Checklist Updates
CLMA KnowledgeLab 2014

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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

- Explain selected changes to the LAP accreditation requirements (checklists) likely to affect your practice
- Identify the newest subjects addressed in the Checklists
- Recognize the most common deficiencies reported in 2013.
Topics that will be covered:

- changes that affect the whole lab
- changes in pre-analytics
- changes to test method management
- changes in post-analytics
- entirely new sections
- changes within selected specialties
Editorial timeline for 2014 Checklists

New edition drafted
July thru November

Changes vetted within CAP
December thru January

Final draft reviewed at CMS
February and March

Publication on April 21

The 2014 timeline is abbreviated.
The 2015 timeline is likely to be extended.
Activity menu

The laboratory's current CAP Activity Menu accurately reflects the testing performed.

Key points —

- all tests in use
- discontinued tests removed
- include methods and services
- call CAP to discuss tests or services not listed on the Master Activities Menu
Phase level

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 levels - 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 or designee.

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.

CHM.11800 Specimen Identity/Integrity  Phase Two

Procedures are adequate to verify the identity and integrity of samples, including capillary specimens, aliquots and dilutions.
The proficiency testing attestation statement is signed by the laboratory director or designee and the individual performing the testing.

**Key points —**

- Physical signatures must appear on the original paper attestation form.
- A listing of typed names on the attestation statement does not meet the intent of the requirement.
The laboratory has a document control system to manage policies, procedures, and forms.

Key points —

- “forms” has been moved to the stem of the requirement
- only the current policies, procedures, and forms are in use
- a control log is recommended
New director procedure approval

Following a change in laboratory directorship, the new laboratory director approves the laboratory policies and procedures over a reasonable period of time.

Key points —

- moved from COM to TLC
- all procedures must be reviewed
- format is at the discretion of the lab director
- itemization of the documents reviewed and approved and dates
- should be completed within 3 months of a change in directorship
Thermometers

Five requirements have been moved to the All Common Checklist:

- availability of an accurate device traceable to NIST standard
- all non-certified thermometers are checked against the standard
- all temperature-dependent equipment and environments checked and recorded each day of use
- acceptable ranges have been defined
- corrective action is evident when ranges have been exceeded
Instruments and Equipment

Seven requirements have been moved to the All Common Checklist:

- manufacturer's instructions followed for waived testing devices
- standard procedures for start-up, operation and shutdown
- maintenance and function checks are performed and documented
- tolerance limits are defined and corrective actions are documented
- instructions are provided for minor troubleshooting and repairs
- records are available to, and usable by, the technical staff
Instrument and equipment maintenance and function check records are reviewed and assessed at least monthly by the director or designee.

Key points —

- See TLC.11425 for “Delegation of Director Responsibilities”
- For slide preparation instruments, including those using liquid-based technology and cytocentrifuge or filtration methods, the requirement is met by the routine microscopic review for technical acceptability.
Comparability of instruments & methods

If the laboratory uses more than one non-waived instrument/method to test for a given analyte, the instruments/methods are checked against each other at least twice a year for comparability of results.

Key points —

- moved from specialty checklists to All Common
- only for non-waived instruments/methods accredited under a single CAP number
- quality control data may be used for comparison in some cases
- only applies when the instruments/reagents are producing the same reportable result.
Acceptability criteria are defined for comparability of instruments/methods used to test the same analyte, with documentation of corrective actions when the criteria are not met.

*Key point* —

- limits should be defined statistically for quantitative tests
Personnel files are maintained on all current technical personnel and personnel records include all of the following items.

**Key changes —**

- Laboratory personnel license, if required by state, province, or country
- Appropriate documentation of qualifications varies by laboratory locale
- Description of current duties and responsibilities as specified by the laboratory director:
  a) Procedures the individual is authorized to perform,
  b) Whether supervision is required for specimen processing, test performance or result reporting,
  c) Whether supervisory or section director review is required to report patient test result
Competency assessment

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

Key points —

- annual assessment for waived testing; at 6 mo and one year for non-waived testing (annually thereafter)
- all six elements for non-waived testing; may select the elements for waived testing
- assessment by section director or general supervisor for high complexity testing; assessment by technical consultant for moderate complexity testing
Performance assessment

GEN.55525

The performance of section directors/technical supervisors, general supervisors, and technical consultants is assessed and satisfactory.

