Laboratory Inspection: How to ensure your lab will always meet the regulatory guidelines – AFP
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Speaker Disclosure

No Disclosures

In the past 12 months, I have not had a significant financial interest or other relationship with the manufacturer(s) of the product(s) or provider(s) of the service(s) that will be discussed in my presentation.
Agenda

• Review Laboratory Accreditation & Licensure Agencies
• Discuss CMS Requirements for the Laboratory
• Overview of the CLIA Regulations
• Review Tips for working with inspectors
• Discuss strategies to respond to inspection citations and warning signs of potential vulnerabilities
• Explore best practices at MedStar Health
Laboratory Structure at MedStar Georgetown University Hospital (MGUH)

- Georgetown University sold Georgetown University Hospital to MedStar Health in 2000
- MedStar Health is a 10 hospital health system in Baltimore, MD / Washington, DC area
  - All of the laboratories are interconnected and function as one unit
  - One LIS; Share Samples between labs; Conduct internal inspections; Multi-disciplinary workgroups; Same equipment; etc
Laboratory Structure at MedStar Georgetown University Hospital (MGUH)

**Faculty**

- **Chairman**
  - AP Division Chief
  - Molecular (PhD)
  - CP Division Chief
  - Blood Bank (MD)
  - HLA (PhD)
  - Clinical Faculty

**Staff**

- **Administrative Director**
  - Core Lab Manager
  - Specialty Lab Manager
  - AP Lab Manager
  - QM Coordinator

*Sections with 10 or more FTEs have two Laboratory Supervisors*
## Laboratory Accreditation Agencies

<table>
<thead>
<tr>
<th>Center for Medicare &amp; Medicaid Services (CMS)</th>
<th>CMS Deemed Status Agencies</th>
</tr>
</thead>
<tbody>
<tr>
<td>• CLIA Regulations</td>
<td>• CAP</td>
</tr>
<tr>
<td>• Local Department of Health Offices</td>
<td>• COLA</td>
</tr>
<tr>
<td></td>
<td>• Joint Commission</td>
</tr>
<tr>
<td></td>
<td>• AABB</td>
</tr>
<tr>
<td></td>
<td>• ASHI</td>
</tr>
<tr>
<td></td>
<td>• FDA</td>
</tr>
</tbody>
</table>
General CMS Standards for the Laboratory

• Patient Confidentiality
• Specimen identification & integrity
• Complaint investigation
• Communication
• Personnel competency assessment
• Evaluation of proficiency testing
CLIA Regulations

• CLIA is outcome oriented
• CLIA standards give the laboratory director a framework to operate the laboratory
• It is up to the laboratory director to interpret the guidelines and implement practices applicable to the laboratory
• Key questions to ask about your laboratory:
  – Is the laboratory providing accurate and reliable test results?
    • Not: Is the laboratory capable of providing accurate and reliable test results?
  – Does the laboratory satisfy the test performance requirements for accurate test results?
  – The documentation in your laboratory needs to demonstrate overall compliance to these key questions
CLIA Regulations

• CLIA activities focused on Quality Assessment:
  – Detect problems
  – Correct problems
  – Prevent future problems
  – Documentation

• CLIA reviews the entire process
  – Pre-analytical
  – Analytical
  – Post-analytical

• End Goal: Ensure accurate & reliable results
CLIA Regulations

• Quality Control
  – Written procedures to monitor & assess operational performance of test results
  – Take corrective action as needed
  – Review effectiveness of corrective action
  – Review process to prevent future occurrences
  – Staff training
  – **Documentation of all of the above**
CLIA Regulations

• Proficiency Testing (PT)
  – Each analyte must be compared with an external method twice a year
  – Satisfactory score of 80% except for:
    • ABO group & D(Rho) typing must be 100%
    • Cytology must be 90%
  – Proficiency Testing Options
    • Enroll in a formal PT program
    • Split samples with another laboratory
    • Incorporate unknown materials into testing
  – Must follow the same process of patient care testing:
    • No repeating unless outlined in policy & same practice followed in patient care testing
    • Do not engage in inter-laboratory comparison
    • Do not send sample to reference laboratory
CMS Deemed Status Agencies

• CAP, COLA, Joint Commission are all well respected accreditation agencies
  – Select the accreditation agency that most closely aligns to the needs of your laboratory
  – Each agency produces documents outlining the laboratory standards that ensure the CLIA guidelines are fulfilled
  – Just because your laboratory is accredited by a deemed status agency does not mean that CMS will not conduct an unannounced inspection
Laboratory Accreditation Agencies

