HOW TO GET READY FOR YOUR CAP INSPECTION

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HOW TO GET READY FOR YOUR CAP INSPECTION

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Preparing Inspection Documentation
Learning Objectives

• Identify key types of documentation required to demonstrate compliance.

• Develop a documentation organization system that will facilitate the inspection process.
Why Accreditation?

Participation in a Voluntary Laboratory Accreditation Program Improves the Quality of Services for Patients.
The LAP Mission

The CAP Laboratory Accreditation Program improves patient safety by advancing the quality of pathology and laboratory service through education, standard setting, and ensuring laboratories meet or exceed regulatory requirements.
LAP Philosophy

• Promote a Culture of Quality
  – Quality control
  – Performance improvement
  – Proficiency testing

• Regulatory role
  – Assess compliance with CAP requirements, including CLIA-88 regulations
History of CAP Laboratory Accreditation Program

• In Existence Since 1961
• Progressive Growth
• Relationships with other Organizations
CAP Laboratory Accreditation Program

- Over 6,600 Participating Laboratories
- Ten to Twelve Inspections per Day
- Worldwide Recognition
  - 124 Civilian International labs.
  - 70 US Military Labs Overseas.
  - 38 Countries including four Arab countries.
Goal of CAP Inspection

Quality Improvement, accomplished by:

• Educational process.

• Peer review.

• It is an opportunity for improvement.
LAP Inspection: Maintaining Balance

Education

Quality Improvement

Regulatory Compliance
Standards and Checklists

• Purposes:
  – Standards are the broad principles the laboratory must meet in order to achieve accreditation
  – Checklists provide detailed requirements that inspectors use to determine whether laboratories meet the Standards
The Standards for Laboratory Accreditation

- Standard I  Director
- Standard II  Physical Facilities & Safety
- Standard III  Quality Control and Performance Improvement
- Standard IV  Inspection Requirements
Good Preparation

Results in:

• Better patient care

• A more enjoyable inspection day
Documentation is Key

If it isn’t:

• Written down
• Reviewed and
• Signed

It isn’t happening !!
Famous Last Words

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

Dr. I. M. Complacent,  
Medical Director  
Mediocre Laboratories, USA
Don’t Reinvent the Wheel

• Ask your friends or instrument manufacturer for electronic copies of procedures and policies.

• Customize them to your lab.
An Open Book Test

The inspection is an open book test:

• Do a mock inspection yourself

• Have a colleague from another lab do a mock inspection
What Will Inspectors Look for?

• Documents that show the existence of a policy, procedure or process that fulfills the intention of a checklist requirement(s).

• Evidence of review.

• Evidence that it is being followed.
Do You Know Where Your Documents Are?

• Note by each checklist question where to find answers and documents.

• Make a notebook with a tab for each checklist question, and file a sample response behind each tab.
Prepare All Year Long

• Don’t wait until your reapplication arrives in the mail (5 months prior to inspection anniversary date).

• Divide procedures and policies into 12 parts and do 1/12 each month.

• Delegate work to as many people as possible to make them aware of process.
Lab General (GEN) as a Guide

We will:

• Discuss specific GEN questions
• Give sample responses that you can modify for your own lab
  – Everything in GEN applies to all lab disciplines
• Give a copy of GEN to each section supervisor
Sections of GEN

- Summary of checklist changes
- Proficiency Testing........... PT
- Quality management......... QM
- Quality Control................ QC
- Specimen collection, data handling and reporting
Sections of GEN

- Water quality/glassware washing
- Test method validation
- Computer
- Personnel
- Physical facilities
- Safety
Checklist Changes Section

New section of each checklist, created to assist you in preparing for inspection:

• List of new, revised and deleted questions

• Descriptors (new, revised) are also included by each affected question in the body of the checklist
Proficiency Testing

• Write down your procedure.

• Make a chart of all analytes for which PT is done (purchased or alternative).

• Keep track of PT mailing dates.

• Have a backup plan when supervisors are away.
Proficiency Testing 2

• Have documentation prohibiting sharing results.

• Keep track of and flag for inspector review challenges with problems
  Use PT exception by lab report.

• Treat PT samples like patient samples.
Quality Management

• Write down your plan, based on:
  – NCCLS GP22-A and GP26-A2
  – ISO 9000
  – AABB model
  – Edit a plan used by a colleague.

• Choose indicators each year.

• Cover all areas of the lab.

• Pre-analytic, analytic and post-analytic variables.
Quality Management 2

• Show evidence of review of quarterly data.

• What was done about problems?

• Communicate with other hospital department.

• Report to institutional QI/QM committee.

• Use graphic tools.