Key points —

- Refers to role in management of patient testing
- Unsatisfactory performance must be addressed in a plan of corrective action
- GEN.55500 applies if the individual performs patient testing
The laboratory director ensures the professional competency of pathologists who provide interpretive services to the anatomic pathology laboratory.

**Key points** —

- written policy for assessing professional competency, criteria for the assessment, and records of the assessment

- documentation may consist of
  - participation in a peer educational program
  - metrics developed from diagnostic QM reports
  - quality management records
  - individual assessment according to defined criteria
Consultants

Technical consultants meet defined qualifications and fulfill expected responsibilities. Clinical consultants meet defined qualifications and fulfill expected responsibilities.

Key points —

- applies to labs performing moderately complex but not highly complex testing
- qualifications must be in accord with CLIA regulations
- responsibilities must be in accord with CLIA regulations
- must be available for consultation
Director responsibility for personnel

The laboratory director ensures sufficient **numbers of** personnel with **appropriate educational qualifications**, documented training and experience, **and adequate competency** to meet the needs of the laboratory.

**Key point —**

- Staffing should be considered insufficient only if there is clear evidence from quality monitoring records, data derived from complaints or concerns, turnaround time, and error statistics, etc.
Testing personnel qualifications

All testing personnel meet the following requirements:
  high complexity... associates degree...
  moderate complexity... high school diploma...

Key points —

- standardized across the Checklists wherever possible
- significant change for cytogenetics and molecular testing
Unacceptable specimens

There are documented criteria for the rejection of unacceptable specimens, instructions for the special handling of sub-optimal specimens, and documentation of disposition of all unacceptable specimens in the patient/client report and/or quality management records.

Key points —

- Applies to all types of testing
- Evidence of compliance
  - Records of rejected specimens AND
  - Instructions for special handling of sub-optimal specimens AND
  - Documentation of disposition of unacceptable specimens
Specimen collection training

There is documentation that all personnel collecting patient specimens have been trained in collection techniques and in the proper selection and use of equipment/supplies.

**Key points** —

- applies to all types of specimens and all collection modes
- applies to all personnel collecting samples under that laboratory's number (including those at remote sites)
- training must be documented in accord with any manufacturer's instructions
Phlebotomy adverse reactions

The laboratory has procedures to care for patients who experience adverse reactions from phlebotomy.

Key points —

- Emphasize injury prevention in training.
- Serious reactions must be recorded in an incident log (e.g., vomiting, nerve damage, seizures and head injuries)
Tissue/Cytology assessment

If a statement of adequacy, preliminary diagnosis, or recommendations for additional studies is provided at the time of tissue and cytology sample collection, documentation of that statement is maintained.

Key point —

- Documentation may be in the medical record, in the final report, or in a laboratory record
Quality control data are reviewed and assessed at least monthly by the laboratory director or designee.

Key points —

- new language in the Note: “The review of quality control data must be documented and include follow-up for outliers, trends, or omissions that were not previously addressed.”
- delegation of functions must be in writing (TLC.11425)
Method performance specifications from COM

- Validation/verification required for all non-waived tests regardless of date of implementation
  - validation: tests not FDA cleared/approved (LDTs)
  - verification: unmodified, FDA cleared/approved tests

- Retain records as long as the method is in use and for two years thereafter
There is a summary statement, signed by the laboratory director (or designee who meets CAP director qualifications) prior to use in patient testing, documenting evaluation of validation/verification studies and approval of each test for clinical use.

**Key points** —

- include an written assessment of the study, the acceptability of the data, and approval for patient testing
- include validation of any clinical claims
AMR verification

Verification of the analytical measurement range (AMR) is performed with matrix-appropriate materials which, at a minimum, include the low, mid and high range of the AMR, appropriate acceptance criteria are defined, and the process is documented at least every 6 months and following defined criteria.

