CAP Inspection Process

Francis E. Sharkey, MD
Vivian Mire, MT
Rene Martinez, MLS

April 6, 2022

1

Questions that this seminar hopes to answer…

- **Why do we inspect?**
- **What does "accreditation" mean?**
- **How do I prepare for an inspection?**
- **What's the right approach?**
- **What do I look for?**
- **How do I document my findings?**
- **How do I get out of there alive?**

2

CAP Accreditation Programs

- **Laboratory (LAP)**
- **Biorepository**
- **Forensic Drug Testing**
- **Reproductive**
- **CAP 15189 (ISO 15189)**

3

Why Do We Inspect?

- **Clinical Laboratory Improvement Acts (CLIA) of 1967 and 1988**
  - **Laboratories licensed by Federal Government (CMS)**
  - **Organizations "deemed" by CMS to accredit federally licensed laboratories: CAP, The JC, AABB, ASHI, etc.**
  - **Inspection is part of the accreditation process**

4

When Do We Inspect?

- **On-site inspection performed once every 2 years**
- **Unannounced, but in 90 day period prior to "Anniversary date"**
- **Conducted by "peer" laboratory**
- **Self-inspection - off-year inspection by lab**
  - **Reported to CAP**
  - **Lab must keep records**

5

CAP Laboratory Accreditation Program (LAP)

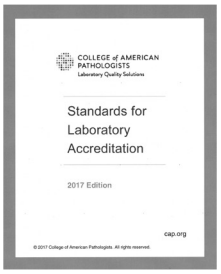
- **Began in 1961**
- **>7,000 laboratories in program**
  - **43% of hospital laboratories**
  - **80% of large hospital laboratories**
  - **95% of university hospital laboratories**
  - **2/3rds of large reference laboratories**
  - **100% of (VA and) military laboratories**
  - **~300 international laboratories**
- **10-12 inspections per day**
- **Participation is purely voluntary**

6

What Governs CAP Accreditation?

Standards for Laboratory Accreditation

- **Director and Personnel**
- **Physical Resources**
- **Quality Management**
- **Administrative Requirements**



CAP

7

What Goes into a CAP Inspection?

Inspection tools from CAP

- **Laboratory demographics**
- **Test menus and methods**
- **Instrumentation list**
- **Previous deficiencies & PT problems**
- **Laboratory Accreditation Manual (on line)**
- **Standards for Laboratory Accreditation**
- **Checklists & Deficiency/Recommendations forms**

Inspectors - Pathologists & PhD's, Technologists, Residents & Fellows

CAP

8

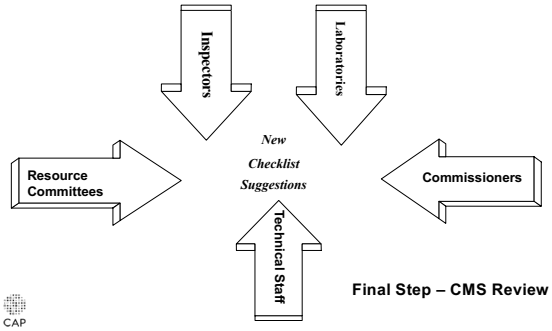
Inspection Checklists

- **Checklists**
  - **A series of requirements that inspectors use to document whether the inspected laboratory meets the Standards**
- **16 checklists, organized by lab section**
- **Total checklist items ~2,900**
- **Reviewed annually**
- **Changes in 2018:**
  - **41 new**
  - **241 significantly changed**
  - **77 moved/merged**
  - **0 deleted**

CAP

9

Annual Checklist Revision Process



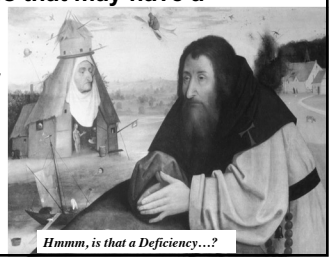
Final Step – CMS Review

CAP

10

What is a "Deficiency"?

