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CAP Accreditation and Checklists Update

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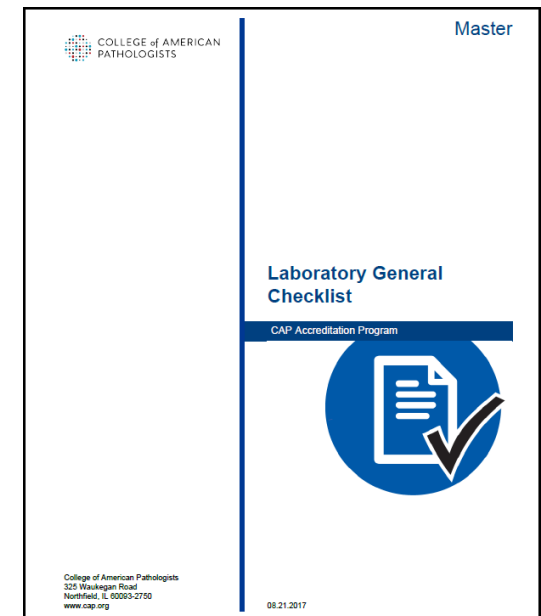
November 3, 2017

Objectives

- **Discuss CAP Checklists and highlight changes in the 2017 checklist edition**
- **Describe key changes for laboratories with California clinical laboratory licensure**
- **Review tips for staying current with checklist changes**
- **Provide an update on implementation of individualized quality control plan (IQCP) requirements**

What are the CAP Checklists?

- Detailed standards developed based on broad principles defined in the CAP Standards for Laboratory Accreditation
 - 21 different checklists with about 2,900 requirements
- Tool for laboratories to prepare for inspection
- Roadmap guide for inspectors to perform an inspection
- Customizable based on tests and activities performed by the laboratory
- Updated annually based on input from experts in the field



Summary of Changes in 2017

Checklist	Requirements	New	Significant Changes	Deleted	Moved or Merged
ANP	187	8	13	0	2
BAP	170	1	3	0	1
CGB	83	0	0	0	11
CHM	152	0	4	4	29
COM	75	3	14	0	0
CYG	57	1	4	0	0
CYP	83	15	8	0	0
FDT	125	0	1	0	7
FLO	48	0	6	0	2
GEN	328	32	36	0	3
HEM	193	2	14	0	3
HSC	157	7	12	0	7
IMM	65	1	2	0	1
LSV	278	2	16	0	11
MIC	255	1	15	1	63
MOL	164	17	15	0	10
POC	56	2	7	0	1
RLM	115	2	8	0	2
TLC	18	1	5	0	1
TRM	256	1	52	1	3
URN	29	0	0	0	2
TOTAL	2894	96	235	6	159

Major Topics for the 2017 Update

- Laboratory General**
 - Personnel
 - Specimen Collection and Handling
 - Laboratory Computer Services
 - Safety/Physical Facilities
 - Laboratories with California Licensure
- All Common**
 - Proficiency Testing
 - Instruments & Equipment
 - Test Method Validation/Verification
 - Individualized Quality Control Plans
- Director Assessment Checklist**
- Discipline Specific Checklist Changes**

Laboratory General Checklist Changes



Personnel: Qualifications

GEN.54400 Personnel Records:

Personnel records are maintained (in electronic or paper format) and readily available for all testing personnel, supervisory personnel, and other laboratory personnel...

- Personnel trained outside of the US must have an equivalency evaluation performed by a nationally recognized organization* such as:
 - National Association Credential Evaluation Services, Inc. (NACES) (<http://www.naces.org>)
 - Association of International Credential Evaluators, Inc. (AICE) (<http://www.aice-eval.org>)

*** A California laboratory personnel license or license to practice medicine in the state are acceptable evidence of equivalency assessment**



Personnel: Training

GEN.55450 Personnel Training:

There are records that all laboratory personnel have satisfactorily completed training on all tasks performed, as well as instruments/methods applicable to their designated job.

