line, CD-ROM)
- Audioconferences (live and virtual on-line)
- Inspector training seminars
- Ask questions (1-800-323-4040 option 2, accred@cap.org)

Preparing for the Inspection

- All Team members should spend 1-2 hours in preparation for each checklist assigned
- Don’t wait until the night before the inspection!

Preparing for the Inspection

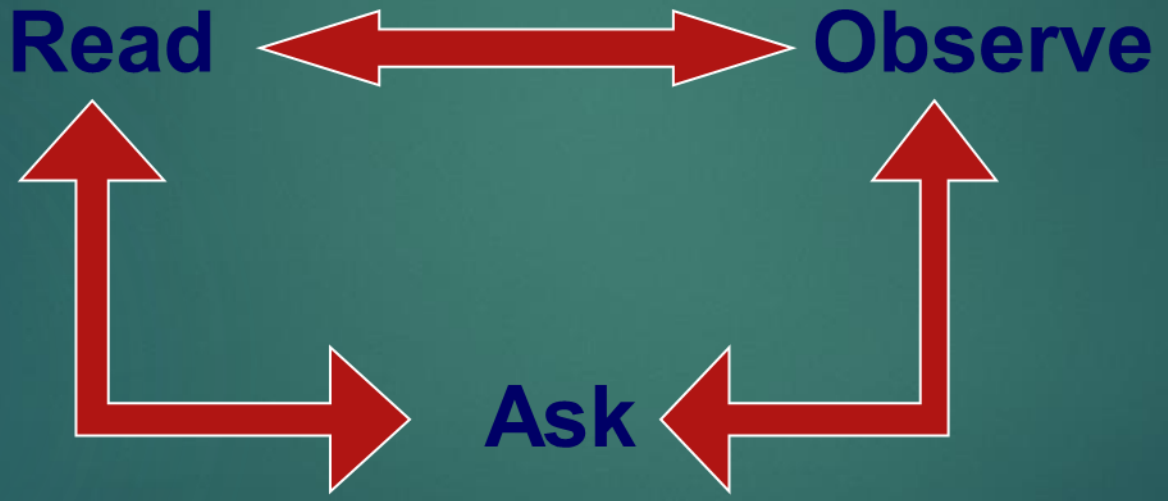
- The team leader should meet with the team prior to inspection to answer any questions and teach new inspectors
- Review the Standards for Laboratory Accreditation prior to inspection

- Inspections can be stressful for both the lab and inspection team
- Goal is to minimize stress, maximize efficiency

- There is nothing as boring as an inspection done completely from the checklist, question by question, for the lab or the inspection team!

- Using good inspection techniques, the process takes less time, gathers more information and is a lot less stressful for all involved.

How to Get Information: Inspection Techniques



Questioning Technique

- Ask hypothetical questions that are taken from real situations that have challenged you in your own lab.

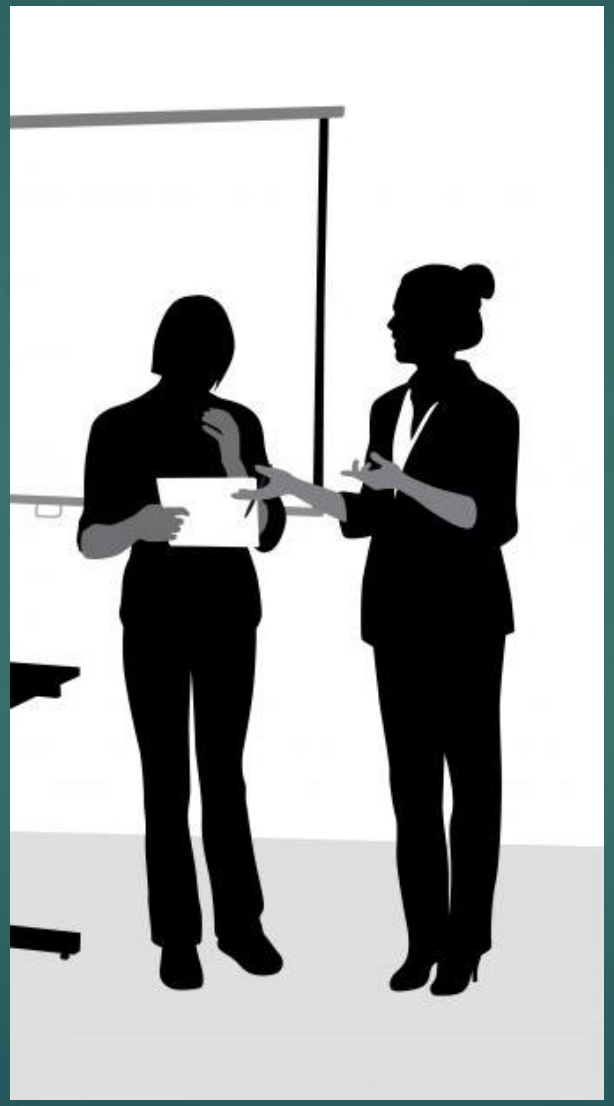
Observation

- Do not confuse “paper” compliance with actual compliance. Be present in the lab to observe practices.
- Inspection reviews frequently note the inspector spent too little time in the lab
- Procedures usually look great but sometimes (often) don’t match what actually is done
  - Procedure “drift”
  - Shortcuts

