

# Be Inspection Ready with the 2018 CAP Accreditation Checklists

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# Learning objectives

## After this webinar, you will be able to:

- Describe key changes to the 2018 CAP Accreditation Checklist edition
- Interpret the rationale for the changes made to the checklist
- Use CAP resources to identify and understand key changes
- Recognize and implement necessary changes to ensure compliance with new accreditation requirements

# Faculty Disclosures

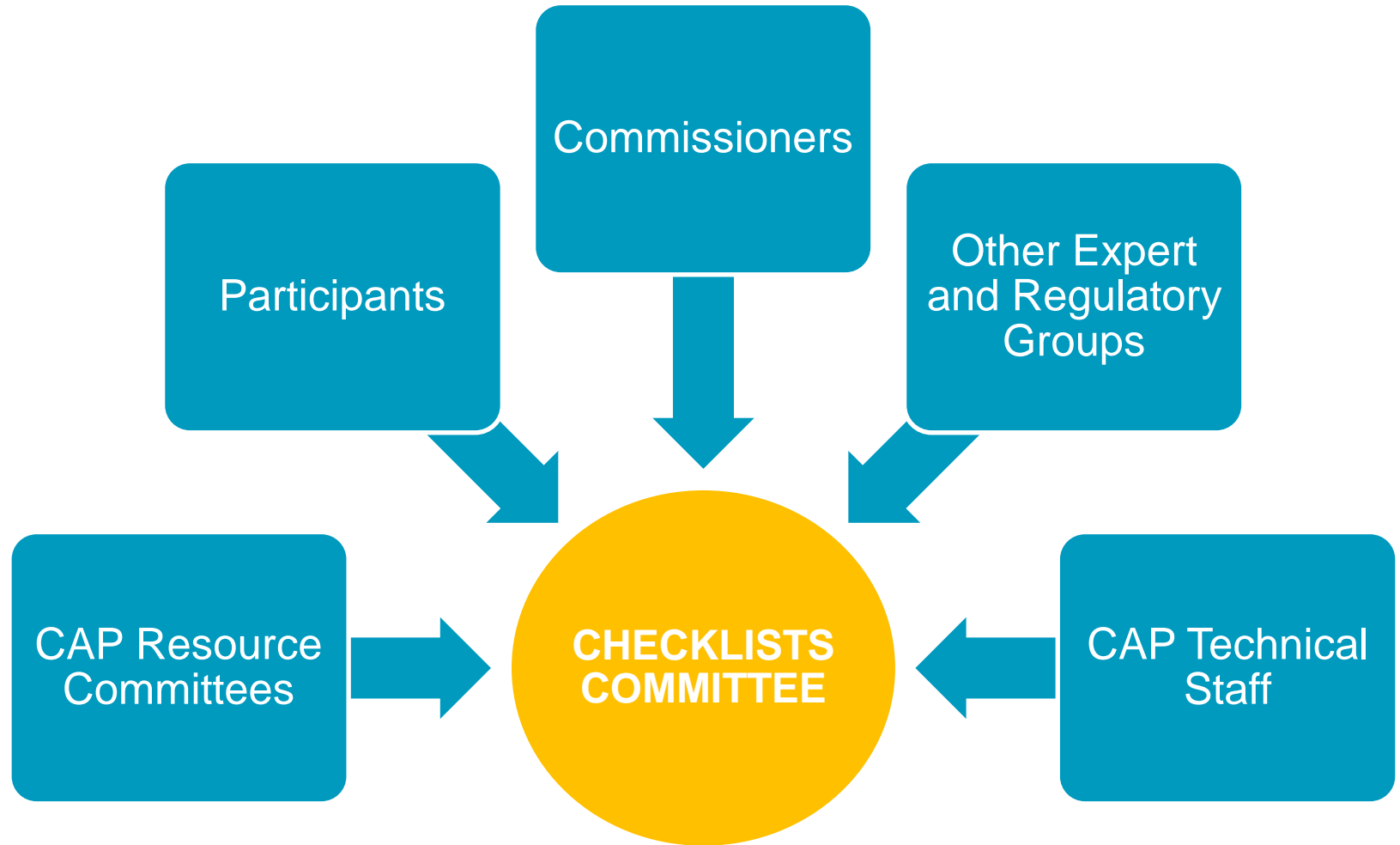
William W. West, MD, FCAP – No financial interests/relationships to disclose

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# What are the checklists?