• Do annual appraisal for effectiveness.
Document Control (NEW)

• Make a table of all documents including: Policies, procedures, forms, records.

• Keep track of annual review.

• Where are copies filed? (Control Log).

• Do all personnel read procedures? (Knowledgeable).

• Keep retired policies and procedures 2 years.
Satisfaction Surveys

• Every 2 years.

• Ask your clients and patients how you are doing.

• Make your own survey or participate in one used by your hospital. Survey your clinicians and patients.

• Hand deliver or follow up with the lab person who visits clients to ensure a good response.
Quality Control

• Overall lab plan.

• Section-specific plan.

• Instrument / analyte specific.
Quality Control 2

- What materials are to be used?
- What analytes are being tested?
- What are the tolerance limits?
- What is the corrective action when out of range?
Quality Control 3

• Compare different methods or instruments across the hospital.

• At least to be done twice per year.
Lab Manual for Clients

• Every client, nursing station, drawing station (OR, ED, OPD, physician offices).

• The manual could be paper or electronic.

• Evidence of updating and review.

• Tell them how to get the best specimen.

• Tell them what are the times you will perform the tests.

• Tell them the turnaround time for the test.

• Tell them whom to call with problems.
Documentation of Phlebotomy Training

• Competency – patient age-specific.

• Patient identification.

• Specimen identification policies.

• Volume collected – policy.

• Feedback when problems occur.
Specimen Transport

- In hospital – by transport or pneumatic tube:
  - Date and time of receipt in lab.

- To reference labs – people trained in accordance with federal, state and local regulations.

- Training documentation.

- Tracking system to ensure that everything picked up was delivered and in good shape.

- Problem log with review and corrective action.
Accuracy of Communication

- Policy to read back telephone and verbal orders.
- Policy to document critical results are called, to whom and when, and that they are read back.
- Documentation that clinicians were consulted to determine what should be considered a critical value.
Criteria for Selection of a Reference Lab

• Show Lab Director has input into selection.

• It should be CAP-accredited.

• Show procedure for review of initial selection.

• Show how quality is monitored.
Record Retention

• Must follow most stringent:
  – State regulations.
  – Federal regulations.
  – CAP checklist
Water / Glassware

- Determine quality of water needed for analyte / method.

- Show records of testing (SOURCE) water.

- Show corrective action.
Test Method Validation

- For each method, have data organized:
  - When it was put into service?
  - How are changes communicated to clients?
  - How were reference ranges determined?
AMR and CRR

- **AMR: Analytical Measurement Range.** It is a range of values that instrument can report directly (less accurately called *linearity*).

- **CRR: Clinically Reportable Range.** It is a range of values that can be reported with dilution or concentration of samples.

- The reportable range must be verified or established for each analytic procedure before implementation.
Computer

- Evidence Lab Director has reviewed procedures.
- Evidence that the Director has approved all changes.
- Show access level for each employee.
- How calculations are checked periodically.
- Lab Director reviews report content and format.
Computer 2

- Show example of corrected reports with the original data still visible.

- Who can modify data?

- Document that client receives same data you entered
  - Went across all interfaces (HL-7, LIS to HIS, HIS to printers).

- Downtime backup system.
Personnel – Lab Director

• Lab Director must meet *Laboratory Accreditation Standards*.

• If responsibilities are delegated, have it in writing.

• If a consultant is used – document visit times and content
Personnel

- Non-pathologists – do they meet established requirements.

- Organizational chart.

- Evidence of continuing education.

- Up to date personnel files – in lab or HR.
Physical Facilities

• Clean the lab.

• Don’t have too much inventory crowding the space.

• Make sure all pieces of paper hanging up are current, dated and signed.
Safety

- Have your procedures up to date.
- Ensure all personnel are aware and trained.
- Have fire drill records on hand.
- Update your Chemical Hygiene Plan and MSDS sheets
Safety 2

• Plan to reduce or eliminate mercury.

• Evaluate lab for ergonomics.

• Have procedures for liquid nitrogen, UV light, radiation safety.

• Part of hospital’s employee safety plan
• Are people using PPE?
Safety 3

Address these issues:

- Body fluid exposure.

- TB exposure

- Latex gloves

- Fumes
Morphologic Consistency

Particularly applicable to Hematology and Urinalysis:

- Multiple laboratorians examining slides.
- Important they arrive at same cellular conclusion

Ways to ensure consistency:
- Review unknown slides
- Use 35 mm CAP proficiency testing slides
  - Record answers
  - Compare to correct PT result
Areas to Focus On

- Safety
- Competency
- POCT
- Document control
- Quality management
- Team Leader Checklist
- Patient safety policies
- Handling of complaints
- PT exceptions
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