- **Lack of compliance with CAP checklist requirements; deviation from best practice**
- **Phase I: Deficiencies that do not seriously affect patient care or the safety of laboratory workers**
- **Phase II: Deficiencies that may have a <u>serious</u> effect on patient care or worker health/safety**



CAP

11

Identifying Deficiencies

- **Compliance? Yes, No, or N/A**
- **How to deal with partial compliance:**
  - **Is the degree of partial compliance observed likely to affect patient care or worker safety?**
  - **Does the partial compliance observed reflect a general lack of attention to good lab practices?**
  - **What is the educational value of citing as a deficiency**
- **Don't cite it if you don't understand it!**
  - **Review with another inspector or the Team Leader**
  - **Call CAP**

CAP

12

13

Philosophy of Inspection

- **Laboratory improvement**
  - Not a punitive expedition!
- **Exchange of observations & experiences**
  - Educational value to both lab and team
- **Inspector must be fair, objective, open-minded, supportive**
  - Avoid accusatory/judgmental/threatening tone.
  - Does the lab meet the *intent* of the checklist?
  - There's more than one way to do things!
  - But, do cite if lack of compliance.

CAP

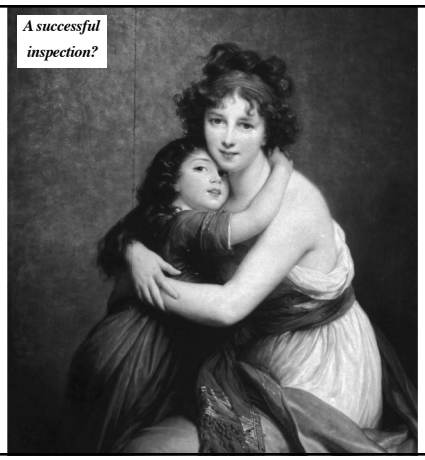
14

Philosophy of Inspection

- **Don't be afraid to cite a deficiency**
  - Lab doesn't want a superficial inspection
  - Important for Director to know of problems
- **Both inspector and inspectee should be pleased with the result**
  - "Golly, we learned so much..."
  - "I really appreciate your input..."
  - "We wish all inspections could be like this..."

CAP

15



16

Preparing for the Inspection

- **Web-based inspector training - *www.cap.org*, then enter "Inspector Team Member Training" in upper right hand corner Search window**
- **Review inspection packet: Demographics, test menu, instrumentation, PT issues and prior deficiencies**
- **Review checklist thoroughly; perform a "dummy" inspection at your facility**
- **Questions? Call or email CAP:**
  - ***Accred@cap.org***
  - **1-800-323-4040 (x6065)**

CAP

17

CAP Inspection Documents on UT Server

- **Laboratory Accreditation Manual**
- **Standards for Laboratory Accreditation**
- **IQCP Inspector Guide**
- **To Cite or Not to Cite**
- **CAP Inspection Process.ppt**

https://lsom.uthscsa.edu/pathology/cap-documents/

CAP

18

Inspection Day: Starting Off Right?

19

Inspection Day

- **8:00 am - Arrive at laboratory**
- **8:00-8:30 am - Introductions, schedule, brief tour**
- **8:30-noon - Inspect with first checklist**
- **Noon-1:00 pm - Lunch; meet with Team Leader**
- **1:00-3:00 pm - Inspect with second checklist**
- **3:00-4:00 pm - Presummation conference: Team meets, discusses deficiencies, completes Deficiency and Recommendations forms**
- **4:00-5:00 pm - Summation conference**

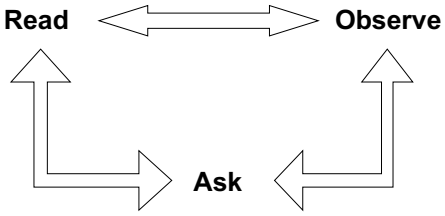
20

Using Your Time Effectively

- **First hour - Physical inspection; review procedure manuals, proficiency testing, QM and QC documents**
- **Second hour - In-lab inspection: Watch testing, speak with technologists, review maintenance records**
- **Third hour - Continue in-lab inspection; ask follow-up questions**
- **New feature: Pre-inspection review of selected policies & procedures**

21

Inspection Techniques: How to Get Information



22

Inspection Techniques

- **Read, Observe, Ask, Discover (ROAD)**
- **Follow the specimen**
- **Drill down: In-depth analysis of select analytes**
- **"Teach me…"**
- **Use open-ended questions**
  - **"Tell me how you…"**
  - **"How do you document that you…"**

23

What Do I Look At?