Effective Inspection Approaches

- Teach Me (Pretend I am a new trainee)
- Drill Down (in-depth analysis of select analytes)
- Follow the Specimen

Teach Me



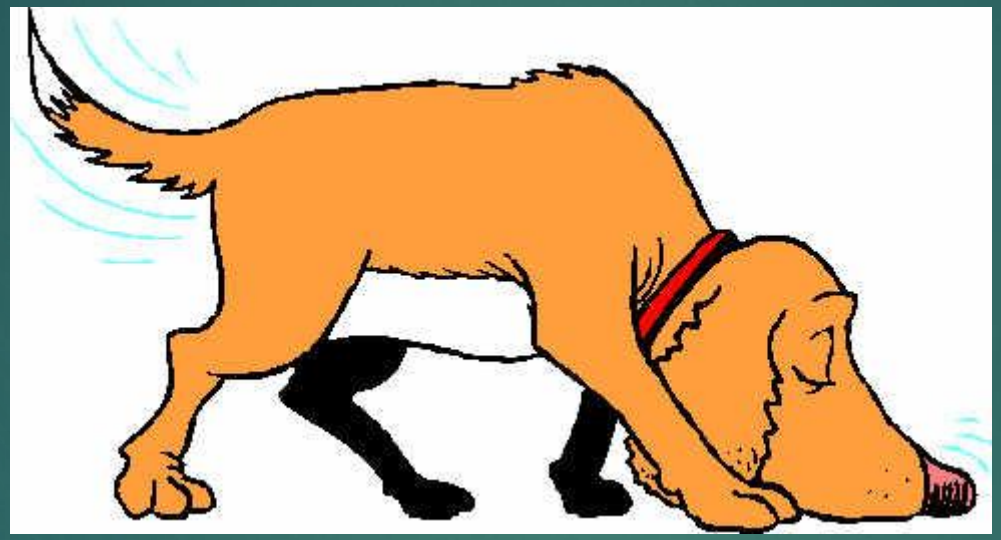
Drill Down

“Drill Down” or in-depth analysis of specific analytes

CAP philosophy

- Mission: To improve the quality of laboratory medicine through
- QM and education
- Peer review
- Volunteer inspectors
- Regulatory role