- Listing of the requirements for the CAP's accreditation programs
- 21 different checklists focusing on different laboratory disciplines and services
- Tools used by inspectors to perform an onsite inspection
- Laboratory preparation- living blueprints to ensure quality and patient safety
  - Undergo review by the Centers for Medicare and Medicaid Services prior to publication

# Checklist Content



# Summary of Changes in 2018

Checklist	Requirements	New	Significant Changes	Deleted	Moved/Merged
ANP	200	15	35	0	3
BAP	171	1	5	0	0
CBG	83	0	3	0	0
CHM	165	13	5	0	0
COM	75	0	11	0	6
CYG	57	1	7	0	1
CYP	82	0	10	0	1
DRA	18	0	1	0	0
FDT	125	0	16	0	0
FLO	49	2	5	0	1
GEN	331	3	30	0	0
HEM	193	0	8	0	34
HSC	158	1	6	0	0
IMM	65	0	7	0	0
LSV	280	2	17	0	25
MIC	253	0	17	0	2
MOL	164	1	6	0	1
POC	56	0	2	0	0
RLM	116	1	20	0	2
TRM	257	1	30	0	1
URN	29	0	0	0	0
<b>TOTAL</b>	<b>2927</b>	<b>41</b>	<b>241</b>	<b>0</b>	<b>77</b>

# Major Topics for the 2018 Update

- Laboratory General Checklist
  - Document Control/Data Preservation
  - Restricted Laboratory Access
  - Remote LIS
  - Personnel
  - Safety
- All Common Checklist
  - Activity Menu
  - Critical Result Reporting
  - New Reagent Lots and Shipments
  - LDT and Class I ASR Reporting
  - Individualized Quality Control Plans
- Director Assessment Checklist
- Discipline Specific Checklist Changes

# Laboratory General Checklist Changes





# Document Control

- GEN.20375 Document Control

*The laboratory has a document control system to manage policies, procedures, and forms that are subject to CAP accreditation...*

- Clarified that discontinued documents must be archived and removed from general access
- Added that document master files be
  - Stored in a manner to prevent loss, damage or unauthorized access
  - Backed up to allow access in case of power or network system outages



# Data Preservation

- GEN.43946 Data Preservation/Destructive Event

*There are written procedures for the preservation of data and equipment in case of an unexpected destructive event (eg, fire, flood, malicious incident), software failure and/or hardware failure...*

- Added “malicious incident” as an example of an unexpected destructive event



# Restricted Laboratory Access

- GEN.59980 Restricted Laboratory Access

*The laboratory has a written policy for restricting access to the laboratory to authorized individuals...*

- **\*NEW\*** requirement
- Requires a written policy for restricting access to the laboratory to authorized individuals
- Must define:
  - How restricted access is maintained
  - Who is authorized
  - How temporary authorization is obtained



# Restricted Laboratory Access (cont.)

- Questions received about GEN.59980:
  1. My hospital has a policy on restricted access, does our laboratory need its own?
  2. Our laboratory is a small reference laboratory and our entry door requires a key to enter. Are we in compliance?
  3. My laboratory is in a hospital and currently anyone can walk through the laboratory unrestricted. What can we do?

# Restricted Laboratory Access (cont.)

- Answers:

1. Laboratory policy versus hospital policy

*A separate laboratory policy is needed unless the hospital policy covers laboratory-specific concerns.*

2. Small reference laboratory with key access

*A locked door is a start; however, a written policy is still needed to define other aspects, such as visitors and vendors.*

3. Completely unrestricted access

*Take action now!*

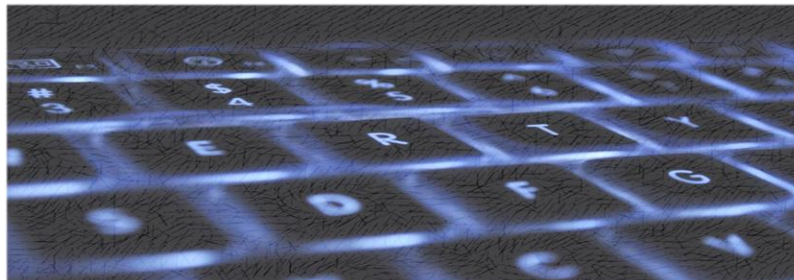
- *Carefully evaluate laboratory set up and practices*
- *Identify issues relating to patient privacy, safety hazards, infection control, and special issues (eg, blood irradiator, chain-of-custody specimen handling) to develop a written policy*
- *Involve administration if needed to address problems with unrestricted laboratory access*