- **Documentation**
  - **Procedure manuals**
  - **QC, maintenance and PT records**
- **Practices**
  - **Follow a specimen**
  - **Match practice to procedure**
- **Environment**
  - **Space and safety**

24

How Much Do I Look At?

- **Be selective**
  - **High-volume and low-volume tests**
  - **Tests with greatest impact on patient care**
  - **Tests with proficiency testing problems**
- **Be thorough**
  - ***Sample* throughout last two years**
- **Be comprehensive**
  - **Fewer tests, greater depth**
  - **All phases of laboratory processes**

CAP

25

All Common Checklist

- **Proficiency testing**
- **Quality Management**
- **Procedure manuals**
- **Reagents and equipment**
- **Test method validation/verification**

CAP

26

Proficiency Testing

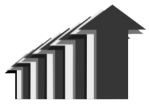
- **Participation in CAP-approved proficiency testing, if available, is required for most analytes.**
- **When CAP-approved proficiency material not available, an alternative method must be used.**
- **Review of PT performance:**
  - **Integrated within routine workload?**
  - **Rotated among regular testing personnel?**
  - **Documented review by director or designee?**
  - ***Evidence of evaluation and corrective action?***
  - ***Evidence of referral to or consultation with another laboratory? (A serious no-no…)***

CAP

27

Frequent Deficiency: Alternate Proficiency Testing

When no external PT is available, lab must have a documented system for determining accuracy and reliability of test results, exercised at least semi-annually.



CAP

28

Scenario - Proficiency Testing

At Friars Medical Center, the main Chemistry lab was having trouble with serum sodium testing. When proficiency testing samples arrived last month, the Chemistry supervisor compared the results of the main Chemistry section to those in the Blood Gases section before sending in the results.

Was this acceptable?

CAP

29

Scenario - Proficiency Testing

At Marvelous Health System, the Oncology Clinic laboratory performs CBCs, but routinely sends manual white cell differentials to the main laboratory for reading. The same procedure was followed with their proficiency testing sample.

Was this acceptable?

CAP

30

Quality Management (QM) Program
(Laboratory General Inspector)

- **Documented operational plan, implemented as designed**
  - **Review 12 months prior to inspection**
- **Involves all aspects of the laboratory service**
- **Key quality indicators monitored and evaluated**
  - ***Include pre-analytic, analytic and post-analytic***
- **Systematic program to document & correct problems**
- **Coordination with institutional QI program**
- **Annually appraised for effectiveness**

CAP

31

Examples of Quality Indicators

- **Amount of blood used for testing**
- **Turnaround times**
- **Preservation of specimen ID integrity**
- **Frozen vs. permanent section diagnosis**
- **Correlation between PAP test and biopsy**
- **Accuracy of report transmission across an interface**

CAP

32

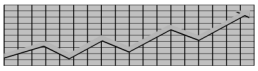
QM: What to Look For

- **Each section has its own QM activity**
- **Periodically changing monitors that cover entire spectrum of section activity**
  - **Pre-analytic, analytic and post-analytic**
- **Focused on potential problem areas**
- **Rational benchmarks for monitors**
- **Corrective action if benchmarks not met**
- **Periodic documented meetings for reporting, evaluation and planning**

CAP

33

Quality Control (QC)
Things to Look For



- **Technical quality plan: Well-organized, clearly defined and written**
- **Analyst must review QC acceptability before reporting patient results.**
- **Secondary review of QC records at least monthly by lab director or designee; includes maintenance and temperature records**