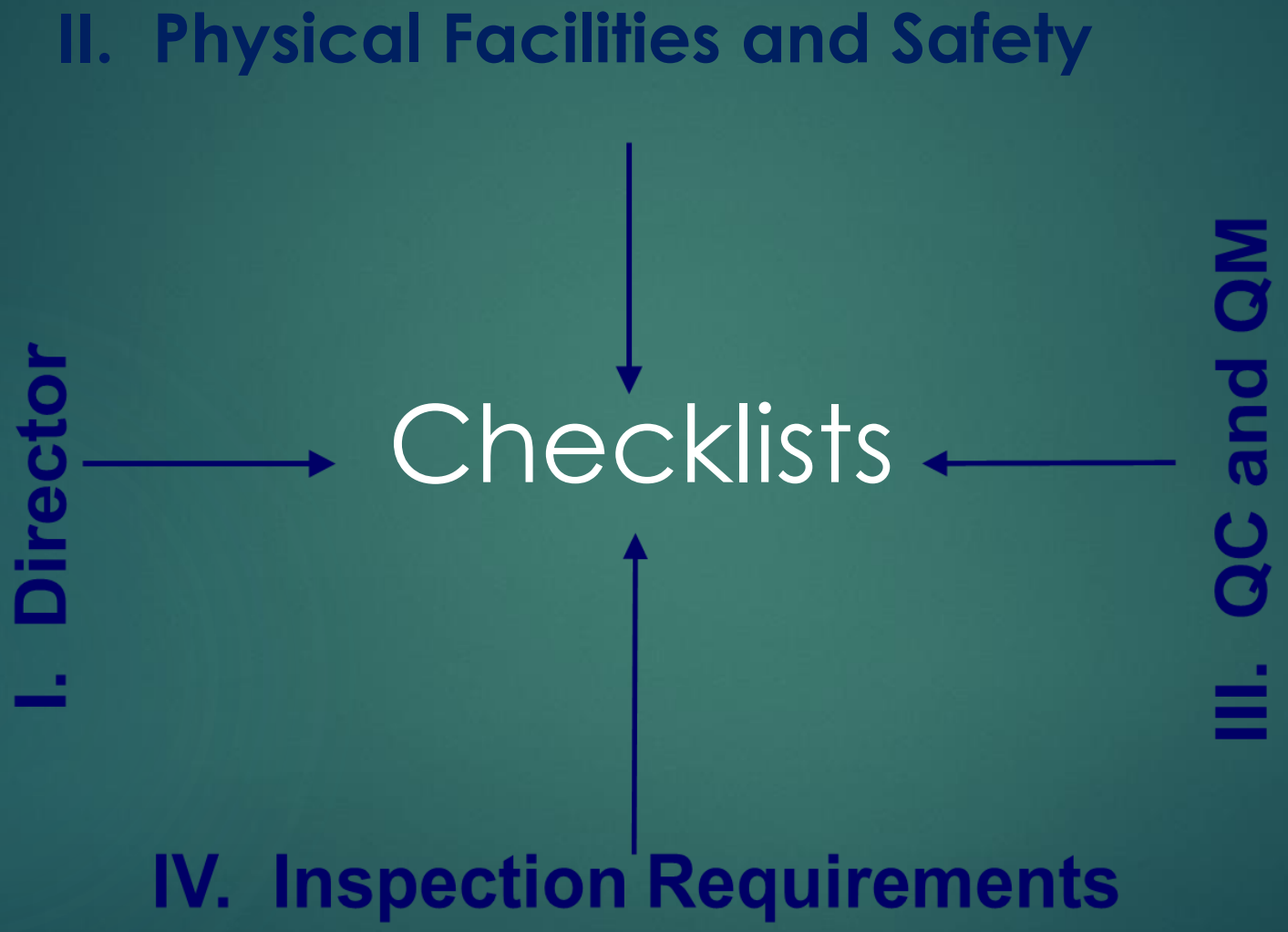
Follow The Specimen



Selecting Analytes for In-depth Review

- High volume tests
- Low volume tests
- High patient impact tests
- Tests from variant PT report
- Concern from previous deficiency
- New analyte, new instrument

- Focus on major topics first, then delve into details in problematic or questionable areas
- Focus on trends, not isolated incidents; were corrective actions implemented?
- Call CAP central office regarding interpretation of requirements phone: 847-832-7000 or 800-323-4040
- Review compliance with previously cited deficiencies (Previous ISR pages)
- Use checklists to take notes


II. Physical Facilities and Safety
I. Director
Checklists
III. QC and QM
IV. Inspection Requirements

Director

- Qualifications
- Authority
- Roles and responsibilities

Physical Facilities and Safety

- Sufficient resources
- Employee safety
- Physical facilities
- Space
- Ventilation
- Utilities
- Security

Quality Control and Performance Improvement

- Quality Management plan
- Proficiency testing
- Quality Control
- Instrument maintenance

Inspection Requirements

- Onsite inspection
  - Lab: Demonstrates that its practices comply with intent of the checklist questions
  - Inspector: Verifies compliance and highlights areas for improvement

Inspection Requirements

- Self-inspection
  - Alternate years
  - Opportunity for improvement
  - Involve laboratory staff

Use this as an opportunity to conduct a full inspection, including interviewing of employees, introduction conference, presummation and summation conferences.

Checklists

- Phase I/Phase II deficiencies
- How seriously patient care and health/safety of lab employees affected
- Customized to lab's activity menu
- Updated regularly
- Inspector must use version provided in inspection packet

Checklists

- Determine the intent of the question
- Develop open-ended probing questions
  - Describe your proficiency testing program.
  - What are your specimen handling
  - procedures?
  - Describe the role and degree of involvement of your off-site director
- Focus on groups of checklist items

Inspection Day

- Arrive on time
  - Plan to arrive by 7:30 – 8:00 am on the day of the inspection
  - Present the inspection announcement letter
- Meet your host director/supervisor
  - Introduce team to laboratory personnel and emphasize the purpose of the inspection and the role of the team
- Discuss the day's schedule
  - Discuss with the lab director the audience and format of Summation Conference
  - Determine who should be notified of any deficiencies

Inspection Day

- Take a brief tour
  - Keep lab tour to 15 – 30 minutes depending on the size of the facility
- Be positive/professional
  - Representative of the College
  - These are your peers
  - Goal is improvement, not punishment

Time Management

- General recommendations: for each 3 hours in a lab section, spend:
  - 1 hour reading
  - 2 hours observing and asking
- Pace yourself
- Don't over-focus on small details, but don't overlook them either

Time Management

- Continue to inspect while the lab searches for documentation
- If a document can't be found, cite but tell the lab they can submit it after the inspection and the deficiency may be expunged.
- If found after cited but before the inspection concludes, strike through with a single line and note that it was found/remedied/corrected onsite.

