CAP IS COMING– WHAT DO I DO NOW?

TRICORE REFERENCE LABORATORIES

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Learning Objectives

- Describe the steps to take to prepare for a CAP inspection
- Discuss what to do when the inspector arrives
- List and address the top citations for POCT

Inspection Readiness

- Goal is to be prepared at all times for inspection
- CAP website is an excellent resource
- Know your checklist!
  - Consider making a crosswalk for your answers
  - Make a crosswalk notebook for remote sites
- Use your interim inspection

Inspection Planning

- How it looks from the inspector viewpoint
  - First impressions count
- Organizing the day
  - Paperwork first
  - Unit visits later

Make a Plan–Before the Window Opens!

- Personnel list updated
- Technical consultant documents completed
- Policies and procedures up to date
- Proficiency testing complete, reviewed, signed off
- QC records complete, reviewed, signed off
- Validations, 6 month studies, calibration, etc. records complete, reviewed, signed off

Prepare Operators

- Send out notification that inspection is imminent
- Explain CAP–who they are and the process
- List items that should be checked
  - Competency records
  - Controls labeled; not expired
  - Understand disinfection policies
- Share questions the users could be asked

Inspection Day!

- Contact unit managers and others so they are aware
- Contact HR to be available
- Have contingency plans for POC staff on vacation
- Gather documents
- Set up laptop or other access to electronic records
- Plan unit visits

The Inspector's Approach

1. CAP Inspector Training:

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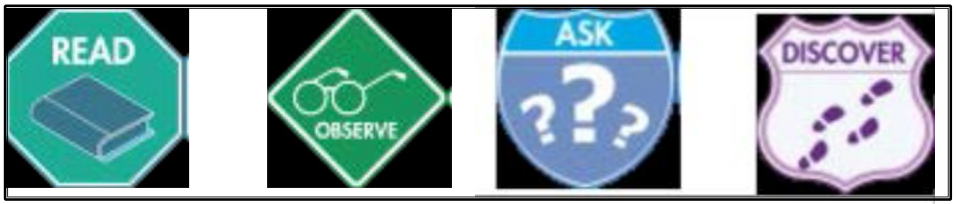

2. Evidence of Compliance

3. Follow the Specimen

Source: CAP Laboratory Accreditation Manual, 2013

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Personnel Documentation

- Where are the records?
  - CAP roster
  - Electronic learning system
  - Human resources
  - Paper records
  - Need 2 years of records
  - Diplomas for non-waived testing
- Technical consultant designations
  - Qualifications
  - Documentation

Common Citations-PERSONNEL

GEN.54400 /GEN.54750
- Education requirements by complexity
- proof of education
  - *If PSV: TEST the process*

GEN.53625: Technical Consultant
GEN.54000: Org chart
GEN.54025: CAP Roster—**reviewed** by Director or designee

GEN.55500 Competency Assessment: non-waived
- Adequate proof of competency evaluation on time
  - Tracking semi-annual can be difficult-create a system
- Need to reflect all 6 CLIA elements:
  - Jean Ball presentation "Is Your Competency Assessment a Competent Assessment?" (Whitehat.com)

Training vs. Competency

- Training
  - Before patient testing-New employees, new methods
  - Doesn't need 6 elements
  - Non-waived doesn't require Technical Consultant

- Competency
  - Non-waived: semi-annually first year, then annually
  - Requires 6 elements
  - Requires Technical Consultant
  - Waived-annually, choose elements

Proficiency Testing

- Last 2 years of records
- Make sure attestation statements are signed
  - Testing personnel
  - Medical director or designee
- Any PT failures or near misses documented
- Performed the same as patient testing
- Follow the law!

Common Citations-Proficiency Testing

First element evaluated in ALL COMMON checklist!
Often the first thing an Inspector wants to see.

Results **reviewed** by director or designee

Corrective Action **Documented** and reviewed

Attestation Sheet: signed by Director or Designee
(sometimes forget when submitting online)

Quality Control

- Waived-follow manufacturer instructions
- Electronic
  - Daily QC acceptability
  - Monthly review
- Paper
  - Daily QC acceptability
  - Monthly review
- QC corrective action

AMR/Calibration Verification/Instrument Comparability

- Waived-follow manufacturer instructions
- Calibration verification/AMR verification
- Comparability of instruments and methods

Instrument Validation

- Waived-follow manufacturer instructions
- Do you have a policy for new tests, methods, instruments?
- CAP will look closely at tests introduced the last 2 years.
- Signed off for testing by medical director
  - Pre-2009
- Instrument moved?

Miscellaneous

- Temperature logs-Storage areas
- Maintenance logs
- Safety
- Disinfection of devices

Quality Assurance

- POCT should have a Quality Management Program
- Don’t forget the organizational chart
- Quality indicators-preanalytic, analytic, postanalytic
- Unusual laboratory results
- Results reporting

IQCP

- Initial risk assessment
- Initial QC Plan-signed by medical director
- Annual summary-signed by medical director or designee
- List of IQCPs

Common Citations–IQCP

Significant Impact to POCT

Consider **pre-analytical, analytical, post-analytical** phases for the five elements of testing:

Specimen
Test System
Reagents
Environment
personnel

Include the **Three Steps**

Risk Assessment > Quality Control Plan > Quality Assurance Plan

Ensure Initial **Approval** by Director and then annual review

Unit Visits

- Be aware of issues that arose from document review
- Inspector should ask questions of operators as well as look for reagent labeling
- Storage area temperatures

Common Citations–Miscellaneous

Safety
- Eyewash, fire drills, Chemical Hygiene, Ergonomics, etc.

Reagent labeling and storage
- Manufacturer's instructions: Open? Expiry? Both?

Analytic Systems
- Define your acceptability criteria

Corrective Action
- It's ok to make an error—you must document its remediation

Relax—You've Got This!

Excellent opportunity to highlight your relationships with nursing units

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Resources

- CAP Website:
  Inspector Dos and Don'ts
- Industry Publications/Webinars
- Peer groups/listservs

CLIA UPDATE – January 2017
Division of Laboratory Services
Centers for Medicare & Medicaid Services
Top 10 Deficiencies in the Nation – CMS Surveys

https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIAtopten.pdf

Questions?

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