- Requires training for all laboratory personnel **for all tasks performed** (including instruments)
- Clarifies that training must be completed **prior to starting patient testing**
- Allows ongoing competency assessment records to be used in lieu of training after the initial two year period (or five years for transfusion medicine)

Personnel: Competency Assessment

GEN.55500 The competency of each person performing patient testing to perform his/her assigned duties is assessed...

- **Split into three separate requirements:**
 - **GEN.55499 Waived Testing**
 - **GEN.55500 Nonwaived Testing**
 - **GEN.55510 Qualifications to Assess Competency**

Point-of-Care Testing Checklist revised to be consistent:

- **POC.06875 Waived Testing**
- **POC.06910 Nonwaived testing**
- **POC.06920 Qualifications to Assess Competency**
- **POC.09600 Provider-Performed Microscopy (Nonwaived)**

Personnel: Competency Assessment, cont'd

GEN.55500 Nonwaived Testing:

- Competency must be assessed at **the specific laboratory (CAP/CLIA number) where testing is performed.**
- All test performance variations must be included in the competency assessment specific to the site or laboratory.
- Records may be maintained centrally within a health care system.
- Records must be available upon request.



Personnel: Competency Assessment, cont'd

GEN.55499 Waived Testing:

- **Laboratory director may determine how competency will be assessed for personnel performing testing at multiple test sites (same or different CAP/CLIA number).**
- **Variations in test performance at different test sites or laboratories must be included in competency assessment specific to site or laboratory.**
- **Laboratories may continue to select which competency assessment elements to assess.**
- **More stringent state or local regulations must be followed.**

Personnel: Competency Assessment, cont'd

GEN.55510 Qualifications to Assess Competency:

- **Assessor qualifications vary depending on the complexity of testing:**
 - **High complexity - Section director/technical supervisor or individual meeting general supervisor requirements**
 - **Moderate complexity - Technical consultant or individual meeting those qualifications**
 - **Waived testing - Determined by the laboratory director**

Personnel: Supervision

- Deleted requirements in discipline specific checklists for “person in charge of bench testing” (eg, CHM.25800, HEM.40000):

~~The person in charge of bench testing/section supervisor in chemistry has education equivalent to an associate’s degree (or beyond) in chemical, physical or biological science or medical technology and at least four years of experience (one of which must be in clinical chemistry) under a qualified section director.~~

- Use supervision requirements in Laboratory General instead
 - GEN.53600 (General Supervisor) for high complexity testing
 - GEN.53625 (Technical Consultant) for moderate complexity testing
- Change is consistent with CLIA roles and the CAP’s Laboratory Personnel Evaluation Roster

Personnel: Supervision, cont'd

GEN.53600 General Supervisor Qualifications

Supervisors/general supervisors meet defined qualifications and fulfill expected responsibilities.

- Revised NOTE: *The general supervisor's training and experience must be in the designated discipline or area of service for which the individual is responsible.*
- Previous version only required training and/or experience in high complexity testing

Specimen Collection and Handling: Chain of Custody

- **Added six new requirements to the Laboratory General Checklist.**
 - **GEN.40502 Chain-of-Custody Procedures**
 - **GEN.40503 Chain-of-Custody Records**
 - **GEN.40504 Chain-of-Custody Acceptability Criteria**
 - **GEN.40506 Secured Specimen Storage**
 - **GEN.40507 Specimen Retention and Storage**
 - **GEN.40509 Secured Records**
- **Removed “legal testing” section from the Chemistry & Toxicology Checklist**
- **Applies to:**
 - **Any collection process that follows a chain-of-custody (CoC) procedure**
 - **CoC testing referred to another laboratory**
- **Does not apply to laboratories in the RLAP or FDT programs**

Laboratory Computer Services

GEN.43150 User Authentication

There are explicit written policies that specify who may access the computer system, how the access is obtained, and how the security of access is maintained (e.g. inactivated when personnel leave, not posted on terminals).

- **Clarified to require written policies for:**
 - **Who may access the computer system**
 - **How access is obtained**
 - **How security of access is maintained**

Laboratory Computer Services, cont'd

GEN.43200 User Authorization Privileges

There are written procedures and access privileges in place to confine the level of access of authenticated users to those functions they are authorized to use to fulfill their job responsibilities.