Time Management

- Items “corrected onsite” have to be reasonable
- Can correct review of a document, missing signature, etc.
- Cannot write a QA program in a day

Communication

- Notify director/supervisor of deficiencies as they are identified
- There should be NO surprises at the summation conference
- Inform Lab Gen inspector of Lab Gen issues in your sections

Pre-Analytical Phase

- Requisitions
- Specimen collection
- Accessioning
- Referrals

Assessing Pre-analytical Support

- Ask technologists and order entry personnel if they have adequate support from management when problem situations arise

Analytical Phase

- Policies and procedures
- Safety
- Proficiency testing
- Quality control
- Training and competency
- Instrument maintenance & calibration
- Carryover studies, AMR, reagent validation

Inspection QC Records

- Written QC policy/plan
- Performed and reviewed before reporting patient results
- Monthly review; documentation of delegation
- Validation of target range
- Tolerance limits/corrective actions
- Statistics, graphs, etc.

Analytical Phase

- In reviewing QC for a section, ask to review records of analytes that have variable (noisy) QC data, are frequently calibrated, or are reagent lot sensitive.

- If QC ranges are too broad, ask about acceptance criteria and troubleshooting procedures

Analytical Phase

- When multiple employees are questioned about an issue and different answers are given, reconcile discrepancies with the supervisor.

Safety

- When assessing safety, ask multiple staff members:
- Where safety policies are found
- What to do in case of fire
- How hazardous spills handled
- How often eyewash is checked
- Where MSDS sheets are found

Safety

- Evacuation routes
- Waste disposal
- Fire extinguishers & flammables
- Showers, sinks, eyewash
- Availability and use of PPE
- Ventilation, biohazard cabinets
- Bench & storage space

Safety

- Ask individual technologists about the training they received on safety issues
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→ LN death at GA cryobank

Post-Analytical

- Reporting
- Include corrected reports
- Critical values
- LIS procedures
- Filing and retrieval of results
- Specimen retention guidelines

Post-Analytical Phase

- Ask lab employees: What is the laboratory's procedure for handling complaints?
- Review the patient / customer surveys
  - Be sure the survey includes the lab!

Evaluating the QA Plan

- Overview of section plan
  - Preanalytic, analytic & postanalytic
  - Inclusive of all section activities
  - Compare the lab's activity menu to their procedure manuals, QC data, instruments/equipment
- Review of monitors
  - Data collection
  - Corrective action
- Incorporation into lab's overall QA program

Wrapping up the Inspection

- Identify systematic problems
- Discuss inconsistencies with other team members
- Complete the Deficiency and Recommendations pages and make copy(ies) as needed for yourself, director, supervisor, MD
- Complete ISR Section A (page one is not copied or shared with lab)
  - Confidential statements, info for next inspector
- Complete evaluation and CME forms if time permits, otherwise complete at home

When to Cite a Deficiency

- No policy/procedure
- Policy not being followed
- Incomplete or absent documentation

- *Notify director/supervisor before Summation Conference!*

When to Give a Recommendation

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

Summation Conference

- Thank Director and staff for hospitality and acknowledge hard work in preparation
- Explain various forms
- Explain process to address deficiencies and challenges to a deficiency
  - It is important to state explicitly that the team is a fact-finding team and that the lab may challenge any deficiency by providing supporting documentation. The final decision will be up to the Regional or Accrediting Commissioner and, eventually, the Accreditation
- Find something to compliment especially if it was a difficult day
  - Lead with positives then discuss the issues
  - Compliment sandwich – surround deficiencies with something that was good

Summation Conference

- If there are issues potentially embarrassing to the director, address those in private, not with staff.
  - Discuss TLC deficiencies privately with Laboratory director and explain that these will not necessarily be presented at the Summation Conference
- Encourage dialogue but do not allow confrontations.
- Maintain educational focus

The Party's Over.

- Have laboratory director sign Part A of ISR; leave a copy of Part B.
- Remind the lab director about the 30 day response time and leave the envelope with the Deficiency Response Instructions and forms
- Discuss the proper response method and documentation for phase I, II and recommendations Retain and return colored pages to CAP as soon as possible
  - Not recommended to give packet to lab to mail.
- Return ISR pages within 24 hours using pre-paid mailer
- Return reimbursement forms (with receipts) and evaluation forms within 90 days.
- Dispose of any inspection-related materials in manner that maintains confidentiality

Summary

- Spend significant time in the lab
  - Observe practices
  - Ask questions of laboratory staff
- Focus on patient care and laboratory safety requirements
- Be thorough, fair and professional
- Utilize CAP resources

Thank You

Questions and Answers