2019 Focus on Compliance

2019 CAP ACCREDITATION CHECKLIST UPDATES: CHANGES THAT MATTER

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Learning Objectives

2019 CAP CHECKLIST REVIEW

- Describe key changes and the rationale for the changes in the 2019 version of the CAP Accreditation Program requirements
- Learn more about and leverage CAP resources to identify changes
- Implement any necessary changes to help ensure compliance with new accreditation requirements

What are the Checklists?

CAP accreditation program requirements

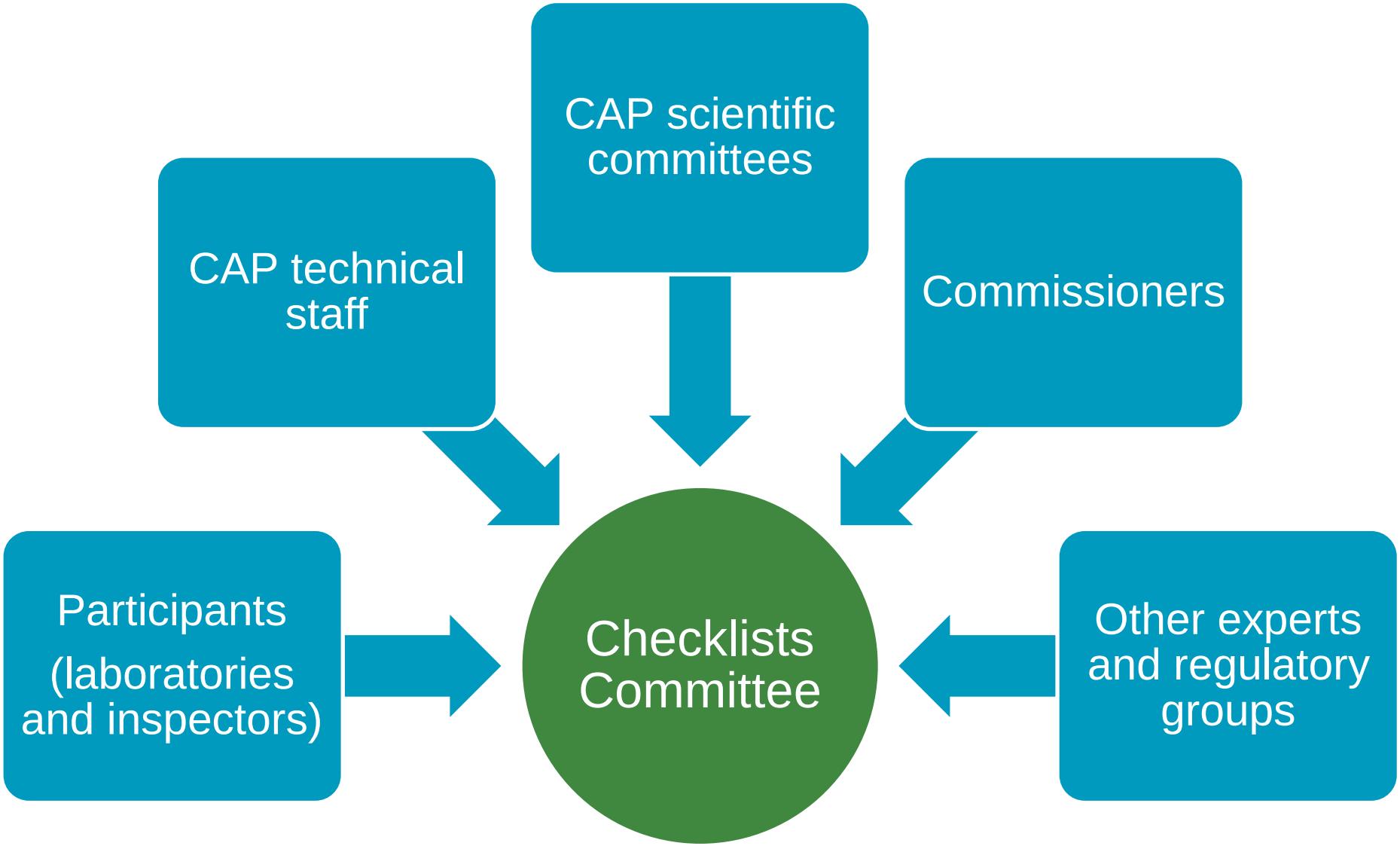
Laboratory inspection preparation tools

Blueprints for quality and patient safety

On-site inspector tools

CMS-approved documents

Where do checklist changes come from?