• Laboratory requirements may differ between the agencies
  – Ensure that the laboratory selects the most stringent requirement to follow (i.e. centrifuge calibration every 6 months vs. centrifuge calibration every 12 months)
  – Most standards allow the laboratory director to decide how to apply the specific standard within the laboratory
    • Example: Validation Studies
    • Just ensure that the reason 10 samples for validation were selected was documented

• Call and ask for assistance from the regulatory agency
  – Ask for an example of how to apply the laboratory standard
  – Ask about the intent of the laboratory standard
Tips for Working With Inspectors

• Always provide an inspector with a response / documentation to his or her question even if it is not exactly what is being requested
  – Ask the inspector how he or she applies this standard in his or her laboratory

• Prepare inspection guides and instructions that several laboratory managers / supervisors can follow in case the one true person is absent on inspection day(s)

• Never leave an inspector’s side
  – Get a partner to work with the inspector
  – One person sits with the inspector and reviews the documentation while the other person pulls additional material

• Manage the inspection to ensure minimal downtime
  – Guide the inspector through the documentation
  – Provide food for the inspector
  – Try not to allow a question to remain unanswered for too long
Tips for Working With Inspectors

• Ensure that all material is reviewed before it is shared with the inspector

• Laboratory associates should discuss material being presented to the inspector in private
  – Example: If documentation is missing, this should be shared between the two laboratory associates before engaging the inspector
Tips for Working With Inspectors

- Do not argue with inspector if you do not agree; contest the inspection finding with the regulatory agency after the inspection has ended.

- If you do not know the answer to an inspector’s question, inform the inspector that you will need to do research and follow-up shortly. Then go ask another member of the laboratory management team for assistance. But make sure to follow-up with the inspector on the outcome before the end of the day.
Tips for Working With Inspectors

• If an inspector takes copies of laboratory documents, ensure that the laboratory retains a copy of what is given to the inspector

• Ask for a copy of the laboratory standard if there is a disagreement between the inspector and the laboratory representative
  – Within the laboratory standard guidelines it should state what is an acceptable form of compliance
  – CAP has updated each checklist to state “Evidence of Compliance”

• Limit inspection to what is being requested
  – Do not offer additional information unless asked
  – Do not tour other areas unless relevant to the inspection

• Every inspection is a learning opportunity
Unannounced Inspections

- Communicate with all agencies that inspect the laboratory regarding the unannounced inspection to ensure everyone is on the same page.
- Include agencies that may inspect or regulate the hospital / corporate owner of the laboratory.
- After the inspection, fill-in the other agencies on the status of the laboratory.
Responding to Laboratory Citations

• **Do not** submit a response with an action plan of when this will be completed in the future
• Pay attention to deadlines
  – Calendar days vs. business days
  – Timeframe: 10 days vs. 30 days
• Citation response should include the following:
  – Corrective action and assurance that this will not occur in the future
  – Revised policy / procedure
  – Re-training completed and documented
• Consider suspending testing if all items cannot be fully addressed before the citation response deadline
Themes for Laboratories in Trouble

- Cost-driven to the extreme
- Weak Management
- Unhealthy culture
- Reliance on outside inspectors
- Reactive organization
MedStar Health Laboratories

• Mock CAP inspection is scheduled for all laboratories during their self-inspection timeframe
  – Serves as a training opportunity for new supervisors / managers
  – Aids in sharing ideas across the health system
  – Another review before the actual inspection
  – If skill set does not exist within the health system to conduct the inspection (HLA, Molecular) outside consultants have been hired
  – Citations are tracked on an excel spreadsheet and follow-up is completed & documented in 30 days
MedStar Health Laboratories

- Proficiency testing
  - All testing personnel sign an attestation that they have not previously participate in the same PT nor will they discuss the results with another laboratory
  - PT sample results are not entered into the LIS
  - Designed a web-based education seminar on proficiency testing for all laboratory employees
MedStar Health Laboratories

• Peer Education
  – Share learning's and outcome’s from regulatory inspections at monthly laboratory director meetings
    • Distribute helpful templates
    • Review current articles
    • Update policies & procedures
  – Discipline workgroups also discuss mechanisms for complying to the new and/or changing laboratory regulations
MGUH’s Work Practices to Comply with the Regulatory Needs

• New employees
  – Inspection readiness is part of the department orientation
  – An educational booklet about the regulatory bodies of the laboratory is distributed and reviewed as part of the department orientation

• Current employees
  – Participating in CAP inspections is part of the career ladder program; serve as an inspector, review checklist, redesign SOP manual
  – Townhall meetings to discuss the inspection date as well as outcome from the inspection
MGUH’s Work Practices to Comply with the Regulatory Needs