- **Revised to:**
 - **Confine the level of access of authenticated users to the functions they are authorized to use**

Safety: Emergency Preparedness

GEN.73800 Emergency Preparedness

There are written policies and procedures defining the role and responsibilities of the laboratory in emergency preparedness for harmful or destructive events or disasters.

- Previous version referred to internal and external disasters – now refers to **harmful or destructive events or disasters**.
- Revised NOTE to introduce a **risk-based approach** for determining the types of situations that must be addressed in the emergency preparedness plan.
- Based on a new CMS rule for Medicare and Medicaid providers and suppliers.

Safety: Emergency Eyewash

GEN.77400 Emergency Eyewash:

The laboratory has adequate plumbed or self-contained emergency eyewash facilities....

- Focused requirement on potential exposure to the eye from **corrosive chemicals** (refer to SDS)
- May use a **risk-based approach** to determine appropriate placement of eyewash facilities
- Clarified that availability of disposable eyewash bottles in work area does not replace the need for an eyewash facility in areas at risk for eye exposure from corrosive chemicals

Safety: Visitors

Expanded safety requirements to include provisions for laboratory visitors:

- **GEN.74000 Bloodborne Pathogens - include potential hazards that visitors may encounter in exposure control plan**
- **GEN.74100 PPE Provisions and Usage - make personal protective equipment available to laboratory visitors**

Physical Facilities

GEN.62020 Centralized Reagent and Supply Storage

If reagents and supplies are stored in a centralized area outside of the laboratory, they are stored and handled in accordance with the manufacturer's instructions, and temperatures are checked and recorded daily using a calibrated thermometer.

- **Added to address centralized storage areas outside of the laboratory**
- **Requires storage and handling following manufacturer's instructions and daily temperature monitoring**
- **Storage of reagents and supplies in the testing areas will continue to be inspected with the All Common requirement COM.30350**

Laboratories with California Licensure

- **NEW** section created in Laboratory General with 10 requirements.
- Requirements included in customized checklists for laboratories that have a California clinical laboratory license
- Applies to:
 - Most laboratories within the state of California
 - Other laboratories that test specimens that originate in California
- The CAP has been granted deeming authority with the state to inspect for compliance with state law.

Laboratories with California Licensure, cont'd

Requirements focus on items unique to California law, including:

- **Laboratory director and testing personnel qualifications and licensure**
- **Qualifications and duties of unlicensed personnel and phlebotomists**
- **Posting of licenses and certificates**
- **Listing of the laboratory owner on the laboratory license**
- **Training program requirements**
- **Inclusion of the director's name on patient reports**
- **Use of locked specimen storage boxes**

Laboratories with California Licensure, cont'd

Two cytopathology requirements were revised to address differences for cytology workload recording (CYP.08500, CYP.08550):

- **CYP.08500 - Manual screening of gynecologic smears limited to 80 slides in a 24-hour period**
- **CYP.08550- Workload for cytotechs performing automated and semiautomated gynecologic smears under California state laboratory license limited to 200 gynecologic slides in a 24-hour period**

All Common Checklist Changes



Proficiency Testing

COM.01700 PT and Alternative Assessment Result Evaluation

There is ongoing evaluation of proficiency testing (PT) and alternative assessment results with appropriate corrective action taken for each unacceptable result.

Revised NOTE:

- **Each unacceptable PT or alternative assessment result (any result or sample not meeting defined acceptability criteria) must be evaluated. It is recommended that the laboratory investigate acceptable results that show significant bias or trends.**

Proficiency Testing: Interlaboratory Communication

COM.01800 PT Interlaboratory Communication

There is no interlaboratory communication about proficiency testing samples until after the deadline for submission of data to the proficiency testing provider.

Revised NOTE for clarification:

- PT must be **performed** at the laboratory (CAP/CLIA number) for which it was ordered.
- PT must be **reported** at the laboratory where testing was performed.
- Laboratories sharing an LIS or personnel **must follow strict policies and procedures** to ensure that personnel do not access PT records from other laboratories.