# Remote LIS

- GEN.42195 Remote LIS

*If components of the LIS are located at a facility other than the one under this CAP accreditation number, there is evidence that the remote facility complies with CAP requirements for host LIS functions.*

- NOTE modified to require laboratories and host LIS sites to have records of compliance with site-specific LIS requirements
- Records may include studies/activities performed by laboratory and/or by the host LIS site on behalf of the laboratory

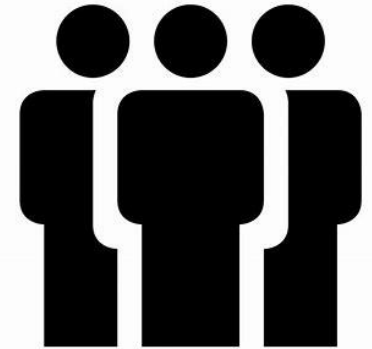


# Remote LIS (cont.)

- Site-specific LIS requirements:
  - GEN.43055 Computer System Training
  - GEN.43066 Computer Malfunction Training
  - GEN.43150 User Authentication
  - GEN.43450 Calculated Patient Data Verification
  - GEN.43837 Downtime Result Reporting
  - GEN.43875 Autoverification Validation
  - GEN.43993 Autoverification Suspension
  - GEN.48500 Interface Result Integrity

# Personnel – Laboratories Subject to US Regulations

- Modified the checklist NOTE in multiple requirements
  - GEN.53400 Section Director (Technical Supervisor)
  - GEN.53600 General Supervisor Qualifications
  - GEN.53625 Technical Consultant Qualifications
  - GEN.53650 Clinical Consultant Qualifications
  - GEN.54400 Personnel Records
- Clarified the types of records to show equivalency of qualifications for training obtained outside of the US





# Personnel – Laboratories Subject to US Regulations (Cont'd)

- Accepted documents for equivalency include:
  - Equivalency evaluation performed by a nationally recognized organization, such as the National Association Credential Evaluation Services, Inc. (NACES) and the Association of International Credential Evaluators, Inc. (AICE)
  - \*License to practice medicine issued by state where laboratory is located
  - \*Laboratory personnel license in states where required
  - \*Department of Defense laboratories - use process approved by the Center for Laboratory Medicine Services

**\*NEW**

# Safety - Formaldehyde and Xylene

- GEN.76820 Formaldehyde and Xylene Safety
  - **\*NEW\*** requirement created from existing requirements in other checklists
  - Checklist requirements from other checklists were **removed**:
    - Anatomic Pathology - ANP.08216
    - Cytopathology - CYP.09900
    - Microbiology - MIC.53050

# Safety - Liquid Nitrogen (LN2) and Dry Ice

- GEN.77500 Liquid Nitrogen and Dry Ice

*Adequate policies, procedures, and practices are in place for the use of liquid nitrogen (LN2) and dry ice...*

– Revised to include

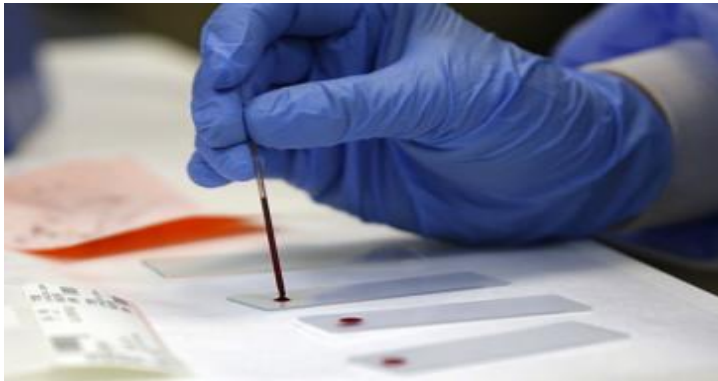
- Dry ice handling and appropriate PPE usage
- Use of LN2 and dry ice only in well-ventilated areas
- Training of the safe handling of LN2 and dry ice
- Display of signage where LN2 is used and/or stored



