



COLLEGE of AMERICAN
PATHOLOGISTS

CAP 2015

Most Frequent Deficiencies and How to Avoid Them

Jean Ball MBA,MT(HHS),MLT(ASCP)
Inspection Services Team Lead
Laboratory Accreditation Program

March 11, 2015

Objectives:

- **Participants will be able to identify the top deficiencies cited in a POC program**
- **Participants will be able to determine why these citations happen**
- **Participants will hear some ideas for ensuring that these citations do not occur in their own laboratory**

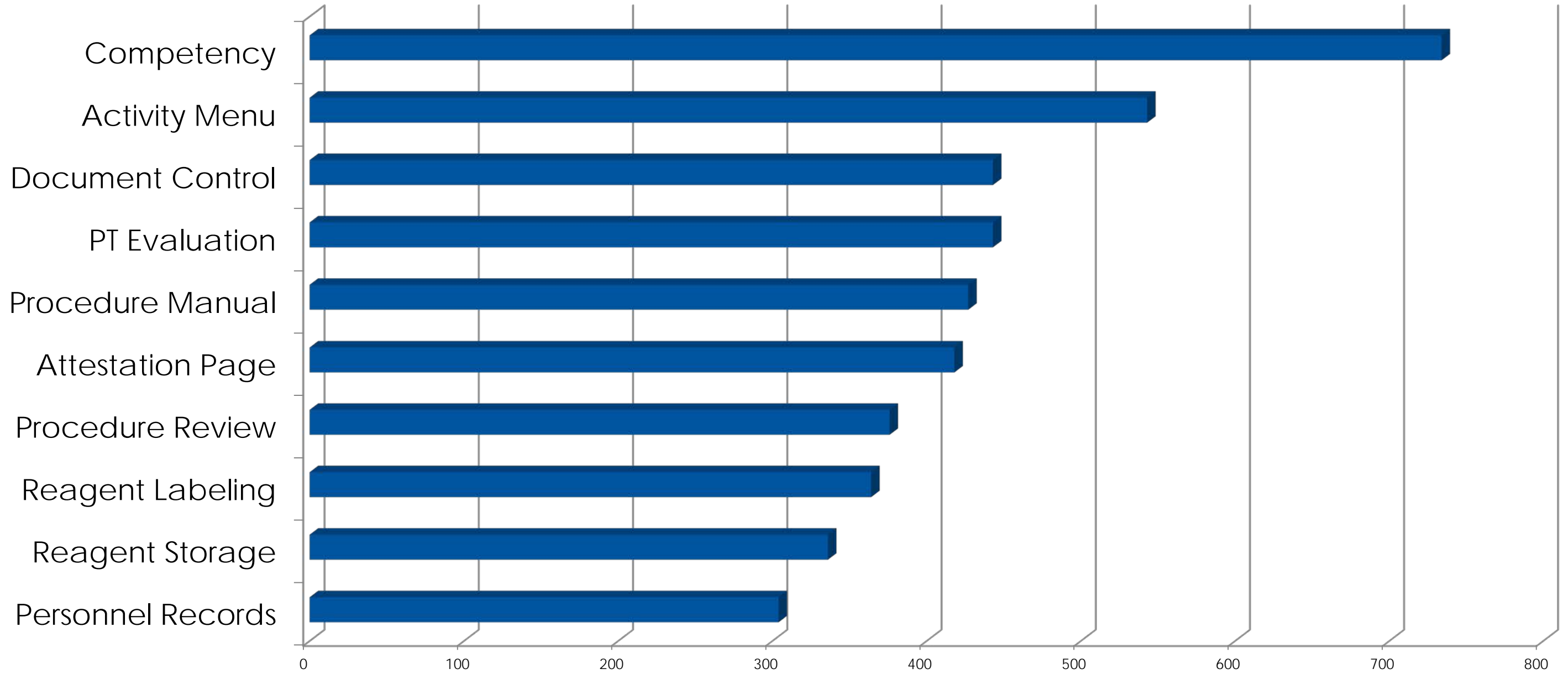
Checklist Changes

“Where does it say that?”

- **Summary of Checklist Edition Changes**
- **All Common Checklist, 4/21/2014 edition**
 - **18 New**
 - **20 Revised**
- **Thermometers**
- **Instruments and Equipment**
- **Comparability of Instruments & Methods**

A Question for you...