Instruments and Equipment: Microscopes

NEW microscope maintenance requirements added to the All Common Checklist (removed from discipline specific checklists):

- **COM.30680 Microscope Maintenance**
 - Properly maintained (cleaning, optically aligned)
 - Equipped for intended use (low, high dry, oil immersion lenses)
 - Preventative maintenance at least annually
- **COM.30685 Microscopes for Fluorescence Testing**
 - Monitoring for sufficient light source
 - Use of appropriate filters/slides
 - Minimization of ambient lighting during use



Instruments and Equipment: Performance Verification

COM.30550 Instrument/Equipment Performance Verification

The performance of all instruments and equipment is verified prior to initial use, after major maintenance or service, and after relocation to ensure that they run according to expectations.

- Revised to further specify when/what must be verified.
- Clarified NOTE:
 - **Instrument/equipment** performance verification **≠** verification of **test method** performance specifications.
 - Instruments/equipment must perform according to expectations for intended use and within defined tolerance limits.
 - **Appropriate function checks are required after relocation***.

**This does not apply to portable equipment used following the manufacturer's instructions.*

Test Method Validation/Verification

Method Performance Specifications (Nonwaived)

Changes to the introduction:

- **Added information to address the moving of instruments (FAQ):**
 - **If an instrument is moved, the laboratory is responsible for determining that the method performance specifications are not affected by the relocation process or any changes due to the new environment (e.g. refer to the manufacturer's manual regarding critical requirements, such as set-up limitations, environmental conditions, etc.).**

Test Method Validation/Verification, cont'd

Changes to the introduction:

- **Emergency Use Authorization (EUA):**
 - **Definition:** The legal mechanism used by the FDA to allow the use of an unapproved medical product (eg, diagnostic device) or an unapproved use of an approved medical product during an emergency to diagnose, treat, or prevent a serious or life threatening disease condition caused by a chemical, biological, radiological, or nuclear agent (CBRN).

Test Method Validation/Verification, cont'd

Emergency Use Authorization (EUA)

- **Often unable to validate (accuracy, precision, etc.)**
- **Must follow assay or test protocol without modification**
- **Document alternative assessment used to ensure accurate test results**

Individualized Quality Control Plan (IQCP)

COM.50200 List of IQCP's

The laboratory has identified all tests using an IQCP on the CAP's List of Individualized Quality Control Plans form.

- Previously required two separate CAP forms for IQCP's:
 - Summary Form
 - List Form
- **IQCP Summary** form discontinued
- Updated **IQCP List** form to include new fields (test sites, number of devices in use, implementation/revision date)
- Revised list form available on CAP.org (IQCP Resources page)

Individualized Quality Control Plans (IQCP), cont'd

COM.50300 Risk Assessment

The IQCP for a test/device/instrument includes a risk assessment to evaluate potential sources of error to include all of the following...

- Clarified that in-house data collected for the risk assessment must **support the frequency selected for external quality control** (maximum interval between runs of external controls)

Individualized Quality Control Plans (IQCP), cont'd

COM.50500 Quality Control Plan Elements

The individualized quality control plan must define all aspects monitored based on the potential errors identified during the risk assessment, including the following parameters as applicable:

Modified NOTE:

- Removed provision that “external control material samples must be analyzed at least every 31 days”
- Laboratories may now define lesser frequency if supported by the **laboratory’s risk assessment and the manufacturer’s instructions.**

Individualized Quality Control Plan

COM.50600 Quality Assurance Monitoring

Ongoing quality assessment monitoring is performed by the laboratory to ensure that the quality control plan is effective in mitigating the identified risks for the IQCP and includes records of the following.....

- Added a new statement based on CMS input:
 - **“Reevaluation of the quality control plan if changes to the reagents, environment, specimen, testing personnel, or test system elements of the risk assessment occur.”**
- An example form for annual QA assessment of the IQCP is available on the CAP.org (IQCP Resources page).

Director Assessment Checklist



Director Assessment Checklist

“Team Leader Assessment of Director & Quality Checklist” changed to “Director Assessment Checklist” to focus on role.