# Safety - Liquid Nitrogen (LN2)

- GEN.77550 Liquid Nitrogen Environmental Monitoring
  - **\*NEW\*** requirement
  - In areas where LN2 is used, laboratories must
    - Use oxygen sensors with a low oxygen alarm
    - Place alarms at breathing height in areas close to where LN2 is used or where a leak would occur
    - Have sufficient airflow to prevent asphyxiation

# All Common Checklist Changes



# Activity Menu

- COM.01200 Activity Menu

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

- Clarified NOTE for reporting to the CAP

- Laboratories subject to CLIA - report all tests and activities performed under its CLIA number to the CAP, even if that test is also accredited by another organization
- Laboratories not subject to CLIA – report all tests and activities meeting all of the following criteria:
  1. Performed under the same laboratory director;
  2. Under the same laboratory name; and
  3. At the same physical premises (contiguous campus)

# Activity Menu Questions

- Questions receive on COM.01200:
  1. Do I need to report testing inspected by my hospital's accreditor under a separate CLIA certificate on our CAP activity menu?
  2. Where can I find my lab's activity menu?

# Activity Menu Questions

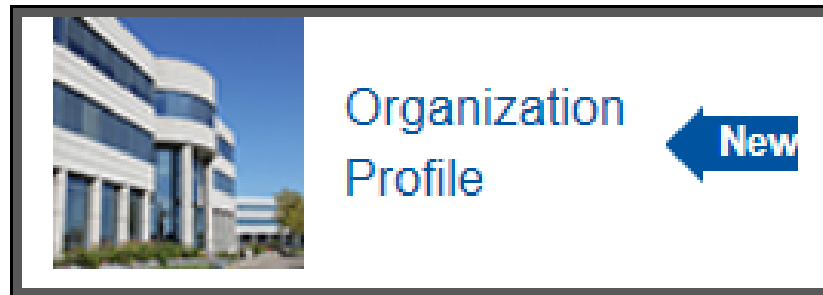
- Answers:

1. Reporting activities from a separate CLIA number

*No, do **not** report testing performed under a separate CLIA certificate under your laboratory's CLIA number.*

2. Location of laboratory's CAP activity menu

*Visit Organization Profile on cap.org in e-LAB Solutions Suite to view sections/departments and activities. Submit changes online.*





# Critical Result Reporting

- COM.30000 Critical Result Notification

*The laboratory has written procedures for immediate notification of “critical” results...*

- Revised NOTE to state that:

- an appropriate notification includes a direct dialog with the responsible individual OR
- electronic communication with confirmation of receipt by responsible individual

- Added a bulleted list of the notification records that must be retained

# Critical Result Reporting Scenario

A laboratory reports critical results via its secure internal email system. An administrative assistant confirms the next day that all of the previous day's critical result emails have been read.



# Critical Result Reporting Scenario (cont.)

Is the laboratory in compliance with COM.30000?

- A. Yes, sounds great to me!
- B. No, confirmation of receipt needs to be done on a more timely basis.
- C. No, email is not an acceptable form of communication.

# Critical Result Reporting Scenario (cont.)

Is the laboratory in compliance with COM.30000?

- A. Yes, sounds great to me!
- B. No, confirmation of receipt needs to be done on a more timely basis. ✓
- C. No, email is not an acceptable form of communication.

*B. Confirmation the next day does not meet the intent. It does not ensure “immediate” notification.*

# New Reagent Lots and Shipments

- COM.30450 New Reagent Lot Confirmation of Acceptability
  - Added #5 to the listing of suitable reference materials to check new lots and shipments of qualitative reagents

*Examples of suitable reference materials for qualitative tests include:*

1. *Positive and negative patient samples tested on a previous lot;*
2. *Previously tested proficiency testing materials;*
3. *External QC materials tested on the previous lot;*
4. *Control strains of organisms or previously identified organisms for microbiology reagents used to detect or evaluate cultured microorganisms;*
5. ***If none of the above options is available, control material provided by the assay***

# LDT/ASR Reporting

- COM.40850 (LDT and Class I ASR Reporting)

*Reports for laboratory-developed tests (LDTs), including those performed using class I analyte-specific reagents (ASRs), contain the following:*

- *A statement that the assay was developed by the laboratory AND*
- *A brief description of the method and performance characteristics needed for clinical use, unless the information is readily available to the clinician in an equivalent format (eg, test catalog).*
  - Renumbered from COM.40630
  - Combined existing COM laboratory-developed tests (LDT) and discipline-specific analyte-specific reagent (ASR) reporting requirements
  - Removed ASR requirements from Cytogenetics, Anatomic Pathology, Flow Cytometry, Microbiology, and Molecular Pathology Checklists

# LDT/ASR Reporting (cont.)

- Questions received on COM.40850:



- How much detail do I need to include for the description of the method?
- Our doctors don't want the detailed information on the method and the performance characteristics on the patient report and we have limitations on characters in our test catalog. What can we do?