Most Commonly Cited Deficiencies



Activity Menu

What tests are you currently performing?

- **COM.01200**
 - **All tests in use**
 - **Discontinued tests removed**
 - **Call CAP to discuss tests or services not listed on the Master Activities Menu**

Reagent Storage and Reagent Labeling

For waived tests, the laboratory follows manufacturer instructions for handling and storing reagents, cartridges, test cards, *etc.*

- **COM.30250**
 - Per manufacturer's requirements
 - Temperatures
 - Change in storage = change of expiration
 - Audit this!

Reagent Storage and Reagent Labeling

For non-waived tests, all reagents, calibrators, controls, solutions...

- **COM.30300** **Labeled with appropriate elements**
- **COM.30350** **Stored and handled per manufacturer**
- **COM.30400** **Used within expiration date**
 - Per manufacturer's requirements
 - Temperatures
 - Change in storage = change of expiration
 - Audit this!

PT Attestation

The proficiency testing attestation statement is signed by the laboratory director or designee and the individual performing the testing.

- **COM.01400**
 - **Physical signatures must be present**
 - **Must be on the original attestation page**
 - **Designee's must be delegated in writing**

Document Control

The laboratory has a document control system to manage policies, procedures, and forms.

- **GEN.20375**
 - **Control versus Management**
 - **How many copies are “out there”?**
 - **Job Aides / Cheat Sheets**
 - **Document Control Log recommended**

New Director Procedure Approval

Following a change in laboratory directorship, the new laboratory director approves the laboratory policies and procedures over a **reasonable** period of time.

- **TLC.11485**
 - **Moved from COM to TLC**
 - **Recommend completion within 3 months of change**
 - **Recommend Document Control Log**

Personnel Records

Personnel files are maintained on all current technical personnel and personnel records include....

- **GEN.54400**
 - Copy of **academic diploma or transcript**
 - License, if required by state
 - Summary of training and experience
 - Certification, if required by state or **employer**
 - Records of continuing education

Personnel Records (Continued)

Personnel files are maintained on all current technical personnel and personnel records include....

- **GEN.54400**

- **Description of current duties and responsibilities as specified by the laboratory director**
 - **What procedures is the individual authorized to perform?**
 - **Is supervision required (processing, testing, result reporting)?**
 - **Is supervisory or section director review required to report?**
 - **Job Description may not be specific enough**

Competency Assessment

The competency of each person performing testing to perform his/her assigned duties is assessed.

- **GEN.55500**
 - **Annual assessment for waived testing (6 month not required)**
 - **Annual assessment for non-waived (semi-annual in 1st year)**
 - **All six elements for non-waived (less for waived)**
 - **On going process**

Competency Assessment (Continued)

The laboratory director must ensure that the **individuals performing competency assessments are qualified** through education and experience to meet the defined regulatory requirements.

Competency Assessment (Continued)

- **High complexity - assessments by section director, or individual meeting **general supervisor** requirements for high complexity**
 - **Doctoral / Master's / Bachelor's degree in clinical laboratory science or chemical, physical or biological science and **1 year training and experience in high-complexity****
 - **Associate's degree in Medical Laboratory Technology and **2 years laboratory training and/or experience in high complexity testing.****

Competency Assessment (Continued)

- **Moderate complexity – assessments by individual meeting the qualifications of a **technical consultant** for moderate complexity testing**
 - **Doctoral / Master's degree in clinical laboratory science or chemical, physical or biological science and **1 year training and/or experience in non-waived testing in designated specialty****
 - **Bachelor's degree in clinical laboratory science or chemical, physical or biological science and **2 years experience in non-waived testing in designated specialty****

Do you have the right person assessing competency?

Do you have the right person assessing competency?

- **MLT in hematology**

Do you have the right person assessing competency?

- **Associate degree MLT can assess competency for high complexity (hematology differentials) but not moderate complexity (automated hemogram)**

Do you have the right person assessing competency?

- **MLT in hematology**
- **RT in blood gas lab**

Do you have the right person assessing competency?

- **Associate degree Respiratory Therapist **can not** assess competency for ABG testing**

Do you have the right person assessing competency?

- **MLT in hematology**
- **RT in blood gas lab**
- **RN in POC**

Do you have the right person assessing competency?

- **Bachelor degree Nurse (BSN) can assess competency for non-waived POC testing**

Do you have the right person assessing competency?