- **“TLC” will continue to be used to identify each requirement (eg, TLC.10100, TLC.11425).**
- **All checklist versions generated on or after August 21, 2017 will display the new name, including older editions (eg, 2015 and 2016).**

Director Involvement and Responsibilities

- **Removed the “Director Not On-Site Full Time” section**
- **Revised existing requirements to strengthen and reinforce the role of the director (whether routinely on-site or remote)**
- **Directors must perform an on-site assessment on a periodic basis, which must be defined in a written policy (periodicity NOT defined by the CAP).**

Director Involvement

TLC.10435 Director Involvement

The involvement of the laboratory director, including activities performed on-site and through remote consultation **is considered adequate by the laboratory administration, medical staff, and the inspection team, and follows written policy or agreement.**



Director Responsibilities: Self-Inspection

TLC.10445 Director Responsibility – Interim Self-Inspection **NEW**

The laboratory director ensures that a thorough interim self-inspection is performed and all deficiencies are corrected in a timely manner.

- **Focuses on director's role to ensure that a thorough self-inspection is performed with correction of cited deficiencies**
- **GEN.23584 Interim Self-Inspection – Revised to reinforce record retention, including records of corrective action**

Director Responsibilities: Delegation

TLC.11425 Director Responsibility – Delegation of Functions Revised

- Must ensure that designees are qualified to perform assigned duties and that duties are properly carried out
- May **not** delegate personal on-site assessment of physical and environmental conditions and the adequacy of staffing to others - on-site assessment must be done on a **periodic basis** (as defined in lab policy)
- Designees may **not** sub-delegate functions to others, except as in outlined in other requirements (see GEN.53400 and GEN.53600)

Discipline Specific Checklist Changes



Discipline Specific Checklist Changes, cont'd

- **Anatomic Pathology** – added **NEW** section **Flow Cytometry Data Interpretation**
- **Cytopathology** – added **NEW** section on **Immunochemistry Staining**
- **Microbiology** – consolidated the **Molecular Microbiology** section
- **Chemistry and Toxicology** – removed **Legal Testing**
- **Chemistry and Toxicology/Molecular Pathology/Clinical Biochemical Genetics** – removed **Radiation Safety** requirements and consolidated them into **Laboratory General**

Discipline Specific Checklist Changes, cont'd

- Point-of-Care Testing – renamed Provider-Performed Testing section to **Provider-Performed Microscopy and Limited Waived Testing** and updated terminology for consistency with CLIA
- Transfusion Medicine – updated requirements across the checklist to clarify the intent and align with the FDA
- Histocompatibility – updated the **Molecular HLA Testing** section
- Histocompatibility/Molecular Pathology – added a **NEW** section **Stem Cell Engraftment Monitoring**

How to Keep Up to Date



Resources Available on CAP.org

Resource	Location
Accreditation Checklists	e-LAB Solutions Suite - secure log in required
Focus on Compliance Webinar Series	Home – Accreditation – Accreditation Learning
CAP Today	Home - Publications
eAlerts	Home – Accreditation – News and Updates
Inspector Training	Home – Accreditation – Inspector Training and Resources
Personnel FAQs	Home – Accreditation – Regulatory Information – Personnel Evaluation Form Requirements
IQCP Resources (including FAQs)	Home – Accreditation – Regulatory Information – Individualized Quality Control Plan Resources
Proficiency Testing/ External Quality Assurance Tool Box	e-LAB Solutions Suite - secure log in required

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

Checklist Type Options:

- Master
- Custom
- Changes Only

Checklist Format Options:

- PDF
- Word/XML
- Excel

Top Ten Deficiencies: 2016 Inspection Data

Checklist Requirement	CAP-Wide*
GEN.55500 Competency Assessment	1
COM.01200 Activity Menu	2
COM.10000 Procedure Manual	3
COM.04250 Comparability of Instruments/Methods	4
COM.30600 Maintenance/Function Checks	5
COM.10100 Procedure Manual Review	6
COM.30300 Reagent Labeling	7
COM.01700 PT Evaluation	8
COM.04200 Instrument and Equipment Record Review	9
COM.40000 Method Validation/Verification Approval	10