CAP

34

QC - Common Problem Areas

- **Calibration, Verification and AMR**
  - **Use manufacturer's method(s) & recommendations**
  - **Calibration every 6 months, or if calibration verification fails, or manufacturer specifies otherwise**
  - **Matrix-appropriate QC/Cal/Ver materials**
  - **Analytic measurement range performed every 6 mo.**
- **Parallel testing of new reagent lots**
  - **Preferably with patient samples**
- **All components of reagent kit from same lot**
- **On-board (electronic) controls:**
  - **Follow manufacturer's recommendations?**
  - **Mostly OK for daily QC**
  - **Must use external controls with new reagent lot**

CAP

35

QC: What to Look For

- **QC records organized to detect problems**
- **Tolerance limits defined**
- **QC logs; corrective action documented**
- **QC results reviewed/verified before reporting patient results**
- **Daily temperature charts (with acceptance ranges) for all temperature-dependent equipment & reagents**
- **Supervisor review at least monthly**

CAP

36

New QC Option – CMS Individualized Quality Control Plan (IQCP)

- **Voluntary quality control option based on risk management (CMS published January 2014)**
- **CLIA/CMS Default for QC:**
  - **Quantitative tests: Two controls, different concentrations, each day; exceptions for Coagulation and Blood Gas testing**
  - **Qualitative tests: Positive & negative controls each day**
- **Manufacturer guide may allow more lenient**
- **Lab may develop IQCP if wants to deviate from Default (but stay within manufacturer's guide)**
- **An all inclusive approach which evaluates the entire testing process**
  - **Pre-analytic, analytic, and post-analytic phases**

CAP

37

37

New QC Option – CMS Individualized Quality Control Plan (IQCP)

- **IQCP allows development of a customized quality control plan for the laboratory that is specific to lab's specimens, test system, reagents, environment and testing personnel**
- **IQCP will not necessarily reduce the QC testing practices**
- **IQCP regulations contain some restrictions for eligibility of use (see chart in IQCP guide on UTH server)**

CAP

38

38

IQCP Components

- **Risk Assessment**
  - **Identifies and evaluates potential failures & sources of errors in the testing process**
  - **Must include evaluation of: Specimen, test system, reagent, environment, testing personnel**
- **Quality Control Plan**
  - **Describes practices and procedures performed by laboratory to reduce the chance of possible failures and errors in test processes**
  - **Ensures accurate, reliable test results**
  - **Proficiency testing, maintenance, training are components**
- **Quality Assessment**
  - **Continuous process of monitoring the effectiveness of the QCP**
  - **QC reviews, PT performance, complaints**

CAP

39

39

Do Cite if:

- **Risk Assessment (RA) is missing one or more of the five components**
- **RA doesn't cover all three phases of testing**
- **RA did not include in-house data or did not involve lab personnel.**
- **RA done with old data; more than a year old.**
- **QCP not signed**
- **QC performed less frequently than specified by manufacturer**
- **QCP not followed as written**
- **Plan does not monitor devices in all areas of use**
- **Serious quality concerns or adverse patient outcomes have not been addressed**
- **Equivalent QC (EQC) is still in use without an approved IQCP**
- **IQCP in place for ineligible test**
- **Not using the required CAP forms**

CAP

40

40

Do Not Cite if:

- **The format of the RA is not "user-friendly"**
- **The RA doesn't look like the ones in your lab.**
- **You disagree with the acceptability of a specific risk.**
- **You disagree with the frequency of the QC being performed.**
- **You think the QCP does not address potential risks.**
- **You disagree with the acceptability of QC to mitigate risk.**
- **You do not believe the lab has adequately addressed potential patient outcomes.**
  - **Always give the lab a chance to prove their compliance.**
  - **Discuss with team and team leader for advice.**
  - **Call CAP for ruling on evidence of compliance.**

CAP

41

41

Scenario - IQCP

While looking through the Point of Care i-STAT IQCP paperwork at St. Maverick's Hospital lab, you notice that all of the QC reports and supporting documents are all from 2016. The supervisor states that nothing has changed from the creation of the plan. They have not noticed any increase in QC check codes or had any complaints about result accuracy, and the medical director has been signing off on the plan annually.