- **Bachelor degree Nurse (BSN) can assess competency for non-waived POC testing**
- **Associate degree Nurse (RN-ADN or LVN) can not assess competency for non-waived POC testing**

Who decides complexity level?

Who decides complexity level?

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfclia/Search.cfm>

Performance Assessment of Supervisors / Consultants

The performance of section directors / technical supervisors, general supervisors, and technical consultants is assessed and satisfactory.

- **GEN.55525 **NEW** 04/21/2014**
 - **Delegated responsibilities must be in writing**
 - **Refers to role in management of patient testing**
 - **Unsatisfactory performance must be addressed in corrective action plan**

Monthly QC Review

Quality control data are reviewed and assessed at least monthly by the laboratory director or designee.

- **Most checklists ****Revised**** 04/21/2014**
 - **New language in the note: “The review of QC data must be documented and include follow-up for outliers, trends, or omissions that were not previously addressed.”**
 - **Delegation of functions must be in writing (TLC.11425)**

A Question for you...

Glucose Meters

- **Manufacturer's intended use and limitations**
 - Glucose meter is waived complexity **when used as specified** by the manufacturer for specimen types validated by manufacturer and approved/cleared by FDA
- **Modifying manufacturer's instructions**
 - Off label use = **Laboratory Developed Test**
 - Validate per **COM.40250**

Glucose Meters (Continued)

- **Review manufacturer's intended use and limitations**
 - **Diabetic patients only?**
- **Define "Critically-ill"**
 - **Check manufacturer's limitations to ensure population is defined**

Waived + Modification = High Complexity

- **Method validation requirements**
- **Analytical Measurement Range (AMR)**
- **Lot to lot reagent verification**
- **Meter to meter comparisons**

Waived + Modification = High Complexity

- **Testing personnel requirements for high complexity**
 - **Competency requirements – all six elements semi- and annually**
 - **Minimum Associates degree or High School diploma if testing prior to 4/24/1995**
 - **Individuals performing high complexity testing on or before April 24, 1995 with a high school diploma or equivalent with documented training may continue to perform testing only on those tests for which training was documented prior to September 1, 1997 (CLIA Regulation 42CFR493.1489(b))**

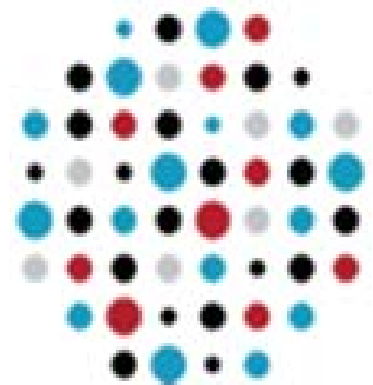
A Question for you...

IQCP

- **CAP is in the process of formulating a plan to address IQCP**
 - **The plan is not yet ready for release**
- **2014 checklist – No new requirements for IQCP**
- **2015 checklist – Some IQCP guidance expected**



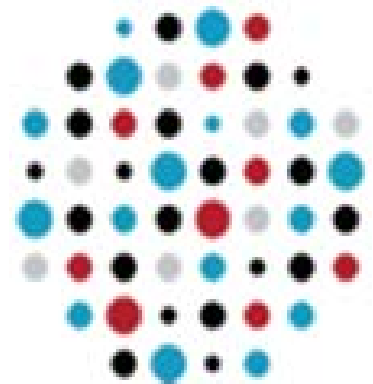
cap



COLLEGE of AMERICAN PATHOLOGISTS

Questions?

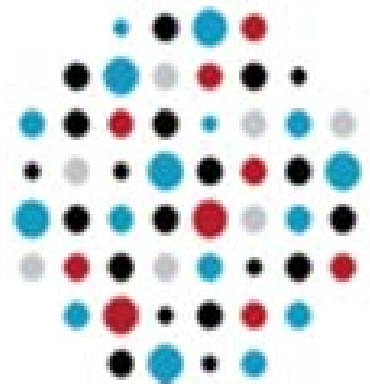
accred@cap.org or 800-323-4040 ext. 6065



COLLEGE of AMERICAN
PATHOLOGISTS

Thanks for your participation and your attention...

...now...bring in the things you put in your trunk and dig up those records in the garden!



COLLEGE of AMERICAN PATHOLOGISTS