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
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” 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

IV. Inspection Requirements

III. QC and QM

Checklists
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.
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
Safety

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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
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