Summary of Changes in 2019

Checklist	Requirements	New	Significant Changes	Deleted	Moved/Merged
ANP	187	0	24	3	10
BAP	181	39	6	0	28
CBG	73	1	5	0	11
CHM	159	5	26	0	12
COM	80	9	12	0	5
CYG	69	15	8	0	3
CYP	81	0	10	0	1
DRA	20	2	1	0	0
FDT	117	0	0	0	8
FLO	49	1	4	0	1
GEN	242	7	17	0	108
HEM	183	2	15	1	11
HSC	148	0	27	2	11
IMM	64	8	7	0	9
LSV	276	15	33	1	20
MIC	256	4	25	0	1
MOL	170	15	39	0	9
POC	61	5	8	0	0
RLM	116	0	7	0	0
TRM	257	2	18	0	2
URN	27	0	4	0	2
TOTAL	**2816**	**130**	**296**	**7**	**252**

Topics for 2019 Checklist Update

- **Quality management (QM)**
- **Safety**
- **Personnel**
- **Proficiency testing (PT)**
- **Instruments and equipment**
- **Test method validation/verification**

Topics for 2019 Checklist Update, cont'd

- **QC/Calibration and related processes**
- **Discipline-specific checklist changes**
- **CAP resources to identify changes**

Toolkit

The following materials are available in the toolkit:

- Summary of discipline-specific checklist changes
- CAP Accreditation Program website tools
- Instructions for downloading checklists (including “Changes Only” version)
- Example forms from Accreditation Resources on cap.org
  - Analytical validation template
  - Analytical verification template

*** These documents can be accessed on this webinar’s material page: https://app.box.com/s/63c3pc9rlg9s5gph0gacebvus6twpfu2**

Quality Management (QM)

GEN.13806 QM Program

- **Revised the note to clarify elements that must be included in the written QM program.**
  - **Your processes must:**
    - **Ensure quality throughout the preanalytic, analytic, and postanalytic phases of testing.**
    - **Detect problems in the laboratory's systems and identify opportunities for system improvement.**
    - **Include plans of corrective action based on the data from its QM system.**

COM.04000 QM Program

- **Differentiated COM.04000 from GEN.13806**
- **Refocused on implementation of QM in each section (department) of the laboratory:**
  - **Addresses all phases of testing**
  - **Includes key indicators of quality, including areas of high patient impact and/or at high risk for error**

What Does This Mean for My Laboratory?

- **Do I need a separate QM plan for each section of the laboratory?**
- **Do I need separate quality indicators for each section of the laboratory?**

GEN.20310 Investigation of Nonconforming Events

- **NEW phase II requirement**
- **QM program must include the following provisions:**
  - **Root cause analysis (RCA) – for nonconforming events that result in death, permanent harm, or severe temporary harm (eg, sentinel event)**
  - **Process to define the scope and extent of investigation required – for other nonconformances that represent a risk to patients, donor, employees, or the health and safety of the general public, but are not sentinel events (eg, near misses)**

Definitions: Sentinel Events and Nonconforming Events

Definition of Terms:

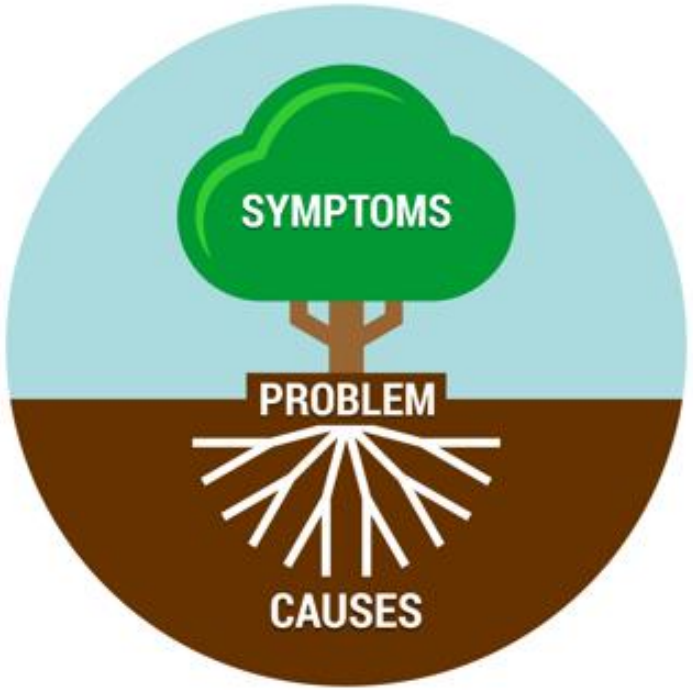
- **Sentinel event – An unexpected occurrence that reaches a patient and results in death, permanent harm, or severe temporary harm, unrelated to the natural cause of the patient's illness or underlying condition.**

- **Nonconforming event – An occurrence that: 1) deviates from the laboratory's policies or procedures; 2) does not comply with applicable regulatory or accreditation requirements; or 3) has the potential to affect (or has affected) patients, donor, the general public, or personnel safety.**

What is Root Cause Analysis (RCA)?