Is this acceptable?

CAP

42

42

Procedure Manuals

- **All procedures must receive biennial review**
- **Manufacturer's procedure acceptable if laboratory documents evaluation**
- **Actual practice must match written procedure**
- **Documentation of technical staff review**
- **Retired procedures retained for 2 years**

43

Procedure Manual Review

- **If director delegates periodic review, designee must be documented in writing *and be qualified*.**
- **Paper manuals:**
  - **No requirement to sign every page of procedure**
  - **One signature on front page of manual is not acceptable.**
  - **Index listing each procedure, with review date and signature for each, is acceptable.**
- **Electronic manuals:**
  - **Secure electronic signature is not required.**

44

Scenario - Procedure Manuals

The Hematology inspector notes that the coagulation procedure manual has not been signed by the Director since one year before the previous on-site inspection. The supervisor immediately notifies the laboratory Director, who comes in and signs each of the 12 procedures in the manual.

Is this acceptable?

45

Reagents

- **Labeled with content, storage, date prepared/reconstituted, and expiration date**
  - **Dates received or opened not necessary unless date opened changes expiration date.**
- ***Must be used within expiration date***
  - **Exception - rare reagents in Blood Bank**
- **All reagents used within their designated "master" lot number, unless indicated for universal use by manufacturer (buffers, etc.)**

46

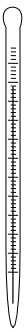
Frequent Deficiencies

- **Precautionary labels not present on containers of all hazardous chemicals:**
  - **Indicate type of hazard**
  - **What to do if contact occurs**
- **New reagent lots not checked against old lots *(preferably using patient specimens)***

47

Instruments & Equipment
What to Look For

- **Maintenance logs & service records**
- **Initials/name and dates on logs and charts**
- **Documentation of corrective action when values not within defined limits**
- **Monthly review by director or designee**
- **Check glassware, pipettes for damage**



48

Safety

49

Accidental Fires in Clinical Laboratories

- **Annual fires in US clinical labs:**
  - **>150 fires**
  - **13 civilian injuries**
  - **$15 million in direct property damage**
  - **Average loss - $16,500/fire**
- **Major causes:**
  - **Electrical**
  - **Chemical**

50

Fire Safety Requirements

- **Automatic fire extinguishing equipment**
  - **Except if no inpatients, or if separated from inpatients by 2-hr construction**
- **Alarm system:**
  - **Convenient to laboratory exits**
  - **Audible in all areas of laboratory**
- **Fire extinguishers wherever flammable or combustible liquids stored or handled**

51

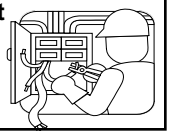
Storage of Flammables

- **Max. limits for stored flammable fluids:**
  - **1 gal./100 sq. ft. outside of safety cans & cabinets**
  - **2 gals./100 square feet within safety cans & cabinets**
  - **Doubled if automatic fire suppression system**
- **Use safety cans rather than glass bottles, if possible**

52

Electrical Hazards

- **Documented policy for initial checks**
  - **Grounding of chassis**
  - **Current leakage**
  - **Shielded in flammable vapor locations**
- **Includes computer equipment (monitors, printers, etc.)**
- **Look for stickers on equipment**



53

Chemical Hazards

- **Orientation and training for personnel**
- **Survey for carcinogens and toxins**
- **(Materials) Safety Data Sheets readily available to testing personnel**
- **Compressed gas containers secured**
- **Hazardous chemicals**
  - **Precautionary labeling**
  - **Spill kits**
  - **Instructions posted for cleanup of spills**

54

Scenario - Safety Inspection

The Laboratory General inspector notes that there are no signs posted in the Anatomic Pathology grossing room regarding the cleanup of formalin spills. The supervisor states that this information is available on-line on the laboratory computer system.

Is this acceptable?