**Expected —**

- after a change in reagent lots
- if QC is out of range and other corrective actions have failed to correct the problem
- after major preventive maintenance or change of a critical component
- when recommended by the manufacturer
IHC assay performance

Laboratories must confirm assay performance when conditions change that may have affected performance.

Key points —

- expected after antibody dilution, antibody vendor (same clone), or the incubation or retrieval times (same method) — **at least 2 positive and 2 negative examples**
- fixative type, antigen retrieval method (e.g. change in pH, different buffer, different heat platform), antigen detection system, tissue processing or testing equipment, environmental conditions of testing (e.g. laboratory relocation), or laboratory water supply — **“sufficient number”**
Body fluid validation

Testing of body fluid specimens using methods intended for other specimen types (e.g. blood or other fluid) has been validated by the laboratory for accuracy, precision, analytic sensitivity, analytic specificity, interferences, and reportable range.

**Key points —**

- applies to routine, orderable tests
- validation using blood specimens acceptable if the lab can reasonably exclude matrix effects
- reference ranges may be taken from the literature
- alternative performance assessment is required
Patient data accessibility

There is a documented protocol in place to ensure that patient data are accessible only to those healthcare personnel individuals who are authorized to review test results.

Key points —

- changed to comply with 42 CFR 493.1291(l)
- includes
  — authorized healthcare personnel
  — the patient
  — the patient's personal representative
Amended reports

Amendments to reports that would significantly affect patient care are reported promptly to the responsible clinician(s).

Key points —

- records should include date, time, and person notified
- evaluation of amended reports records should be part of the quality management program
Returning surgical material to patients

Infectious tissues and other potentially contaminated materials are disposed of with minimum danger to professional, technical, and custodial personnel, and to recipients.

Note —

“Specimens returned to patients (e.g. prostheses, gallstones) or otherwise released to others (e.g. pacemaker or prosthesis to manufacturer) must be disinfected before release.”
HER2

- revised according to 2014 ASCO/CAP criteria
- validation requires
  — 20 positive x 20 negative for FDA cleared approved tests
  — 40 positive x 40 negative for LDTs
- fixation time may be up to 72 hours
- scoring either according manufacturer's instructions or ASCO/CAP criteria
- early-stage tumor, recurrent tumor, and metastatic disease must be tested
Circulating tumor cell analysis

- calibration, recalibration
- quality control
- sample acceptance/rejection criteria
- guidelines for morphologic assessment
- reporting requirements
- qualifications, training, competency of testing personnel
- qualifications of supervision
Whole slide imaging

The laboratory validates whole slide imaging systems used for clinical diagnostic purposes by performing its own validation studies ... before the technology is used for the intended diagnostic purpose.

There is documentation showing that all users of the whole slide imaging system have been trained.

**Key points**—

- validation by a trained pathologist using “real world” components
- user training must include pathologists
Molecular internal controls

For FDA-cleared/approved test systems not modified by the laboratory that involve a closed system incorporating all steps ... batch-specific controls may be limited to the electronic/procedural/built-in internal controls only for tests meeting all of the following criteria:

1. The laboratory has performed validation studies (on at least 20 samples representing the expected heterogeneity of testing results) to validate the adequacy of limiting daily QC to the electronic/procedural/built-in controls.

2. External surrogate sample controls are run for each new lot number and/or shipment of test materials; after major system maintenance; and after software upgrades.

3. External surrogate sample controls are run as frequently as recommended by the test manufacturer, or every 30 days, whichever is more frequent.
Sanger sequencing and pyrosequencing

- validation of sequencing lower limit of detection
- adequacy of information regarding sequence variants (both pathogenic and benign)
- sequencing assay signal optimization
- use of professional guidelines for interpretation (e.g., ACMG guidelines or COSMIC database)
NGS – wet bench testing

- wet bench process validation
- quality management of wet bench testing
- confirmatory testing of detected variants
- test referral policy
NGS – bioinformatics pipeline