- **Definition of Terms:**
  - **Root cause analysis: A systematic process for identifying the causal factor(s) that underlie errors or potential errors in care.**

- **In more general terms:**
  - **Looking deeply into problems to find out why they are happening.**
  - **Uncovering causes that are not obvious.**



Root Cause Analysis is Not…

- **Blaming individuals**
- **Telling people to "pay closer attention"**
- **Requiring people to be retrained**

What Does This Mean for My Laboratory?

- **Do we need to do an RCA whenever we identify an error or problem?**

Tools for Root Cause Analysis

CAP Root Cause Analysis Toolkit

- **Available on cap.org in e-LAB Solutions Suite under Checklist Resources – Quality Management (login required).**

- **Contains resources to define a problem, map current process, find root cause, develop a solution, implement a solution, and assess effectiveness.**

GEN.20330 CAP Sign

- **Revised GEN.20330 for posting of the official CAP sign for reporting quality concerns to the CAP.**
- **Your laboratory is expected to:**
  - **Post the CAP sign in a prominent location in the laboratory***
  - **Ensure availability to laboratory personnel (eg, break room, common areas, staff bulletin board)**
  - **Obtain additional signs by contacting the CAP at:**
    - **800-323-4040**
    - **847-832-7000**

**** Not required in patient care areas.***

GEN.20340 Notifications From Vendors

- **Expanded the requirement for notifications from vendors of defects or issues (eg, product recalls, software patches)**
  - **Applies to reagents, supplies, instruments, equipment, or software that may affect patient care/client services**
- **You can ensure compliance by having:**
  - **A written policy for the handling of recalls and notifications**
  - **Records of manufacturer's recalls received**
  - **Records of laboratory follow-up**

Safety

GEN.76720 Formaldehyde Safety

- **Modified the note for formaldehyde monitoring:**
  - **Must evaluate both the 8-hour time-weighted exposure and 15-minute short-term exposure**
  - **Can use a representative sampling strategy instead of individual exposure monitoring, including:**
    - **Measurement of sufficient exposures within each job classification for each work shift (without underestimating exposure)**
  - **Make monitoring results available to personnel within 15 working days of receipt of results**
  - **Implement engineering controls/work practices to reduce exposure if levels are at or above allowable limits**
  - **Define conditions for additional monitoring**

GEN.77550 Liquid Nitrogen Safety

Oxygen sensors and low oxygen level alarms are required in all areas where liquid nitrogen (LN2) is used and/or stored and there is an asphyxiation risk.

- **If your laboratory uses small volumes of LN2 (eg, ≤1 L), you must use LN2 sensors/alarms or perform a risk-based assessment to determine if LN2 sensors/alarms are needed.**

**** At room temperature LN2 is converted to nitrogen gas at an expansion ratio of approx. 1:700 - hazard for an oxygen-deficient environment.***

GEN.77825 Hazardous Waste

- **NEW phase II requirement**
- **If your laboratory generates hazardous wastes, you are required to do the following based on the amount of wastes generated:**
  - **Register with the Environmental Protection Agency (EPA)* and/or appropriate national/state/local agency, even if waste disposal services are contracted.**
  - **Comply with applicable regulations**

**** Before contacting the EPA, check with your hospital or facility group to determine if your health care facility is registered as a whole.***

GEN.77825 Hazardous Waste

- **Hazardous waste is not the same as medical waste.**
- **It has the following characteristics:**

- **Requirements and enforcement may vary from state to state*.**

Go to EPA.gov for more information on defining wastes and generator categories, variations between states, and state-specific programs.

Interesting reading:

Berlin J. Don't Get Waste-Deep. *Tex Med.* 2017;113(10):37-41.