# LDT/ASR Reporting (cont.)

## Answers:

1. Amount of detail for method description

*The description of the method is intended to be brief. It may be part of the test name.*

2. Alternative mechanisms for communicating test method and performance characteristics

*The test report and test catalog are two examples. Other formats appropriate to the laboratory setting may also be used, such as:*

- *Summary documents available on demand*
- *Information provided in other areas of the electronic health record.*



# Individualized Quality Control Plan (IQCP)

- COM.50300 Risk Assessment

***The IQCP for a test/device/instrument includes a risk assessment to evaluate potential sources of error...***

- Revised the NOTE to clarify how the laboratory's QC study should be conducted:
  - Must include laboratory data
  - Consecutive days of data collection not required if testing done sporadically or lab does not perform testing 7 days a week
  - Refer to MIC.21910 for microbiology susceptibility testing guidelines

# Director Assessment Checklist



# Director Assessment Checklist

- Director Assessment Checklist name was changed from the Team Leader Assessment of Director & Quality Checklist (TLC) in the 2017 edition
- TLC acronym in the requirement identifier has been changed to DRA in the 2018 edition

*Example TLC.10430 changed to DRA.10430*

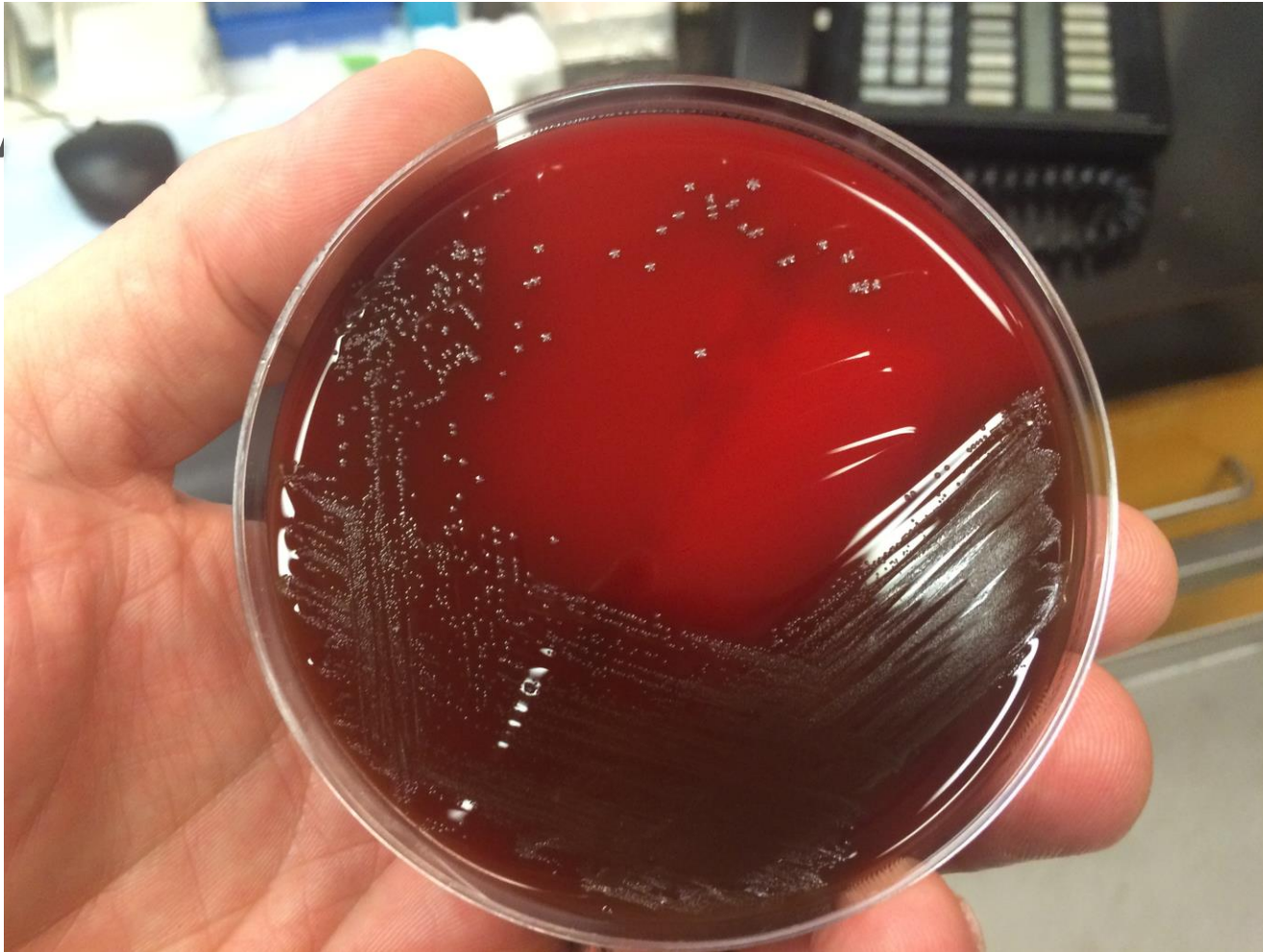
# Laboratory Director Qualifications

- DRA.10100 (Laboratory Director Qualifications)

***The laboratory director satisfies the personnel requirements of the College of American Pathologists.***

- Removed more stringent laboratory director qualifications for laboratories with test volumes exceeding 500,000 tests per year
- Impacts high volume laboratories performing:
  - Moderate complexity testing (eg, blood gas testing, core lab)
  - Provider Performed Microscopy (PPM)
  - Waived testing laboratories

# Discipline-Specific Checklist Changes



# Analytical Balances

- Revised balance requirements in multiple checklists - **Chemistry, Immunology, Clinical Biochemical Genetics, Forensic Drug Testing, Histocompatibility**
- Analytical balance maintenance (eg, CHM.25300)
  - Removed provision that the annual cleaning, servicing, and checking of balances needed to be done via a service contract
