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NJ POC Group

Most Frequent Deficiencies and How to Avoid Them

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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**

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Checklist Changes

“Where does it say that?”

- **2012 we added the All Common checklist**
  - **Proficiency Testing**
  - **Quality Management**
  - **Instruments and Equipment**
  - **Method Validation**
- **Added more into it for 2015**
  - **IQCP – 5 requirements**

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A Question for you…

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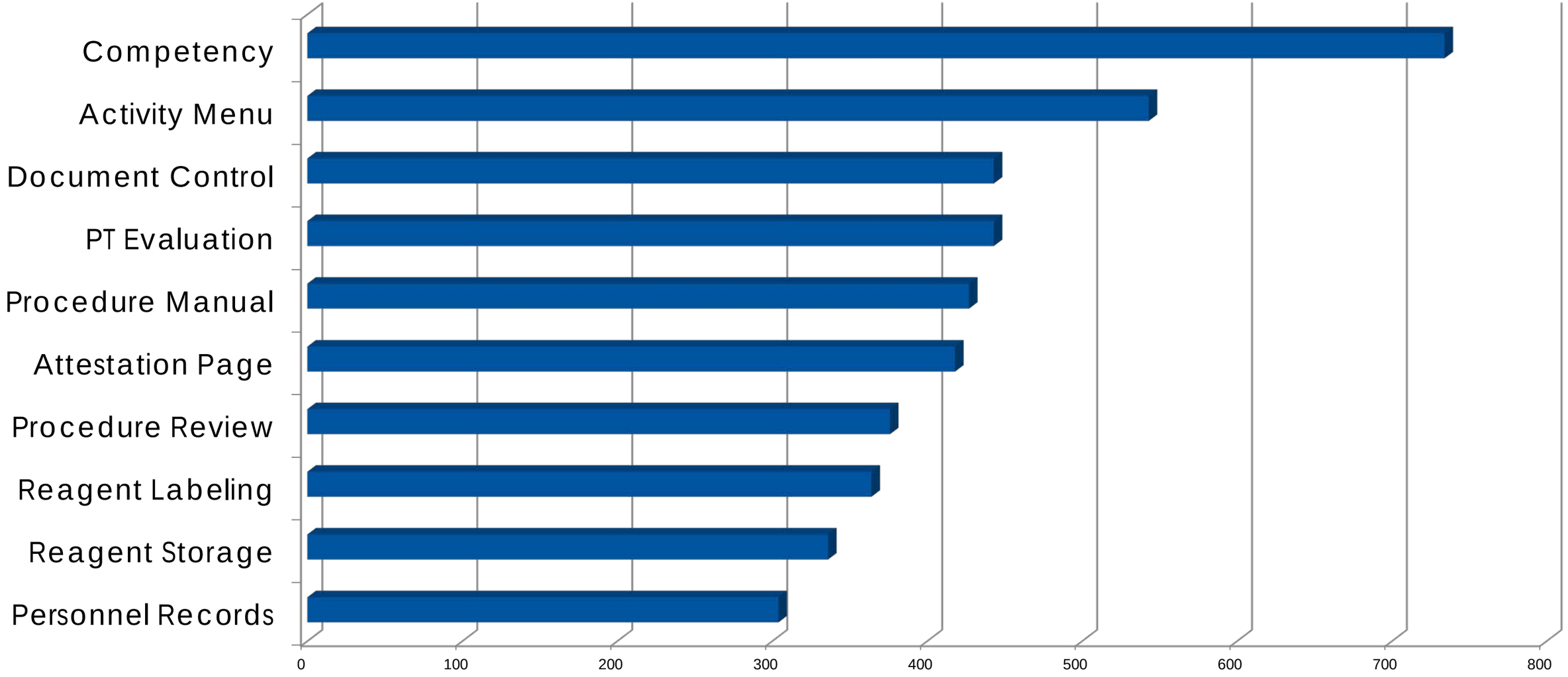
Most Commonly Cited Deficiencies



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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**

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Reagent Storage and Reagent Labeling

<u>For waived tests</u>, 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!**

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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!**
- **COM.30450 Lot-to-Lot checks**

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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**

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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**

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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**

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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**

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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**

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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**

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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.

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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.**

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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**

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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**

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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**

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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**

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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)**

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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**

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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**

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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)**

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IQCP

- **Five new requirements in the All Common checklist**
  - **COM.50200 IQCP List and Summary**
  - **COM.50300 Risk Assessment (5 elements)**
  - **COM.50400 Plan Approval – Laboratory Director (ONLY)**
  - **COM.50500 Written QC Plan**
  - **COM.50600 Quality Assessment Monitoring**
    - **Re-assessment and Re-approval annually**

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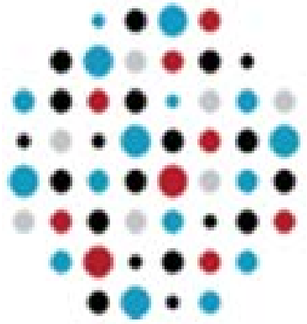

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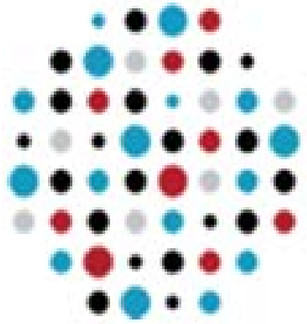
Questions?

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



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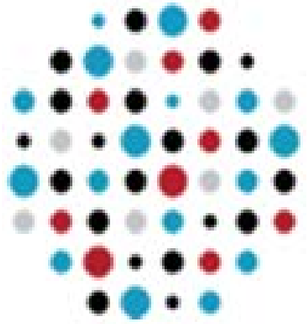
Thanks for your participation and your attention…

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



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