Performing Effective Self-Inspections

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Learning Objectives

• As a result of participating in this activity, you will be able to:
  – Explain the importance of the interim self-inspection
  – Apply best practices and tips to your interim self-inspection
  – Describe how maximizing the interim self-inspection will prepare you for an unannounced external inspection
Purpose of the Self-Inspection

• Ongoing compliance with the Standards
• Current checklist requirements
• Enhancement of next onsite external inspection
• Laboratory improvement and better patient care
Checklist Question GEN.23584

Has the laboratory conducted an interim self-inspection and documented efforts to correct deficiencies identified during that process?
NOTE: The interim self-evaluation inspection is an important aspect of continuing education and laboratory improvement. The use of a variety of mechanisms for self-evaluation (residents, technologists or other inspectors) is strongly endorsed. Documentation of performance of the interim self-inspection with correction of deficiencies is a requirement for maintaining accreditation. The laboratory must document that personnel responsible for each laboratory section have reviewed the findings of the interim self-inspection.
Best Practices #1

- Have the interim self-inspection as closely as possible approximate a real inspection event.
Best Practices #2

- Formalize the inspection procedure
- Complete all checklist questions
- Check documentation on all items
Best Practices #3

- Utilize experienced non-supervisory technical staff, residents, fellows
  - **Cultivates new team members for future inspections**
  - **Provides depth for unannounced inspection**
  - **Prepares staff for possibility that they’ll be interviewed**
  - **Elucidates weaknesses**
Best Practices #4

• Inspect sister facilities, cross discipline lines
  – *Fresh perspective*

• Distribute checklists in advance
New Inspection Emphasis

1. Inspectors: Spend more time in the laboratory!
2. Interview non-supervisory staff (bench techs, phlebotomists, order entry personnel)

Structure the interim self inspection accordingly
Interview non-supervisory personnel during the self inspection -- does everyone know the policies as well as the supervisors?
Best Practices #5

• Use the interim self-inspection to look at your lab as if you were seeing it for the first time.
Best Practices #6

• Consider adding the element of surprise; use the event as an opportunity to test readiness.
Testing Readiness

• “If your supervisor were not here on the day of the inspection, how would you respond if you were asked by the inspector…”

  – …for a certain procedure or practice?
  – …where PT policies are located?
  – …where the Chemical Hygiene plan is housed?
  – …where the maintenance records are kept?
Best Practices #7

• Review the video
• Encourage staff to attend training
  – LAP audioconferences and online courses
    • Select Education from www.cap.org
  – The Virtual Library of Audioconferences is also available on www.cap.org
  – Read the Checklists and the LAM
  – Participate on inspection teams
Best Practices #8

• Review previously cited deficiencies
  – Check deficiency response against current practice.
  – Is the lab still following the corrective procedure as promised?
Example

My own lab’s experience
GEN.41067 (Phase II)

- “Does the Laboratory director review the format of the report on an annual basis?”
- I look at report format every day!
- No written policy.
- No documentation that this is occurring.
Moral of the Story

• Provide documentation that the activity is being performed.

• Failure to document equals non-compliance.

• “If you didn’t document it, it didn’t happen……”
Important Enough to Repeat

- As you’re going through the ISI, treat it as a real inspection, be thorough.
Famous Last Words

“Oh yes, we do all of that stuff…..(I think.)”

Dr. I. M. Complacent,
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Most Common Lab General Deficiencies -- Phase I

- GEN.70824
  - Policy to protect personnel from excessive noise levels

- GEN.20371
  - Documented education on FDA procedure for reporting device-related serious adverse patient events

- GEN.60100
  - Sufficient space
Most Common Lab General Deficiencies -- Phase II

• GEN.20375
  – Document control system
• GEN.55500
  – Competency assessment
• GEN.70250
  – Periodic fire drills
Areas to Focus On

- Safety
- Competency
- POCT
- Document control
- Quality management

- Team Leader Checklist
- Patient safety policies
- Handling of complaints
- PT exceptions
Safety

• Safety procedures and policies posted readily available to all employees?

• Documentation of safety training to new employees?

• Annual fire drill?
Suggestion…

• During the **Interim Self-Inspection**, interview personnel regarding contents of the safety manual.
  – Choose several items to ask non-supervisory staff.
Competency Assessment

1. During the first year of patient testing, competency assessment must be performed every six months.
2. Competency must be reassessed at least annually.
3. Most pertinent elements should be incorporated into competency assessment.
Point of Care Testing

- Inspection of POCT requires the use of the POCT checklist and all applicable portions of the Laboratory General checklist.
- For accreditation, all analytes being measured under the program/site are included in the live CAP inspection.
Point of Care Testing

Checklists requirements are the **SAME** for waived vs. non-waived testing:

- Proficiency testing
- Quality management
- Procedure manuals
- Specimen handling
- Results reporting
- Instruments and equipment
- Personnel
- Safety
Document Control

- All required elements present?
- Documents current?
Document Control

Instructions in use – are they…

1. Current?
2. Correct?
3. Available to everyone?
Elements of Document Control System (GEN.20375)

- Policies and procedures (P/P) **current**
- Personnel have **read** the relevant documents
- P/P have been authorized by the director
- P/P reviewed annually by the director
- Discontinued P/P quarantined in separate file
Team Leader Checklist

1. Evaluate the qualifications of the Laboratory Director.

2. Assess the effectiveness with which that individual implements and supports the Standards of the LAP.
Team Leader Checklist

Directorship Involvement

• Review documents:

  – QM plan -- include review of specific monitors, corrective actions.

  – Organizational chart -- does it represent operations?
Team Leader Checklist

• Conduct a mock interview
  – Have another qualified individual to go through the questions thoroughly with the Director

• Benefit – prepares a back-up
Inspector Summation Report: Five Crucial Questions

1. Does the lab meet the Standards?
2. Is the Director qualified?
3. If no, is there a qualified supervisor for each section?
4. Is administration satisfied?
5. Is the medical staff satisfied?
Quality Management

- Thoughtful selection of indicators
- Corrective actions documented
- Directorship involvement
Patient Safety Policy

- Rigorous adherence to patient identification procedures
- Reporting of life threatening conditions/critical values
- Strategies for preventing medical errors
- Institutional approach
Handling of Complaints

- Honestly review the culture of your lab.
- Do policy and procedure exist?
- Do policy and procedure match actual practice?
PT Exceptions

- Variant PT performance report
- “Drill down” troublesome analytes
- Alternative PT
- Do not share PT results!
Best Practices #9

• This is a good opportunity to update your activity menu, and confirm that PT is being performed for each item.
Completing the Inspection

• Formalize summation of deficiencies
• Discuss corrective actions
• MD: Review all deficiencies and corrective plans
• MD: Implement formal plan to review corrections and ensure ongoing compliance
• File results
Paperwork

• Send to the CAP:
  – Self-inspection verification form
  • Signed by Director
What Inspectors Will Focus on About Your Self-Inspection

• Ask probing questions about the self-inspection
  – How seriously was it taken?
  – Were genuine concerns uncovered and corrected?
• Request list of cited deficiencies and scrutinize documentation of corrective action
Summary of Best Practices

• Involve multiple staff members in the self-inspection
• Formalize the event
• Look upon your lab with “fresh eyes”
• Introduce a surprise element
Questions
Technical Assistance

http://www.cap.org

Email: accred@cap.org

800-323-4040, ext. 6065