Seminar Objectives

- Understand the goals of a CAP inspection
- Prepare for an Anatomic Pathology inspection
- Recognize the changes in policies and procedures needed to accommodate new tests and instrumentation
- Identify common deficiencies and how to avoid or correct them

Why Inspect?

- Clinical Laboratory Improvement Acts (CLIA) of 1967 and 1988
  - Laboratories licensed by the Federal Government (CMS)
  - Organizations “deemed” by CMS to accredit federally licensed laboratories: CAP, The JC, AABB, ASHI, etc.
  - Inspection is part of the accreditation process
Inspection Timing

- On-site inspection performed once every 2 years
  - Unannounced, but in 90 day period prior to "Anniversary date"
- Conducted by "peer" laboratory
  - Inspector assigned by CAP; verified by State Commissioner
- Self-inspection - off-year inspection by lab; reported to CAP

CAP Lab Accreditation Program

- Began in 1961
- >7,000 laboratories in program
  - 43% of hospital laboratories
  - 80% of large hospital laboratories
  - 95% of university hospital laboratories
  - 2/3rds of large reference laboratories
  - 100% of VA and military laboratories
  - ~300 international laboratories
- 10-12 inspections per day
- Participation is purely voluntary

What Governs CAP Accreditation?

Standards for Laboratory Accreditation
- Director and Personnel
- Physical Resources
- Quality Management
- Administrative Requirements
What Goes into a CAP Inspection?

- Inspection tools from CAP
  - Laboratory demographics
  - Test menus and methods
  - Instrumentation list
  - Previous deficiencies
  - Checklists

Inspectors - Pathologists & PhD's, technologists, trainees

Inspection Checklists

- Checklists
  - A series of requirements that inspectors use to determine whether the inspected laboratory meets the Standards
- 21 checklists, organized by lab section
- Total checklist items: ~2,800
- "Deficiency": Deviation from best practices
  - Phase I: Deficiencies that do not seriously affect patient care or the safety of laboratory workers
  - Phase II: Deficiencies that may have a serious effect on patient care or worker health/safety

CAP Philosophy of Inspection

- Laboratory improvement
  - Not a punitive expedition!
- Education: A learning experience for everyone
- Both inspector and inspectee should be pleased with the result
  - "Golly, we learned so much..."
  - "I really appreciate your input..."
  - "We wish all inspections could be like this..."
Preparing for Inspection

- Continuous compliance
- Know all applicable checklists!
  - Laboratory General
  - All Common
  - Anatomic Pathology
- Have readily available:
  - Policies and procedures
  - Documentation of activities
  - (merge supportive docs with checklist)
**Laboratory General Checklist**

- Quality management
- Specimen collection, handling, reporting
- Laboratory computer services
  - Telepathology
  - Whole slide imaging
- Personnel
  - Qualifications, training, competency
- Laboratory safety

**All Common Checklist**

- Proficiency testing
- Quality management
  - Procedure manuals
  - Reagents
  - Instruments & equipment
- Test method validation
- Individualized quality control plan (IQCP)

**Key Documents**

- Quality Management Plan
- Self-Inspection
- Personnel records
- Proficiency testing records
- Equipment maintenance & temperature
- Safety policies and procedures
Digging Deeper

Example: Personnel Records

- Diploma/Transcript
- Qualifications
- Job description
- Training
- Competency
- CME
- Color blindness
- Hepatitis B vaccination

Non-Pathologist Grossing

- Qualified for high-complexity testing
  - BS/AD in Biology or Chemistry
  - 60/24 (6/6/12)
- Defined activities and supervision
- Competency assessment
- Common deficiencies:
  - No training records
  - No records of activities/supervision
  - No periodic evaluation of competency
What’s New in Anatomic Pathology?

- Proficiency testing
- Competency assessment
- Validation/Verification
- Digital image analysis
- Telepathology

Proficiency Testing

- Participation in CAP-approved proficiency testing, if available, is required.
  - Estrogen/progesterone receptors; Her-2
  - Other prognostics not yet mandatory
- Requirements for PT performance:
  - Integrated within routine workload
  - Rotated among regular testing personnel
  - Active review by director or designee
  - Evidence of evaluation and corrective action
  - No interlaboratory query; no referral

Proficiency Testing
Common Deficiencies

- Each mailing seen by same pathologist
- Review by all pathologists before sending answers to CAP
- No documented evaluation of results
- No evaluation of ungraded results
Scenario - Proficiency Testing

At Friars Medical Center, the Histology lab was having trouble with its Her-2 IHC. When the PT samples arrived from CAP, the lab sent the slides to Quest for staining, and the slides were then returned to Friars for interpretation.

Was this acceptable?