- standard operating procedure, QC to assess run performance
- validation of the pipeline; confirmation or revalidation after changes to the software
- quality management program
- documentation of patches and upgrades
- data storage requirements
NGS – bioinformatics pipeline

- version traceability for every report
- exception log
- patient confidentiality and security
- interpretation and reporting of sequence variants
- policy for reporting of incidental findings unrelated to the clinical purpose of testing
D-dimer studies

- report in the units generated by the method
- use to exclude venous thromboembolism (VTE) only if the method is valid for that purpose — report the cutoff value as well as the reference range
- issue disclaimer if the method is insufficiently sensitive to exclude VTE
Flow cytometry antibodies and reagents

The laboratory has documented the initial validation of new antibodies, prior to use in patient diagnosis.

The performance of new lots/shipments of antibody and detection system reagents is compared with old lots/shipment before or concurrently with being placed into service.

**Key points** —

- validate on the cell sub-population of interest in the context of the antibody combination used in an assay
- compare each individual antibody by using a side scatter vs. fluorescence plot (recommendation)
Histocompatibility testing

If the histocompatibility laboratory participates as a member of the United Network for Organ Sharing (UNOS), there is a policy to notify the CAP's Laboratory Accreditation Program when there is a change in section director/technical supervisor.

Key points —
- required under the deemed status agreement between CAP and UNOS
- must occur no later than 30 days prior to the change; or in the case of an unexpected change, no later than 2 working days afterwards
The laboratory incorporates taxonomic changes that potentially affect the choice of appropriate antimicrobials to report and/or the interpretative breakpoints to use.

Key points —

- Changes to the naming of microorganisms may affect the choice of antimicrobials or breakpoints
- Incorporate clinically relevant changes even when commercial systems have not been updated
If the laboratory chooses to pool specimens for tests performed using test systems that have not been FDA-cleared/approved for that purpose ... the testing procedure for pooled samples must be validated, including limit of detection (sensitivity), reproducibility, and accuracy (method comparison).

**Key point —**

- validation protocol must compare pooled vs non-pooled samples and include both weakly positive and strongly positive samples
Provider-performed testing (PPT)

- written policy for including training requirements, sample collection, the use of personal protective equipment, reporting policies, competency assessment, and quality management

- written procedure for each test

- quality management (including PT)

- training prior to performing testing (medical staff credentialing is not acceptable)
PPT competency assessment

There is a documented program to ensure that all providers performing non-waived PPT maintain satisfactory levels of competence.

Key points —

- non-waived testing requirement parallels GEN.55500
- competency may be assessed by an individual meeting the qualifications of a Technical Consultant
- director may determine competency assessment for waived testing
Fire safety

Policies and procedures are documented and adequate for fire prevention and control.

Fire safety training is performed for new employees, with a fire safety review conducted at least annually.

**Key points —**

- Fire safety plans must include the use of alarms, response to alarms, isolation of the fire, evacuation of the area, extinguishment of the fire, and the responsibilities of laboratory personnel for those elements.
- While fire exit drills are not required, yearly evaluation of the escape routes should be documented.
Top Ten Deficiencies

- GEN.55500 – competency records 22.3%
- GEN.20375 – document control 13.5%
- GEN.54400 – personnel files 9.2%
- GEN.75400 – annual fire drills 8.8%
- GEN.77400 – emergency eye wash 7.3%
- CHM.13600 – AMR verification 7.1%
- ANP.23075 – instrument maintenance 6.7%
- CHM.13800 – correlation of instruments 6.5%
- ANP.23410 – cryostat decontamination 6.2%
- TRM.31450 – instruments & equipment 6.0%
Top Ten Expungements

1. COM.01000 – adequate PT procedures
2. COM.40300 – analytic accuracy/precision
3. GEN.23584 – interim self-inspection
4. GEN.16902 – QM implementation
5. COM.01300 – PT participation
6. COM.01500 – alternative performance assessment
7. COM.30100 – critical result readback
8. COM.10100 – biennial procedure manual review
9. COM.10300 – knowledge of procedures
10. COM.10200 – new procedure review

(>100 citations/year; >20% expunged)
Thank you!

Questions?