Surviving a CAP Inspection in Hematology

Su-Chieh Pamela Sun, MPA, MT(ASCP)
CarePoint Health, NJ
Bayonne Medical Center Christ Hospital Hoboken University Medical Center

Objectives

- Accreditation & Inspection Process
- Preparation & Inspection Strategies
- Common Deficiencies & Key Changes
Accreditation Process

Self Inspection
- 12 months Cross Discipline Records

Re-application
- 6 months Demographics Personnel

Inspection Packet
- Customized Checklists

Inspection D-Day
- 90 days

Post-inspection Follow up
- 30 days Written Responses

CAP Review & Accreditation
- 75 days CAP & Regional Commissioner Review

Self Inspection
- 12 months

Inspection Flow

Opening Meeting
- 7:30-8:00A Introductions Pair Up

Lab Tour
- Observe Equipment Safety

Inspection
- Ask Observe Review Discuss/Inform

Working Lunch
- Report back

Inspection
- Ask Observe Review Discuss/Inform

Pre-Summation Conference
- Discuss ISR pages (Pink & Yellow)

Summation
- 3:30-4:00P Thank Positive feedback Then, findings
Inspector’s Summation Reports (ISR)

Inspector Technique
- Read
- Observe
- Ask
- Discover

Inspector Approach
- Teach Me
- Drill Down
- Follow the Specimen
Preparation Strategies

- **Know your Checklists**
- **Know your SOPs**
- **Collect documents**
- **Crosswalk binder**

---

**Must DOs**
- Proficiency Testing
- SOP Review/Signature
- Reagent Labeling
- Environmental Round
- Storeroom
- Corrective action for previous citations

**Must HAVEs**
- Validation/Summary
- SOP
- Written Delegation
- Training / Competency
- Instrument Comparison
- Instrument Equipment PM/QC Record
More Preparation Tip

- Inspection Day Planning
  - Command Center
  - Communication Tool
  - Logistics
  - Food for the team

Scenario A:

ZeroDeficient Healthcare is a health system that has a core laboratory in the main campus and three off-site satellite labs. During inspection in one of the satellite hematology labs, you asked to see the competency records of techs. The hematology supervisor in charge explained that since the instruments are standardized in the system and the techs rotate to cover each lab, all training and competency are done in the main campus with documents filed there. That’s the best way to ensure the training and competency are done most appropriately and consistently. Upon review of the documents, you found all required elements present.
Lab General – Key Changes 2017 Checklist

<table>
<thead>
<tr>
<th>Revised</th>
<th>GEN.53600</th>
<th>Personnel Supervision</th>
<th>General supervisor’s training / experience must be discipline specific for the supervised area</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revised</td>
<td>GEN.54400</td>
<td>Personnel Record</td>
<td>Personnel trained outside of the US must have an equivalency evaluation performed by a nationally recognized organization</td>
</tr>
<tr>
<td>Revised</td>
<td>GEN.55450</td>
<td>Training</td>
<td>Training must be completed prior to patient testing</td>
</tr>
<tr>
<td>Revised</td>
<td>GEN.55500</td>
<td>Competency</td>
<td>Competency must be assessed at the specific lab where testing is performed (non-waived)</td>
</tr>
<tr>
<td>New</td>
<td>GEN.55510</td>
<td>Qualification to assess competency</td>
<td>Director must delegate responsibility in writing. Qualification of assessor vary based on complexity</td>
</tr>
<tr>
<td>New</td>
<td>GEN.62020</td>
<td>Centralized Storage of Reagent and Supplies</td>
<td>Daily temperature monitoring</td>
</tr>
</tbody>
</table>

Source: College of American Pathologists

Scenario B:

You have completed inspection of this lab and moved on to the next location. The first thing you asked to review was proficiency test documentation. While reviewing, you noticed the signature of designee on the attestation page looked similar to the designee signature on PTs for the last lab. The hematology supervisor explained that each lab orders its own PT and she is the person responsible for entering and submitting all results in the CAP website. You then asked for the director’s delegation authorizing her for reviewing and signing PTs. She pulled the relevant SOP with up-to-date director review and approval.
### All Common – Key Changes 2017 Checklist