Competency Assessment

- Evaluate training prior to start testing
- Competency twice during first year, & annually thereafter
- Six elements of competency:
  - Direct observation of performance
  - Recording & reporting of test results
  - Review of QC, PT & maintenance records
  - Direct observation of maintenance/function
  - Blind testing
  - Problem-solving skills

Competency Assessment Scenario

In addition to her usual grossing duties, the pathologist assistant sometimes helps out in histology with cutting and staining. As a result, the histology supervisor performs her overall competency assessment, using all applicable elements, and the laboratory director signs off on it.

Is this acceptable?
Competency Assessment

Scenario

- Competency must cover all test systems
- Individual performing competency must be qualified by training and experience in the test systems being evaluated.
- Personnel who perform high-complexity testing must be assessed by someone with similar qualifications.

Did that histology supervisor fit the bill?
If not the histology supervisor, then who?

Test Validation/Verification

- Validation – performs as claimed by lab
- Verification – performs as claimed by manufacturer
  - Mainly FDA-approved testing
- Examples for Anatomic Pathology:
  - Equipment: Tissue processor, stainer
  - Process: IHC, FISH
- Extent of V/V set by lab director

Test Validation/Verification

Processors, Stainers & Reagents

- Accuracy – comparable to reference method?
  - Pathologist able to make the correct diagnosis?
- Precision – day-to-day results the same
  - Pathologist make the same diagnosis every day?
- Sensitivity – needed feature visible
  - AFB, iron & trichrome stains
- Specificity – unneeded features not visible
  - Acid-fast decolorization
- Reportable range
  - Semiquantitation – i.e., iron stain
Validation/Verification

Common Deficiencies

- No validation of positive control blocks
- No validation of new lots of antibodies
- Inadequate validation of Er/Pgr/Her-2
- No revalidation after change in process (antibody clone, instrument, reagents)
- Annual prognostic result comparison
- Use of outdated antibodies

Validation/Verification Scenario

During an inspection, you note that the lab changed testing for Her-2 from a FISH to an ISH technique. The original validation study for FISH included 50 cases, and the followup study for ISH used 10 cases, with 90% concordance between the two.

Was the ISH validation adequate?

Validation/Verification Scenario

ANP.22978: NOTE: …Test validation must be performed on a minimum of 20 positive and 20 negative samples for FDA-cleared/approved assays…

Must completely revalidate if changing reagents and/or processes.
Digital Image Analysis

- Quantify specific features in tissue
  - Er, Pgr, Her-2, other prognostics
- Calibration (system works as described)
  - Frequency per vendor
- Quality control
  - Positive & negative controls
  - Performed each day of patient testing
  - Same person as performs testing (hi-comp)
  - Must be acceptable prior to reporting
  - Checked monthly for trends

Digital Image Analysis

Common Deficiencies

- Lack of policies & procedures
  - Pre-analytic, analytic & post-analytic
- Qualifications of testing person
- Calibration = QC
- QC person ≠ testing person
- Document pathologist involvement
  - Selection of field(s)
  - Written interpretation

Telepathology

Definitions

- Pathologist examines images and/or data remotely and makes a written interpretive report
  - Primary & frozen section diagnosis
  - Second-opinion consultations
  - Adequacy determination of FNA specimens
- Static, dynamic or virtual images
Telepathology
Key Elements/Documentation

- Policy & procedures
- System training & validation
- Positive slide identification
- Confidentiality of patient information
  - User authentication
  - Message security; encryption
  - Access restrictions
- Requirements for whole slide imaging
  - Training & validation

Telepathology
Common Deficiencies

- ???????? (not enough data...)

Most Common Deficiencies
Anatomic Pathology

<table>
<thead>
<tr>
<th>Task</th>
<th>Percentage</th>
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</thead>
<tbody>
<tr>
<td>Crystal Decontamination</td>
<td>8.0%</td>
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<tr>
<td>Professional Competency</td>
<td>6.0%</td>
</tr>
<tr>
<td>Formaldehyde &amp; Xylene Safety</td>
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<tr>
<td>Reagents</td>
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</tr>
<tr>
<td>Adequate Space</td>
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</tr>
<tr>
<td>Thermometric Standard Device</td>
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<tr>
<td>Specimen Labeling</td>
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<tr>
<td>Antibody Validation</td>
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<tr>
<td>Competency of Non-Pathologists</td>
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</tr>
<tr>
<td>Reagent Expiration Date</td>
<td>0.0%</td>
</tr>
</tbody>
</table>
Cryostat Decontamination

There is a written procedure for the decontamination of the cryostat at defined intervals, and under defined circumstances, and decontamination records are evident.

- Cryostat defrosted and decontaminated by wiping exposed surfaces with tuberculocidal disinfectant.
- Done at an interval appropriate for the institution; this must be weekly for instruments used daily.