  - Can be done by in-house trained personnel
- Analytical balance accuracy (eg, CHM.25500)
  - Non US laboratories may use equivalent certified weights if ANSI/ASTM not available



# Predictive Markers

- Cytogenetics, Molecular Pathology, and Anatomic Pathology Checklist changes
  - **New** definition of the term predictive marker

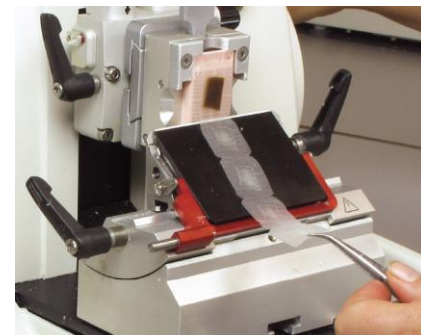
*The term predictive marker used within this section refers to immunohistochemical and in situ hybridization (ISH) tests used to predict responsiveness to a specific treatment independent of other histopathologic findings. Rather than confirming a specific diagnosis, these tests should differentiate predicted responsiveness to a targeted therapy among cases of the same diagnosis.*
  - Updated requirements CYG.49465, MOL.39393, ANP.23002 (HER ISH scoring)
    - Removed scoring criteria table from the checklist
    - Added language referring to the recently updated scoring criteria in the 2018 [ASCO/CAP HER2 guidelines](#)

# Anatomic Pathology

## ANP.21397 Cross-Contamination Histology

*There is a written procedure to prevent cross-contamination of specimens in the histology laboratory.*

- **\*NEW\* requirement** - Procedures must address steps to prevent cross-contamination during the various phases of tissue handling (processing, embedding, microtomy, and slide prep)



## Autopsy Pathology

- General Autopsy – added 6 **NEW** requirements and significantly revised 8 requirements
- Forensic Autopsy – added 9 **NEW** requirements
  - Intended for inspection of forensic autopsy services performed in a hospital setting



# Cytopathology

- CYP.08500 (Manual Screening – Laboratories Subject to US Regulations)

*There is a written workload policy for the manual screening of cytology slides, with evidence of data recording.*

- **Revised** to add the following note for CMS compliance with workload recording:

*\*For all screening personnel, adequacy assessment of fine needle aspiration (FNA) smears or rapid on-site evaluation (ROSE) is not considered primary cytology screening; however, the time spent performing adequacy assessments must be used to prorate the maximum number of slides the individual can screen in a 24-hour period.*

\* Based on Centers for Medicare and Medicaid Services [Memorandum QSO18-14-CLIA](#) released March 16, 2018.



