2013 Continuing Compliance Master Series
Checklist Updates for Anatomic Pathology

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Today’s Presenter

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Dr. Hoeltge has no conflicts of interest to disclose relevant to this presentation.
Objectives

• List the most recent changes to the Laboratory Program accreditation requirements (checklists) that affect anatomic pathology (AP).

• Recognize the most common deficiencies reported in 2012.

• Use the checklist changes to prepare for your laboratory inspection.
Changes that Affect all Checklists

- Definitions
- Phase level reassignment
- Validation and verification
- Competency assessment
Definitions

• Checklists now feature short glossaries

• Examples
  o Check, Confirmation, Correlation
  o Equipment, Instrument
  o Laboratory Director, Section Director

Modification of manufacturer's instructions - Any change to the manufacturer’s supplied ingredients or modifications to the assay as set forth in the manufacturer’s labeling and instructions, including specimen type, instrumentation or procedure that could affect its performance specifications for sensitivity, specificity, accuracy, or precision or any change to the stated purpose of the test, its approved test population, or any claims related to interpretation of the results
Phase Level Reassignment

- Phase II requirements detect conditions that may have a serious impact on the quality of service or may endanger the health and safety of patients, clients, or personnel.
- Phase I requirements detect conditions that may compromise the quality of service without endangering the health and safety of patients, clients, or personnel.

Documentation of correction required

Documentation of correction not required
Phase Level Reassignment - Examples

ANP.11713 Histologic Prep Quality  Now Phase One

There is documented evidence of daily review of the technical quality of histologic preparations by the pathologist.

CYP.03366 FNA Error Prevention  Now Phase Two

If the pathologist performs FNA procedures, there is a documented procedure to prevent errors in the identification of the patient, the site and the procedure.
Validation versus Verification

• Validation
  o “confirmation through a defined process that a test performs as intended or claimed”
  o test methods

• Verification
  o “a process through which a clinical laboratory establishes that its implementation of an FDA-approved and FDA-cleared test performs in substantial conformance to a manufacturer’s stated claims”
  o reagents, instruments, and approved/cleared in vitro devices (IVDs)
Tissue processing programs are validated.

There is documentation of adherence to the manufacturer's recommended protocol(s) for implementation and verification of new instruments.
Competency Assessment

GEN.55500 Competency assessment Phase II

The competency of each person to perform his/her assigned duties is assessed.

**Corollaries**

Evaluation of training

a) Prior to starting work, at six months and annually thereafter for all duties

b) Prior to starting any new test/test systems, methods, or instruments
Competency Assessment

1. Six elements of competency assessment with exceptions.
2. Written procedure for competency assessment.
3. Adherence to laboratory policies and procedures throughout the year.
4. “The laboratory director must ensure that the individuals performing competency assessments are qualified through education and experience to meet the defined regulatory requirements associated with the complexity of the testing.”
Changes Affecting Anatomic Pathology and Cytopathology

- Frozen section labeling
- Histology
- Equipment and instruments
- Predictive markers
- Mohs-only labs
- Autopsy
- Cytology screening and telecytology
- Formaldehyde & xylene safety
Intra-operative Labeling

ANP. 11800 Intra-operative labeling

Phase II

Each slide and container used to submit residual tissue for routine processing is labeled with two identifiers.

NOTE: Acceptable patient identifiers include name, date of birth, medical record, and accession number.
Histology

ANP. 21360 Automated stainers

There is a schedule to change the solutions in automated stainers.

NOTE: Solutions must be changed at intervals appropriate for the laboratory’s workload. Changing, filtering, or addition to solutions should be documented when performed.

Evidence of Compliance:

✓ Written procedure defining frequency of changing staining solutions AND
✓ QC records that document compliance with the procedure
The following special \textit{All histochemical} stains are \textbf{must be} of high quality and \textbf{they satisfactorily daily controls must} demonstrate on each day of use the tissue components or organisms for which they were designed.

(A long list of special stains followed in previous editions.)

\textbf{Evidence of Compliance:}

\checkmark Written procedure for special stain QC AND
\checkmark records of special stain QC
Validated tissue control blocks are required for each special stain.

NOTE: Positive tissue controls assess the performance of the special stain. Special stains are performed on sections of control tissue known to contain components specific to each special stain. Validation of tissue used as a positive control must be performed and documented before being used with clinical specimens.