CAP

55

Protection Of Personnel

- **Personal protective equipment**
  - **Gown, masks and eye protection**
  - **Gloves: Non-latex or unpowdered latex**
  - **Are they using it?**
- **Workplace policies: Sharps containers, autocapping of needles, etc.**
- **Engineering controls: Eye wash & showers, hand washing stations, fume hoods, etc.**

CAP

56

Safety - Things to Look For

- **Safety hazards (sinks, gas tanks, extension cords, flammable storage, food and personal belongings, etc.)**
- **Fire-fighting equipment and alarms**
- **Electrical grounding and leakage checks (including computers, terminals, printers)**
- **Fume hood function checks**
- **Use of personal protective equipment**

CAP

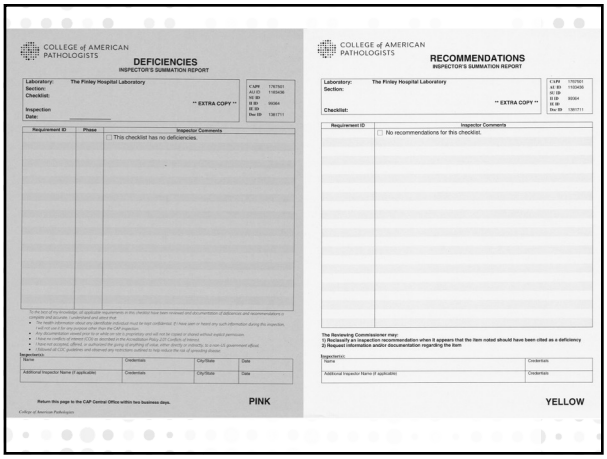
57

Closing the Section Inspection

- **Restate key facts and findings**
- **Review all deficiencies that will be cited**
  - **Prevents confusion and misunderstandings**
  - **Gives lab a chance to correct deficiencies**
- **If requested, provide recommendations for corrective action**
- **Maintain peer/colleague atmosphere**
- **Show appreciation for time and effort spent with you, and in preparing for inspection**

CAP

58


COLLEGE of AMERICAN PATHOLOGISTS

DEFICIENCIES
INSPECTOR'S SUMMATION REPORT

Laboratory: The Finley Hospital Laboratory
Section:
Checklist:
** EXTRA COPY **
Inspection Date:

Requirement ID	Phase	Inspector Comments
		☐ This checklist has no deficiencies.

Inspector(s):

Name	Credentials	City/State	Date
Additional Inspector Name (if applicable)	Credentials	City/State	Date

Return this page to the CAP Central Office within two business days.

PINK

COLLEGE of AMERICAN PATHOLOGISTS

RECOMMENDATIONS
INSPECTOR'S SUMMATION REPORT

Laboratory: The Finley Hospital Laboratory
Section:
Checklist:
** EXTRA COPY **

Requirement ID	Inspector Comments
	☐ No recommendations for this checklist.

The Reviewing Commissioner may:
1) Reclassify an inspection recommendation when it appears that the item noted should have been cited as a deficiency
2) Request information and/or documentation regarding the item

Inspector(s):

Name	Credentials
Additional Inspector Name (if applicable)	Credentials

YELLOW

59

Completing Deficiency Forms

- **Do not repeat the checklist question!!!**
- **Enter the problem identified; be specific:**
  - **No temperature records for January 2011**
  - **QC out for week of 2/14/2011; no corrective action documented**
  - **Biennial review of safety manual not documented for 2013 and 2014**
  - **QI plan lacks pre-analytic monitors**
- **Make it legible!**

CAP

60

Pre-Summation Conference

- **Team meeting at conclusion of inspection**
- **Sets the tone of the summation conference**
- **Review all deficiencies**
- **Answer team members' questions**
- **Team members write deficiencies and recommendations on appropriate pages of Part B of the Inspector's Summation Report**
- **Team members sign and date forms**

CAP

61

Final Words

- **Show respect**
- **Keep it friendly.**
- **Be selective.**
- **Cover *all* checklist questions.**
- **Don't cite a deficiency if you don't understand the checklist question.**
- **Don't play "nice gal / nice guy".**
- **Conclude section inspection with a review of deficiencies and recommendations.**

CAP

62