Personnel

DRA.10100 Laboratory Director – Subject to US Regulations

- **Clarified qualifications for directors of moderate and high-complexity testing for laboratories subject to US regulations:**
  - **Pathologist directors who qualify under the provision of being board-eligible must supply a letter from the board with their current eligibility status.**
  - **PhD directors who qualify under the provision of certification by an HHS-approved board must maintain records of current certification.**

Proficiency Testing (PT)

What is Distributive Testing?

- **NEW: Definition of Terms**

Distributive testing – Laboratory testing performed on the same specimen, or aliquot of it, that requires sharing between two or more laboratories (with different CLIA/CAP numbers) to obtain all data required to complete an interpretation or calculation necessary to provide a final reportable result for the originally ordered test.

COM.01900 PT Referral

- **If your laboratory performs testing using a distributive testing model where portions of the testing process are performed at another laboratory with a different CAP/CLIA number, you must:**
  - **Limit PT to the portion that can be reported by the laboratory (as applicable) OR**
  - **Perform alternative performance assessment at least twice a year**

Exception: Slides may be sent for IHC staining only and be returned to the original laboratory for interpretation.

Instruments and Equipment

Volumetric Glassware and Pipettes

- **NEW section in the All Common Checklist**
- **Combined requirements on volumetric glassware, quantitative pipettes, dilutors, etc**
- **Provided in a customized checklist as needed**
- **Includes four key requirements:**

COM.30810	**Volumetric Glassware Accuracy and Reproducibility**
COM.30820	**Quantitative Pipette Accuracy and Reproducibility**
COM.30830	**Measuring Devices**
COM.30830	**Pipette Carryover**

Analytical Balances

- **NEW section in the All Common Checklist**
- **Provided in a customized checklist as needed**
- **Includes four key requirements:**

COM.30860	Analytical Balance Maintenance
COM.30870	Analytical Balance Mounting
COM.30830	Analytical Balance Accuracy
COM.30840	Weight Maintenance

Test Method Validation/Verification

COM.40300 and COM.40350 Test Method Validation/Verification

- **Reorganized requirements for test method validation/verification**
- **For each nonwaived test, you must have records of:**
  - **Data of verification or validation of applicable test method performance specifications**
  - **Written assessment of the study for each performance specification for tests implemented after June 15, 2009**

Applies to all nonwaived instruments/devices used for a test, even if they are identical.

COM.40300 and COM.40350 Test Method Validation/Verification, cont'd

- **Clarified method performance specifications to be verified/validated based on the type of testing performed**

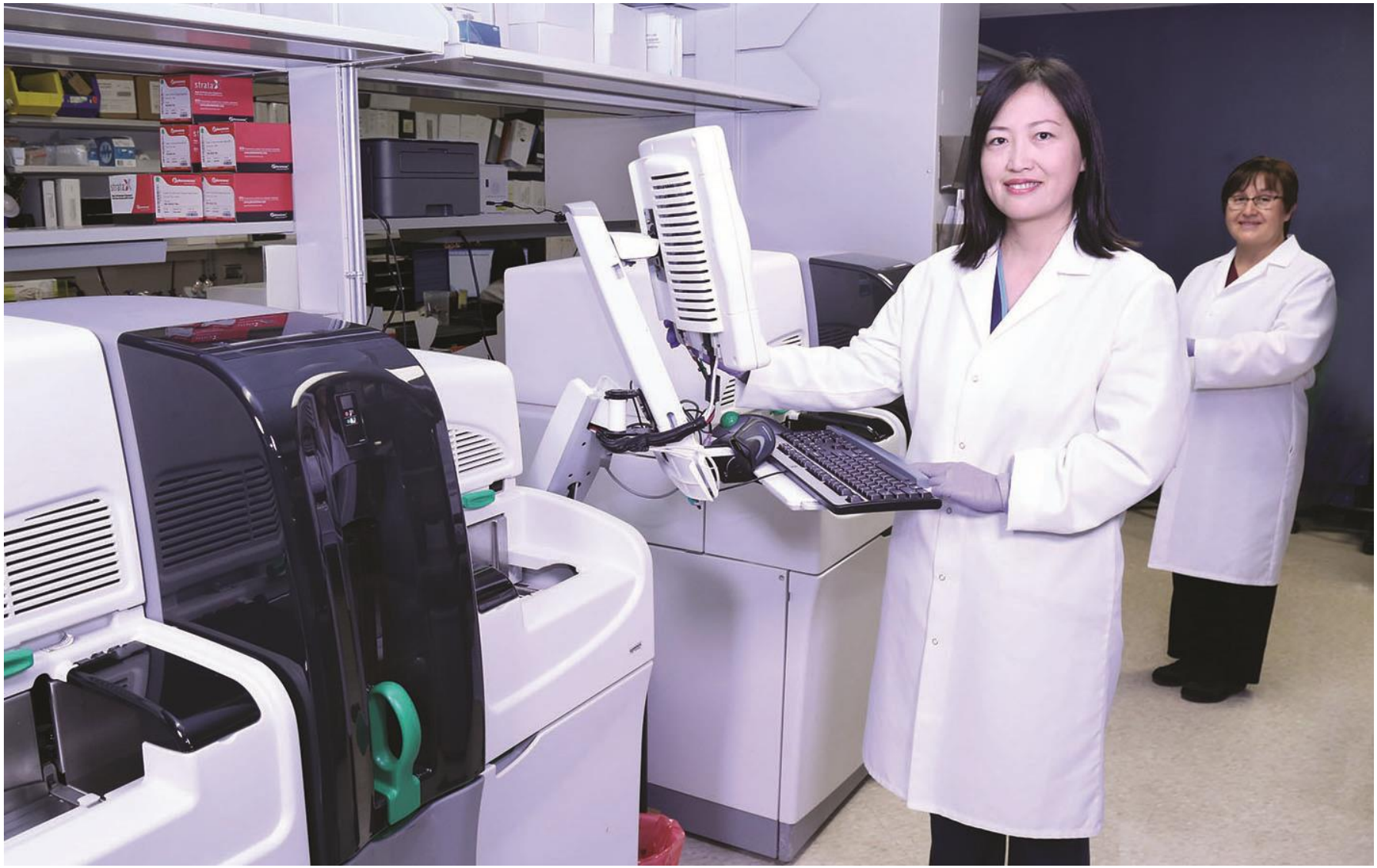
Requirement	Analytical Accuracy	Analytical Precision	Reportable Range	Analytical Sensitivity	Analytical Specificity
COM.40300 (FDA-cleared or approved - Verification)	X	X	X		
COM.40350 (Modified FDA-cleared or approved and LDTs - Validation)	X	X	X	X	X