Evidence of Compliance:
✓ Written results of special stain control tissue validation
Instruments and Equipment

- All instruments and equipment should be properly operated, maintained, serviced, and monitored
- Maintenance procedures and function checks must at least meet manufacturer’s specifications
- Examples:
  - Centrifuges
  - Microscopes
  - Incubators
  - Heat blocks
  - Biological safety cabinets
  - Fume hoods
ANP. 23045 Instrument/Equipment performance

**Phase II**

The performance of all instruments and equipment is verified before use.

**NOTE:** The function of all instruments and equipment is verified upon installation and before use to ensure that it will function as intended. Instrument and equipment function should be re-verified after scheduled preventive maintenance, after major instrument repairs, or if it is relocated. Instruments and equipment include tissue processors, microtomes, cryostats, automated stainers (H&E, histochemical, and IHC), coverslippers, cassette and slide label printers, and digital image scanners.

**Evidence of Compliance:**

- ✓ Written procedure for function verification AND
- ✓ Records of function verification checks
Equipment and Instruments

ANP. 23095 Non-certified thermometers Phase II

All non-certified thermometers in use are checked against an appropriate thermometric standard device before initial use.

**NOTE:** Thermometers should be present on all temperature-controlled instruments and equipment and be checked each day of use.

Evidence of Compliance:

- ✓ Written procedure defining criteria for verification validation of non-certified thermometers AND
- ✓ Records of verification validation prior to being placed in service
ANP. 23120 Tissue processing programs

Tissue processing schedules programs are validated.

NOTE: To validate new processing programs, laboratories should run tissue samples of the same size, thickness and fixation in duplicate. Reagents on the processor(s) should be comparable, eg, all fresh reagents. Process, embed, cut, and stain slides at the same time and evaluate the quality of the blocks, e.g. firmness, ease of cutting. The slides should be evaluated by the pathologist without knowledge of which processing program was used and graded on quality of section and staining. The new processing program must be of equal or better quality before being put into use.

This method may also be used to verify a routine processing program before putting a new processor into production.

Evidence of Compliance:

✓ Written procedure for validation of new tissue processing schedules programs AND

✓ QC records documenting validation
Specific tissue processing schedules are available for different types and sizes of specimens.

**NOTE:** To achieve acceptable results for diagnostic purposes, processing programs may be needed for different sizes and types of specimens. Biopsy specimens may be processed on a shorter schedule than larger specimens; large, dense or fatty specimens and brain specimens will not process adequately on a shorter schedule. A variety of processing schedules should be used to achieve good processing results.

Evidence of Compliance:

✓ Written procedure defining processing schedules for various types and sizes of specimen tissues
Predictive Markers

ANP. 22976 ER/PgR Validation Phase II

If the laboratory performs immunohistochemistry for estrogen receptor (ER) and/or progesterone receptor (PgR) as a prognostic/predictive marker on breast carcinoma, the laboratory has documented appropriate validation for the assay(s).

ANP.22978 HER2 Assay Validation Phase II

If the laboratory performs HER2 testing (HER2 protein over-expression by immunohistochemistry or HER2 gene amplification by in situ hybridization [eg, FISH, CISH*, SISH*, etc.]), the laboratory has documented appropriate validation for the assay(s).
Predictive Markers

ANP. 22976 ER/PgR Validation Phase II
If the laboratory performs immunohistochemistry for estrogen receptor (ER) and/or progesterone receptor (PgR) as a …

ANP.22978 HER2 Assay Validation Phase II
If the laboratory performs HER2 testing (HER2 protein over-expression by immunohistochemistry or HER2 gene amplification …

This requirement is applicable to both new and existing assays. If review of the initial validation does not meet the current standard, it must be supplemented and brought into compliance. It is possible to do this retroactively by review and documentation of past proficiency testing challenges or by sending unstained slides from recent cases to a reference laboratory for correlation. If no documentation exists from the initial validation, the assay must be fully revalidated and documented.

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Predictive Markers

ANP.22999 HER2 by IHC-Scoring

If the laboratory interprets HER2 protein over-expression by immunohistochemistry (IHC), results are reported using either the manufacturer's instructions or the ASCO/CAP scoring criteria.

NOTE: The If the ASCO/CAP scoring criteria are used, the report should include the ASCO/CAP reference below including with the version number (eg, year of publication).

REFERENCE:

Mohs-only Laboratories

ANP. 11605 Gross Examination - Non-Pathologist Phase II

When individuals other than a pathologist or pathology resident assist in gross examinations, the extent of their activities and the nature of supervision (direct vs. indirect) is defined in a documented protocol.

NOTE: This protocol must list the specific types of specimens for which non-pathologists are permitted to assist in the gross examination. The nature of the supervision must be established individually, for each non-pathologist. The laboratory director is responsible for this protocol. For Mohs surgery a dermatologist is also qualified to perform the gross examination and to supervise non-pathologists.
Mohs-only Laboratories

ANP. 11640 Performance Evaluation Phase II

The performance of non-pathologist(s) who assist in the performance of gross tissue examinations is evaluated by the pathologist at least annually.

NOTE: Please refer to GEN.55500, Competency Assessment, in the Laboratory General checklist for a list of criteria for competency assessment. Not all six elements may apply in all cases.

For Mohs surgery a dermatologist is also qualified to perform the gross examination and to supervise non-pathologists.

Evidence of Compliance:
✓ Written procedure and schedule for evaluating performance of non-pathologists AND
✓ Records of evaluation documented at defined frequency

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ANP. 12173 Mohs report

There is a written report generated for each Mohs surgical procedure.

NOTE: A written note, report, or diagram must be included in the patient's medical record or operative report. The report should include required elements such as gross description, accession number, designation of relationship of blocks to the slides, and clear diagnosis on each specimen.
Autopsy

ANP. 33025 Patient Identity Confirmation

The identity of deceased patients is confirmed prior to beginning the autopsy.

Evidence of Compliance:

√ Written policy defining procedure for verifying patient identity during preparation for the autopsy
CYP. 07480 Rescreening or Prescreening Negative Cases  Phase II

For laboratories not subject to US regulations, the competency of each screener of gynecologic cytopathology specimens is assessed by either a pre-screening or rescreening process.

(a long Note follows)

Evidence of Compliance:

- Written rescreening or prescreening policy defining the method to be used for rescreening or prescreening and the criteria for case selection
- Records of rescreened or prescreened cases with comparison to final comprehensive screening results
New Instructions to the Inspector for Cytopathology Workload Assessment

- Determine if the records include the number of slides screened and the amount of time spent screening, including slides screened at other laboratories
- Confirm that daily workload is counted and calculated correctly
- Identify if workload is within the established workload limits for each screener (not to exceed 100 slides/day)
- For cytotechnologists, confirm that gynecologic (including 10% rescreen and 5 year look-back cases) and non-gynecological slides are included
- Select a sampling of automated screening records and follow examples requiring a full manual review to evaluate the workload recording.
Telecytology

(from the GEN Checklist)

“This section applies to telepathology, including the practice of pathology and cytology, in which a pathologist views digitized or analog video or still image(s), and renders an interpretation that is included in a formal diagnostic report or documented in the patient record. It also includes the review of images by a cytotechnologist when a judgment of adequacy is documented in the patient record.”
Telepathology

GEN.52850 Result Documentation

There is a mechanism for documenting the result of intraprocedural results rendered remotely for real-time evaluation cases.

Evidence of Compliance:
√ Reports generated from reviews of images/slides performed by telepathology

GEN.52860 Quality Management Program

Telepathology services must be included in the laboratory's quality management plan.

NOTE: For example, the laboratory might monitor the frequency of deferral cases, comparison to on-site evaluation, or consultation using traditional glass slide microscopy.
Formaldehyde & Xylene safety

• ANP.08216 and CYP.09900

• Xylene vapor concentration monitoring in histology laboratories should include manual and automated coverslipping areas, as these locations are often not ventilated.

• Formaldehyde monitoring must be repeated any time there is a change in production, equipment, process, personnel, or control measures which may result in new or additional exposure to formaldehyde for any employee involved in the activity.
Top Three ANP Deficiencies

- COM.10100 [ANP.03776]  
  Review of all policies & procedures every two years

- COM.40200 [ANP.23075]  
  Monthly evaluation of instrument maintenance and function

- ANP.08216  
  Formaldehyde and xylene vapor control
Top Three CYP Deficiencies

• COM.10300 [CYP.02800]
  All personnel knowledgeable about the contents of the procedure manual

• COM.10100 [CYP.02500]
  Review of all policies & procedures every two years

• CYP.08500
  Workload policy and data recording
Questions to CAP Customer Service Center

- ANP.22976 — ER/PgR validation
- Cytopathology workload recording
- CYP.01650 — exclusion of specimens from cytology examination
Versions of the Checklists

• Custom Checklists
• Master Checklists
• Spreadsheet
• Change document
Thank you!

Questions?