Cryostat Decontamination

During an inspection, you see a histotech cleaning the cryostat. Their procedure and a log document that the cryostat is cleaned every Wednesday with a cleaning solution (9 parts ethanol and 1 part bleach) and is defrosted/decontaminated the last Friday of every month. A log in the frozen section area shows that the cryostat is used two to three times each week. Although this lab has approximately 50% fewer frozen sections than your own lab, your lab defrosts and decontaminates the cryostat with a tuberculocidal disinfectant weekly.

What do you do?

Formaldehyde/Xylene Monitoring

Formaldehyde and xylene vapor concentrations are maintained below the following maxima, expressed as parts per million, in all areas of the Anatomic Pathology Department where formaldehyde or xylene are used.

Formaldehyde monitoring:
- Repeated when a change in production, equipment, process, personnel, or control measures may result in a change in exposure level.
- If personnel report symptoms associated with formaldehyde exposure, the laboratory must promptly monitor the affected person’s exposure.

Xylene monitoring:
- Monitored initially, but no requirement for periodic monitoring.
- Repeated monitoring considered when a change in production, equipment, process, personnel, or control measures is likely to increase exposure levels.
Reagents Labeled and Changed

**ANP.11756 Phase II**

All solutions and stains are properly labeled and changed on a defined schedule.

- Labeled with the contents, and, if applicable, date they are changed/filtered and expiration date.
- Changed or filtered following a defined process, determined by the usage of the reagents.

Adequate Space

**GEN.60000 Phase II**

The general laboratory has adequate, conveniently located space so the quality of work, safety of personnel, and patient care services are not compromised.

**GEN.60100 & GEN.60150 Phase I**

The laboratory has space for...
- 60100 – offices, etc.
- 60150 – technical, storage, etc.

Non-certified Thermometers

**COM.30725 Phase II**

All non-certified thermometers in use are checked against an appropriate thermometric standard device before initial use and as defined by laboratory policy.
Primary Specimen Container Labeling

COM.06100 Phase II

All primary specimen containers are labeled with at least two patient-specific identifiers. A primary specimen container is the innermost container that holds the original specimen prior to processing and testing. This may be in the form of a specimen collection tube, cup, syringe, swab, slide or other form of specimen storage.

Secondary Specimen Container Labeling

COM.06200 Phase II

Adequate specimen identification is provided on specimen containers throughout all phases of testing, including, but not limited to aliquots, dilution, tubes, slides, blocks, culture plates, reaction units, nucleic acids and other extracts, data extract files, images, and other secondary specimens created during the processing or testing of a specimen.

- Slides prepared from specimens in the LABORATORY are considered secondary specimen containers.
- For Histology, each block of tissue is identified by a unique identifier traceable to the primary specimen and any descriptive letter(s)/number(s). Each slide is identified by the unique identifier traceable to the primary specimen and descriptive letters unique to the block from which it is cut.

Slide Labeling Scenario

While inspecting a lab, you notice that all slides are labeled with accession number and block designation. The lab’s policy clearly defines its requirements for specimen labeling and the techs are following the policy as stated. Your own lab includes the patient’s last name on the slide label.

What do you do?
Slide Labeling Scenario

While inspecting a lab, you notice that all slides are labeled with accession number and block designation. The lab's policy clearly defines its requirements for specimen labeling and the techs are following the policy as stated. Your own lab includes the patient's last name on the slide label.

COM.06200: NOTE: A single, unique identifier may be used to label materials derived from the primary specimen for use in subsequent phases of testing.

New and Revised ANP Requirements for 2017

- ANP.11680: Cross-contamination - grossing
- ANP.296xx: Flow Cytometry section
- ANP.30160: Significant/unexpected findings – autopsy
- ANP.34160: Safe handling of bariatric patients - autopsy

New and Revised Requirements

Cross-Contamination

ANP.11680: There is a written procedure to prevent cross-contamination of specimens during grossing.
- Clean instruments between specimens
- Clean surfaces after large specimens
- No reuse of cotton applicators
- No sequential grossing of same specimen type
New and Revised Requirements
Significant/Unexpected Findings - Autopsy

- ANP.30160: There is a written policy regarding the communication and recording of significant and unexpected autopsy findings.
  - Reportable infectious diseases
  - Heritable genetic abnormalities
  - Procedural complications
  - Unexpected fatal malignancy

New and Revised Requirements
Safe Handling of Bariatric Patients - Autopsy

ANP.34160: There are written procedures for the special handling of autopsies on bariatric patients where the patient size could represent an occupational hazard to autopsy staff.

Note: Labs may choose to...
- Set weight and/or BMI limits for policy
- Use special equipment

Final Words

- CAP inspection goals
  - Education
  - Laboratory improvement
- Continuous compliance
- Yearly updates to checklists – keep current with best laboratory practices
- Contact CAP with questions
  - accred@cap.org
  - 800-323-4040