<table>
<thead>
<tr>
<th>Revised</th>
<th>COM.01000</th>
<th>PT Procedure</th>
<th>Unacceptable PT results need to be evaluated for impact on patient results and in timely manner.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revised</td>
<td>COM.01800</td>
<td>PT Interlaboratory Communication</td>
<td>PT records should be inaccessible to personnel of other laboratories, including affiliated laboratory until after deadline of submission of results.</td>
</tr>
<tr>
<td>New</td>
<td>COM.01950</td>
<td>Cease Testing for Repeat PT failures</td>
<td>Lab instructed by CAP to cease testing, need to demonstrate no patient results were released.</td>
</tr>
<tr>
<td>Revised</td>
<td>COM.30550</td>
<td>Instrument/Equipment Performance Verification</td>
<td>Appropriate checks are required after relocation</td>
</tr>
<tr>
<td>New</td>
<td>COM.30680</td>
<td>Microscope Maintenance</td>
<td>moved from HEM checklist to All Common</td>
</tr>
<tr>
<td>New</td>
<td>COM.30685</td>
<td>Microscope for Fluorescence Testing</td>
<td>Records of microscope monitoring and SOP describing filters and slides used.</td>
</tr>
</tbody>
</table>

Source: College of American Pathologists

---

**Scenario C:**

As part of hematology inspection, you always request a few slides to assess if the stain is of good quality. The supervisor *randomly* retrieved a few slides for you to review under the microscope. The stain was beautiful and you asked if they do a QC smear to check for stain everyday. The supervisor said no they don’t do a QC slide per se because all hematology techs should know what a good stain look alike. The protocol is that they check the stain on the patient slide in the morning everyday and if there’s issue they will troubleshoot and notify the supervisor.
## Hematology – Key Changes 2017 Checklist

<table>
<thead>
<tr>
<th></th>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>New</td>
<td>HEM.34320</td>
<td>Stain Reactivity: Stains are checked for intended reactivity each day of use. Must have written procedure and records of QC</td>
</tr>
<tr>
<td>New</td>
<td>HEM.35905</td>
<td>Ocular Micrometer Calibration: Calibration of ocular micrometer for the microscope in which it is used and recalibrated if eyepieces and objectives are changed</td>
</tr>
</tbody>
</table>

Source: College of American Pathologists

---

### To Access Checklist with 2017 Changes Only

**Checklist Download: e-Lab Solutions**

- **Checklist Type Options:**
  - Master
  - Custom
  - Changes Only

- **Checklist Format Options:**
  - PDF
  - Word/XML
  - Excel

Source: College of American Pathologists
Most Cited Lab General Deficiencies

<table>
<thead>
<tr>
<th>LAB</th>
<th>% Labs Cited</th>
</tr>
</thead>
<tbody>
<tr>
<td>GEN.16902 (QM plan implementation and annual review)</td>
<td>5.30%</td>
</tr>
<tr>
<td>GEN.77400 (Eyewash Requirements)</td>
<td>6.50%</td>
</tr>
<tr>
<td>GEN.54400 (Personnel Files)</td>
<td>8.60%</td>
</tr>
<tr>
<td>GEN.20375 (Document Control)</td>
<td>12.10%</td>
</tr>
<tr>
<td>GEN.55500 (Competency Assessment)</td>
<td>29.40%</td>
</tr>
</tbody>
</table>

Source: College of American Pathologists

GEN.55500 Competency Assessment

- **Written procedure (who, what, when, how, what if)**
- **Elements of Assessment**
  - Direct observation of performance
  - Results Reporting
  - Review QC recordsCTS/worksheets/PM
  - Maintenance and Function Check
  - Blind Test / PT
  - Problem Solving
- **At the laboratory (non-waived)**
- **Assessor of competency (GEN.55510)**
  - Qualification
  - Director delegation in writing
  - Records of assessment performed by qualified individuals