** Based on 2016 CAP inspection data*

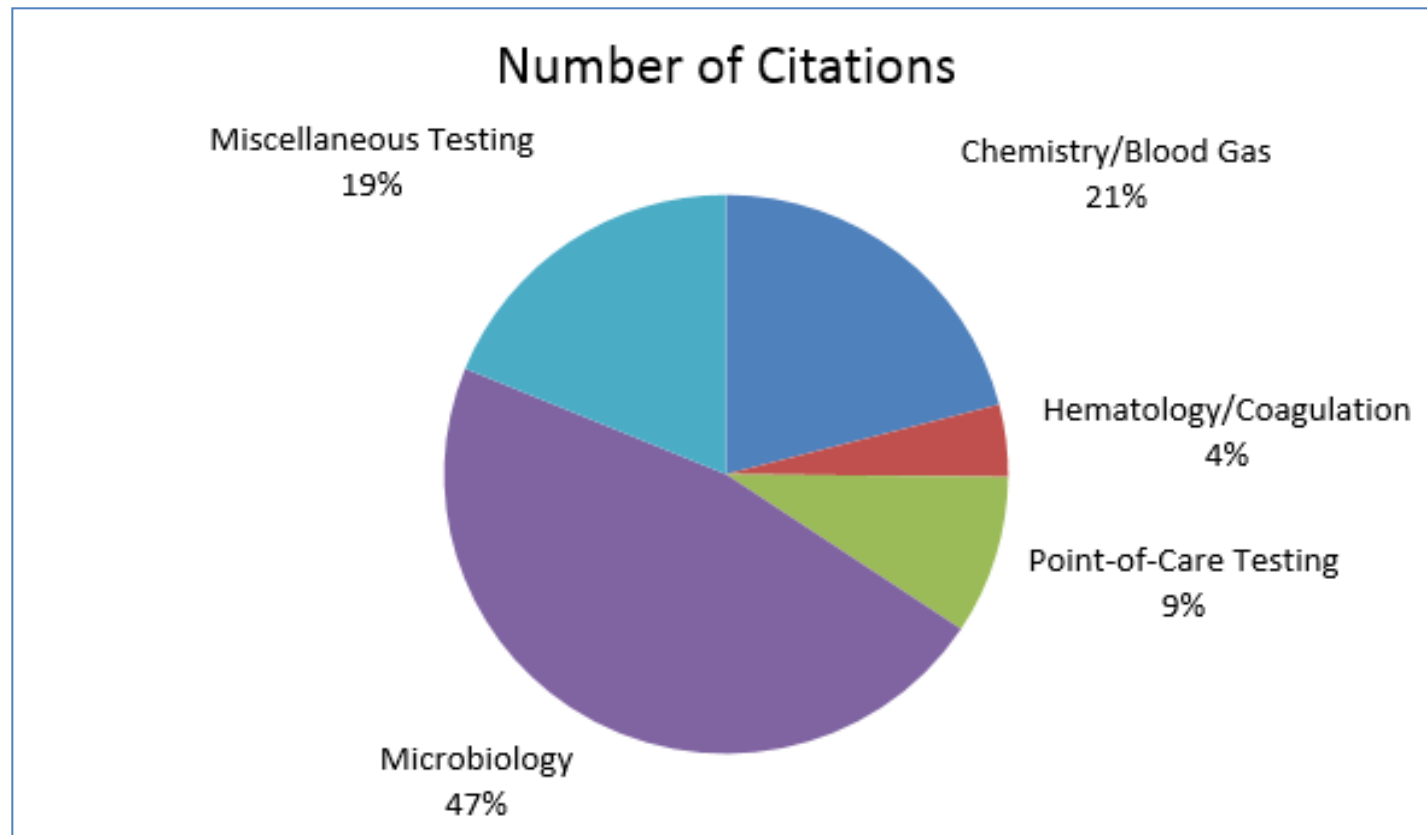
Individualized Quality Control Plan Update

Approximately 1500 deficiencies were cited in 2016 related to IQCP (55% All Common & 44% discipline specific checklists)

- Majority of All Common checklist deficiencies due to incomplete IQCP
 - Missing CAP list and summary form
 - Incomplete risk assessment
 - Missing director signature
 - Quality assessment monitoring not defined

IQCP - 2016 Deficiency Data

The following chart shows the distribution of deficiencies based on the discipline-specific checklist used for inspection:



IQCP – Most Common Discipline-Specific Deficiencies

Most common reasons why laboratories were cited:

- **Laboratories misunderstood the complexity of testing performed**
 - **Waived vs. nonwaived**
 - **Use of different specimen type changed complexity**
- **Laboratories continued to follow Equivalent Quality Control (EQC) regulations and did not implement an IQCP**
- **IQCP implemented after the January 1, 2016 deadline**
- **Microbiology laboratories continued to follow CLSI guidelines for media, ID, and/or susceptibility without implementing an IQCP**

Summary

Success is not about your resources. It's about how resourceful you are with what you have – Tony Robbins



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2017 Focus on Compliance Webinars

Date	Topic/Title	Presenters	Objectives
Feb. 15, 2017 CME/CE	PT Update Proficiency Testing: Making the Grade	Dr. C. Wojewoda Ms L Palicki	<ol style="list-style-type: none"> 1. Describe new and revised proficiency testing (PT) accreditation and enrollment requirements 2. Use CAP tools (eg, CAP Dashboard, Toolboxes) to benchmark and improve PT performance 3. Ensure that the laboratory director's responsibilities regarding PT are being performed 4. Identify patterns of PT failures that place the laboratory at risk for cease testing or adverse events, and implement strategies to prevent these from occurring
April 19, 2017 CME/CE	Personnel Laboratory Personnel: Listing The Right People in the Right Places	Dr. M. Scanlan	<ol style="list-style-type: none"> 1. Describe the purpose and use of the new CAP Laboratory Personnel Roster 2. Explain the qualifications and responsibilities of CLIA-required roles 3. Use the Personnel Requirements by Testing Complexity document to ensure appropriate persons are designated for all CLIA-required roles in different laboratories and disciplines 4. Confirm appropriate delegation of tasks by the laboratory director to qualified individuals 5. Ensure that all required documentation is completed and available at the time of inspection
June 21, 2017 CE only	Avoiding Most Common Lab Gen and All Common Deficiencies Dare to be Different: Avoiding the Most Common Lab Gen and All Common Deficiencies	Dr. G. Gagnon	<ol style="list-style-type: none"> 1. List the most commonly cited deficiencies from the Laboratory General and All Common checklists 2. Implement practical processes to avoid these deficiencies 3. Describe techniques for organizing documentation that demonstrates compliance with these accreditation requirements
July 19, 2017 CME/CE	Performing an effective self-inspection Getting the Most out of Your Self-inspection	Dr. E. Collum	<ol style="list-style-type: none"> 1. Explain the purpose and goal of the interim self-inspection in continuous laboratory improvement and accreditation preparedness 2. Describe techniques to perform a thorough self-inspection and measure progress 3. Document deficiencies and corrective actions to improve laboratory processes and patient safety 4. Define the laboratory director's role and responsibilities regarding the laboratory's self-inspection
Sept 20, 2017 CE only	Checklist Updates Be in the Know: 2017 CAP Accreditation Checklist Updates	Dr. W. West	<ol style="list-style-type: none"> 1. Describe key changes and the rationale for the changes in the 2017 version of the CAP Accreditation Program requirements 2. Use CAP resources to identify changes 3. Implement any necessary changes to ensure compliance with new accreditation requirements
Nov 15, 2017 CE only	IQCP: Lessons Learned IQCP: We Created One, Now What Do We Do With It?	Dr. D. Perry Ms. C. Gandy	<ol style="list-style-type: none"> 1. List lessons learned during on-site inspections regarding the implementation of an Individualized Quality Control Plan (IQCP) 2. Describe efficient implementation strategies for IQCP 3. Use effective techniques to perform the annual assessment of IQCP

Resources

Checklist interpretation questions?

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

Three resources to help you simplify performing inspections:

Need help assembling your team?

Call an Inspection Assignment Specialist



Little time to sort out travel plans?

Call the CAP Travel Desk



Need help with inspector training?

Access Fast Focus on Compliance, mini-training vignettes on new compliance topics; search “Inspector Training” on cap.org



800-323-4040
847-832-7000 option 1
(country code 001)
accred@cap.org
cap.org