COM.40475 Method Validation and Verification Approval

- **Previously COM.40000**
- **Your laboratory's test method validation/verification final approval must include the following for each nonwaived test prior to clinical use:**
  - **Review of the written assessment of the validation or verification study, including data and investigation of discordant results**
  - **Signed approval statement by laboratory director or designee meeting CAP director qualifications**

The Toolkit contains examples forms for test method validation/verification.

QC/Calibration and Related Processes



Control Range Establishment or Verification

- **Standardized requirements for establishing or verifying acceptable control ranges for each lot of control material for nonwaived testing.**

Unassayed Control Materials	**All Tests**	**Establish acceptable control range by repetitive analysis in runs that include previously tested control materials**
Assayed Control Materials	**Quantitative Tests**	**Verify control ranges supplied by the manufacturer**
Assayed Control Materials	**Qualitative Tests (eg, pos/neg)**	**May use manufacturer's supplied control ranges without further verification**

Refer to CHM.14000, CBG.12900, HEM.19380, FLO.23925, IMM.34140, POC.07456, URN.25280.

Calibration and Verification Processes

- **Revised calibration and verification processes section for nonwaived testing in several checklists:**
  - **Streamlined introductory text**
  - **Moved content for appropriate materials to use for calibration verification and analytical measurement range verification directly into the requirements (eg, CHM.13100, CHM.13550)**
  - **Clarified frequency for recalibration or calibration verification to include a statement about single use devices and test devices that do not allow for user calibration (eg, CHM.13400)**

Refer to requirements in the CHM, CBG, IMM, HEM, POC Checklists.

Calibration and Verification Processes, cont'd

- **Revised requirements for analytical measurement range verification (AMR) to clarify:**
  - **That a laboratory may choose to verify and use a range narrower than the range defined by the manufacturer.**
  - **How the requirement applies based on the number of points used for calibration:**
    - **For instruments with one or two-point calibration, your laboratory must verify the AMR.**
    - **For instruments with three or more point-calibration, AMR may be met if the calibrators span the full range of the AMR, with low, midpoint, and high values and the system is calibrated at least every six months.**

Discipline-Specific Checklist Changes

Discipline-Specific Checklist Highlights

- **Molecular-based microbiology – waived testing**
  - **Four NEW requirements: Point-of-Care Testing, Immunology, and Limited Service Checklists (eg, POC.09400, POC.09500, POC.09600, POC. 09700)**
  - **Based on existing requirements in the Microbiology Checklist**
- **Antinuclear antibody (ANA) testing**
  - **NEW phase I requirements: IMM.39700, CHM.33780, LSV.41343, LSV.46240**
  - **Requires test method on the patient report for proper interpretation of results**