# Chemistry and Toxicology

- **\*NEW\*** section on Imaging Mass Spectrometry
- 13 **NEW** requirements on mass spectrometry and data analysis
  - Imaging MS is an emerging technology used to provide molecular information on tissue specimens through visualization of the spatial distribution of proteins, lipids, and other molecules by their molecular masses.
  - Combines the methods of whole slide imaging, matrix-assisted laser desorption ionization mass spectrometry, and a data analysis process.

# Hematology and Coagulation

- Reorganized the checklist to completely split out Hematology from Coagulation
  - Improved the organization and efficiency of the tool
- HEM.37165 (formerly HEM.23575) Coagulation Testing and Anticoagulant Recommendations
  - Expanded requirement to have laboratories provide information to clinicians on potential interferences of anticoagulant medications on coagulation testing
  - Updated the NOTE based on current anticoagulant medications in use

# Microbiology

- MIC.21820 Susceptibility Testing-Pure Cultures  
*Antimicrobial susceptibility testing of isolates must be performed using pure isolates or colonies...*
  - Added NOTE that purity check must be performed at the same time the inoculum is used for susceptibility testing.
    - Non-selective media, such as blood agar, must be used to check purity.
    - **Does not** apply to FDA-cleared/approved systems that allow testing on mixed samples

# Transfusion Medicine

- TRM.32250 Record Retention
  - Expanded retention information to provide more detail and align with the FDA
- TRM.40665 Computer Crossmatches
  - Added **\*NEW\*** requirement to have written procedures for computer crossmatch methods based on validation decision rules



# How to Keep Up-to-Date

- Now that I know about the changes, where do I go from here?



# How to Keep Up-to-Date

- Educational webinars
- CAP Today - view or subscribe on [cap.org](http://cap.org)-  
Publications
- e-Alerts
- On-line inspector training
- CAP website FAQs

# Versions of Checklists

CAP-accredited laboratories can download different versions of the checklists

- ***Custom Checklists*** for your laboratory
- ***Master Checklists*** (includes references and instructions to inspectors)
- ***Spreadsheet*** format
- ***Change document*** to see all additions and deletions



# Checklist Download - e-Lab Solutions

**Download Checklist and Save File**

\* **Section/Dept:**  
List All Modules

\* **Checklist Module:**  
Select Checklist Module

**Checklist Edition:**

Type	Date
<input checked="" type="radio"/> CAP Current	08/17/2016
<input type="radio"/> Onsite Inspection	08/17/2016
<input type="radio"/> Self-Inspection	07/28/2015

**Checklist Type:**  
Changes Only

**Checklist Format:**  
PDF

**DOWNLOAD CHECKLIST**

\*Log-in required

## Checklist Type Options:

- Master
- Custom
- Changes Only

## Checklist Format Options:

- PDF
- Word/XML
- Excel

# Top 10 Deficiencies

CHECKLIST REQUIREMENT	CAP-WIDE*
<b>GEN.55500</b> Competency Assessment	1
<b>COM.01200</b> Activity Menu	2
<b>COM.10000</b> Procedure Manual	3
<b>COM.04250</b> Comparability of Instruments and Methods – Nonwaived Testing	4
<b>COM.30600</b> Maintenance/Function Checks	5
<b>COM.01400</b> PT Attestation Statement	6
<b>COM.01700</b> PT and Alternative Assessment Result Evaluation	7
<b>COM.30300</b> Reagent Labeling	8
<b>COM.10100</b> Procedure Manual Review	9
<b>COM.30750</b> Temperature Checks	10

\* Based on 2017 CAP inspection data

# Summary

- Summarized significant checklist changes in Laboratory General, All Common, and Director Assessment checklists
- Provided a brief overview of changes to discipline specific checklists
- Discussed some common compliance scenarios, questions, and deficiencies on the updated requirements
- Reviewed utilization of CAP resources and an approach on how to stay up-to-date with the 2018 edition

# Resources

Checklist interpretation questions?

- Email: [accred@cap.org](mailto:accred@cap.org)
- Phone: 1-800-323-4040, option 1

# Questions?

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