• Document Control – SharePoint Website

• Proficiency Tests Results
  – Organized by one central location
  – All results are sent to the testing location with an attached form that needs to be completed
  – Sticker is placed on the results for all parties to review and sign

• QM Plan & Meeting Documentation
  – As applicable, next to each metric the CAP requirement number is listed
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Georgetown University Hospital
Department of Laboratory Medicine

Proficiency Testing Requirements and Attestation

Survey:
Received:
Performed By:

By signing below I am attesting to:

1. Testing these samples as I would patient samples.
2. I did not repeat testing on the samples to ensure I received the correct result.
3. I do not nor have not performed the same PT testing for another laboratory.
4. I have not acquired at any time access to the CAP PT database on behalf of any other laboratory.
5. I cannot or have not used the PT results between different laboratories.
6. I have not and will not discuss or communicate, share or disclose PT results with another laboratory before the PT event cut-off date and until after receipt of the PT report and evaluation.
7. I have not and will not send PT testing to another laboratory for testing or for any other reason.
8. I will not perform testing on PT samples received from another laboratory. If I do receive PT samples I will notify the Medical Director and safeguard the samples immediately.

__________________________________________  __________________________
Technologist Signature  Date Tested

__________________________________________  __________________________
Print Name
PROFICIENCY SURVEY SUMMARY

SURVEY ID__________________  A  B  C  YEAR__________
Online data submitted on__________  By ____________________

Proficiency Testing Results

☐ Graded
  ☐ Pass (The signed Performance Evaluation is on file)
  ☐ Fail (complete Proficiency Survey Investigation Form within 30 days, and the failed PT or modified protocol section)

☐ Educational challenge (code 28) / Ungraded

☐ Unable to Analyze (code 11)

Testing/Diagnosis was completed on time, instrument printouts and worksheets are on file, and the attestation is signed by the testing personnel, pathologist who interpreted results, and Lab Director or designee.

Technologist Signature: __________________________ Date: __________
Pathologist Signature who interpreted results: __________________________ Date: __________
Laboratory Director Signature: __________________________ Date: __________

Please review the CAP survey data and ensure all appropriate signatures (on the back signature page). Complete the “Correction Report” form for any unacceptable results, biases or other issues that need to be addressed. Copy and return this survey to the Lab Admn by: ________________

Number of Tests: ________________
Number Correct: ________________
Number Incorrect: ________________

Requested by: __________________________ Date: ________
MGUH’s Work Practices to Comply with the Regulatory Needs

• CAP Checklist Guide
  – Excel spreadsheets created as a crosswalk to compare requirement vs documentation of compliance
  – CAP word documents are typed with specific evidence of compliance
  – Pull specific examples of compliance documentation into a binder (i.e. final reports)

• About every six months sub-section teams meet and review the CAP checklists line-by-line

• New supervisors for the first two years are selected to participate in health system internal inspections
MGUH’s Work Practices to Comply with the Regulatory Needs

- **Safety Team**
  - Representative from every section
  - Each member works with section to complete a safety checklist audit each month

- **Surprise Inspections**
  - What is under the sink?
  - Eye wash log up to date?

- **Career Ladder Program**
  - Criteria for moving from Level I to Level II & Level II to Level III all requires some type of regulatory experience and/or participation
MGUH’s Work Practices to Comply with the Regulatory Needs

• Regulatory requirements are taught at all staffing levels. Bench level staff need to understand the meaning behind specific practices; inspections are not just a supervisor project.

• Documentation of Quality Control Examples:
  – Reported within LIS platform and enables custom reports to be generated
  – Dictated in final report
  – Stain request forms returned indicating quality of material reviewed
MedStar Georgetown University Hospital Laboratory

• Quality Management Coordinator
  – Dual reporting to Laboratory Director and Administrative Director
  – Serves as the central coordinator for all regulatory items
  – Works with the leadership team to outline the Quality Improvement & Quality Assurance program
  – Manages Laboratory General policies & procedures
  – Coordinates all Proficiency Testing for the department
  – Leads the Safety Committee
  – New Employee Training
  – LEAN Process Improvement leader
  – Facilitates the document control program
  – Works with each section to ensure an inspection guide is available and up to date
  – Much, much more…….
Lessons Learned from Past Inspections

• Communicate with all laboratory accreditation agencies timely and openly
• Be honest and upfront with the inspector
• Work with the inspector to manage the inspection process
• Keep hospital administration / corporate informed at all times
Lessons Learned from Past Inspections

• Partner with Quality Improvement and/or Regulatory Affairs office

• **If it was not documented, it was not done**

• Successful laboratory inspections requires **teamwork** at all levels (laboratory director, pathologist, laboratory manager, medical technologist)
Questions?

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