Discipline-Specific Checklist Change Highlights

- **Microbiology Checklist**
  - **NEW phase II requirement - MIC.21835 for direct testing for organism ID and susceptibility**
  - **NEW phase I requirement – MIC.21855 for linking antibiotic resistance determinants and phenotypic susceptibility results to a specific organism in the final report**
- **Urine opioids immunoassay cutoff**
  - **NEW phase I requirement - CHM.28875**
  - **Requires use of immunoassay cutoff values appropriate to the clinical setting**

Discipline-Specific Checklist Highlights, cont'd

- **CYP.06900 (slide retention)**
  - **Revised to change retention of nongynecologic cytology slides (including FNAs) to 10 years.**
  - **Applies to cases diagnosed on or after December 31, 2014.**

  Retention of gynecologic cytology slides is unchanged (five years).

- **CYP.07400 (statistical records)**
  - **Revised to clarify statistics to be maintained for diagnostic category for gynecologic and nongynecologic cases.**
  - **At a minimum, you must:**
    - **Divide cytology cases into two categories: gyn and nongyn.**
    - **For each, evaluate the number of specimens processed, and number of cases reported by diagnostic category (including number reported as unsatisfactory).**

Predictive Marker Testing

- **The CAP defines a predictive marker as:**
  - **IHC and ISH tests used to predict responsiveness to a specific treatment independent of other histopathologic findings.**
  - **Rather than confirming a specific diagnosis, these tests differentiate predicted responsiveness to a targeted therapy among cases of the same diagnosis.**
- **Predictive marker requirements in the ANP, CYG, and MOL checklists revised to apply more broadly**

****CAP guidelines** provide additional guidance (www.cap.org/protocols-and-guidelines/current-cap-guidelines).*

Predictive Marker Changes: COM/GEN

- **COM.01520 (PT and Alternative Performance Assessment for Predictive Markers)**
  - **New phase II requirement**
  - **Outlines requirements for PT and alternative performance assessment for different types of predictive markers performed by IHC and ISH**
- **GEN.40125 (Handling of Referred Specimens)**
  - **Revised**
  - **Clarified that you are required to include information on cold ischemia time and total fixation time with breast tissue pathology specimens suspicious for malignancy sent to referral laboratories**

Predictive Marker Changes: ANP/MOL/CYG

- **Report Elements**
  - **ANP.22969, CYG.47880, MOL.39295**
  - **Outlines essential report elements including specimen processing, the antibody clone/probe, and scoring method used**
- **Validation/Verification**
  - **ANP.22978, CYG.48399, MOL.39323**
  - **Defines validation/verification requirements for all types of predictive markers performed by IHC or ISH, including number of cases used and concordance levels**
- **Fixation – HER2, ER/PgR – Breast Predictive Markers**
  - **ANP.22983, CYG.48932, MOL.39358**
  - **Contains new content on communicating with laboratories submitting specimens and qualifying negative results for specimens not meeting fixation guidelines**

Using CAP Resources to Identify and Implement Changes

- **Checklist download on cap.org – e-LAB Solutions Suite (login required)**

Checklist Type
Master
Custom
Changes Only ✓

- **Focus on Compliance webinar series**
- **CAP TODAY articles – view or subscribe on cap.org**

Top 10 Deficiencies

CHECKLIST REQUIREMENT	CAP-WIDE*
GEN.55500 Competency Assessment	**1**
COM.01200 Activity Menu	**2**
COM.04250 Comparability of Instruments and Methods – Nonwaived Testing	**3**
COM.10000 Procedure Manual	**4**
COM.30600 Maintenance/Function Checks	**5**
COM.01700 PT and Alternative Assessment Result Evaluation	**6**
COM.30300 Reagent Labeling	**7**
COM.01400 PT Attestation Statement	**8**
COM.04200 Instrument/Equipment Record Review	**9**
COM.30400 Reagent Expiration Date	**10**

* Based on 2018 CAP Inspection Data

Summary

- **Summarized significant checklist changes.**
- **Provided a brief overview of changes to discipline-specific checklists.**
- **Reviewed CAP resources to help your laboratory identify and implement changes.**
- **Provided a toolkit for you to review on your own.**

Resources

Checklist interpretation questions?

- **Email: accred@cap.org**
- **Phone: 800-323-4040 option 1**

Thank You!