**Example**

**LAB.GEN.55500**
- **Procedure**
  - Competency Assessment
- **Methods of Evaluation**
  - Direct observation of performance
- **Enforcement**
- **Qualification**
- **Date of assessment**
- **Comments**
  - **Labs eligible for retesting**
  - **Qualification**

**Overall Comments/Unsuccessful Performance Follow up** (refer to further training documentation in employee file):

"I have read the above competency assessment, I understand that by signing this statement, I agree that I am competent to perform the tasks of this assessment as indicated by the above assessment.

Employee Signature: ____________________________ Date: ____________

Supervisory Signature: ____________________________ Date: ____________
GEN.20375 Document Control

- Written Procedure
- Includes derivative documents
  - Forms
  - Job aids
- Only current documents in use
- Approval record up to date

GEN.54400 Personnel File

- Each file to include:
  1. Diploma, transcripts or primary source verification
  2. State lab license if required
  3. Summary of training and experience
  4. Job description, list of responsibilities, duties, supervision
  5. CEs
  6. Incidents/accidents
  7. Dates of employment

- Equivalency evaluation
  - Foreign training & qualifications
  - Nationally recognized agencies (NACES, AICE)
- ASCP/AMT
- Periodic audit for completeness
- Personnel Evaluation Roster
  - All personnel for non-waived
  - Annual audit record (GEN.54025)
Most Cited All Common Deficiencies

<table>
<thead>
<tr>
<th>Common Deficiency</th>
<th>% Labs Cited</th>
</tr>
</thead>
<tbody>
<tr>
<td>COM.10100 (Procedure Manual Review)</td>
<td>4.20%</td>
</tr>
<tr>
<td>COM.30600 (Maintenance &amp; Function Checks)</td>
<td>4.30%</td>
</tr>
<tr>
<td>COM.04250 (Method Comparison)</td>
<td>4.80%</td>
</tr>
<tr>
<td>COM.10000 (Procedure Manual)</td>
<td>5.30%</td>
</tr>
<tr>
<td>COM.01200 (Activity Menu)</td>
<td>7.10%</td>
</tr>
</tbody>
</table>

Source: College of American Pathologists

COM.01200 Activity Menu

- Reflect currently performed test methods & analytes
- Periodically audit
- Retain documentation of changes
- Periodically review the CAP master activity menu
COM.10000 Procedure Manual
COM.10100 Procedure Manual Review

- Written procedure matches practice
- Available to all personnel
- Downtime plan for electronic documentation system
- Biennial review by director/designee (delegation in writing)
- Timely re-approval of SOPs if change in director

Does the record satisfy the intent of the standard?
COM.04250 Method Comparison

- Non-waived
- Methods under a single CLIA/CAP # that produce the same reportable result
- Every 6 month irrespective of test volume
- Written procedure
  - Identify methods/analyzers
  - Specimen type and number
  - Acceptance criteria
  - Document review and actions if out
- Patient samples, control material

COM.30600 Maintenance & Function Checks

- All equipment and instruments
- Written procedure
- Conforms to schedule specified by manufacturer
- Records of performance and supervisory review
Bonus Tip

Morphology Observation Competency VS. Consistency Assessment

HEM.34400 Morphologic Observation Assessment - CBC
HEM.35566 Morphologic Observation Assessment - Body Fluid
HEM.35851 Morphologic Observation Assessment - Sperm
URN.30800 Morphologic Observation Assessment - UA

Day of Inspection

- Don’t get defensive
- Don’t argue
- Have a pen & note pad
- Eat when you can

Google photo-Let’s do this/Brave Bosom
Helpful Links:

College of American Pathologists
http://www.cap.org/web/home7?_afriLoop=1031325702965414#!%40%40%3F_afriLoop%3D1031325702965414%26_adf.ctrl-state%3D8zsvtsmt_4

CMS website for looking up complexity of test
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm