2013 CONTINUING COMPLIANCE MASTER SERIES
Checklist Updates for Anatomic Pathology
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OBJECTIVES
After participating in this Audioconference you will be able to:

• 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.

CE (CONTINUING EDUCATION FOR NON-PHYSICIANS)
The CAP designates this educational activity for a maximum of 1 credit/hour of continuing education. Each participant should only claim those credits/hours he/she actually spent in the activity.

ASCP STATEMENT
The American Society for Clinical Pathology (ASCP) Board of Certification (BOC) Certification Maintenance Program (CMP) accepts this activity to meet the continuing education requirements.

CALIFORNIA AND FLORIDA STATEMENT
This activity is approved for continuing education credit in the states of California and Florida.
Objectives

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• 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
  - Check, Confirmation, Correlation
  - Equipment, Instrument
  - 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.
Phase Level Reassignment - Examples

ANP.11713 Histologic Prep Quality Phase One
There is documented evidence of daily review of the technical quality of histologic preparations by the pathologist.

CYP.03366 FNA Error Prevention 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
  - “confirmation through a defined process that a test performs as intended or claimed”
  - test methods

- Verification
  - “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”
  - reagents, instruments, and approved/cleared in vitro devices (IVDs)

Validation/Verification - Examples

ANP.23120 Tissue Processing Programs Phase II
Tissue processing programs are validated.

CYP.05257 Implementation/Verification Protocol Phase II
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/systems, methods, or instruments

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 Phase II

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

Histology

ANP. 21450 Special stain quality Phase II

The following special histochemical stains are must be of high quality and 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.)

Evidence of Compliance:
√ Written procedure for special stain QC AND
√ Records of special stain QC
Histology

ANP. 21460 Special stain controls  Phase II

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:
  o Centrifuges
  o Microscopes
  o Incubators
  o Heat blocks
  o Biological safety cabinets
  o Fume hoods

Equipment and Instruments

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 repair, or if it is relocated. Examples include tissue processors, microtomes, cryostats, automated staining stations (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 Phase II
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 should be comparable, e.g. 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.

Evidence of Compliance:
√ Written procedure for validation of new tissue processing schedules programs AND
√ QC records documenting validation

ANP. 23130 Tissue processing schedules Phase II
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 overexpression by immunohistochemistry or HER2 gene amplification by in situ hybridization [e.g., FISH, CISH*, SISH*, etc.]), the laboratory has documented appropriate validation for the assay(s).

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.

**ANP.22999 HER2 by IHC-Scoring Phase II**

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: If the ASCO/CAP scoring criteria are used, the report must include the ASCO/CAP reference below including the version number (e.g., 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.

Evidence of Compliance:

- Written procedure and schedule for evaluating performance of non-pathologists
- Records of evaluation documented at defined frequency

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
- Records of evaluation documented at defined frequency

Mohs-only Laboratories

ANP. 12173 Mohs report Phase I

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 Phase I

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

Cytopathology

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 AND
√ 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 Phase I

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 Phase I

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?