TRAINING UPDATE

Lab Location:	GEC, SGMC & WAH	**Date Distributed:**	7/5/2019
Department:	Mgmt & QA	**Due Date:**	7/31/2019
		Implementation:	**7/23/2019**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

College of American Pathologists (CAP) Terms of Accreditation SGMC.QA2003 v1

Description of change(s):

This is a 'new' SOP that replaces 2 previous corporate policies:

- *Policy for Compliance with the College of American Pathologists (CAP) Terms of Accreditation*
- *Notification of Federal and State Agency Laboratory Performance Investigations, Inspections, Complaints or Adverse Media*

It is very similar to the old SOPs but has been converted to our local SOP format and info that did not pertain to our labs was deleted. The content of the 'Notification' policy was added as an addendum.

This SOP will be implemented on July 23, 2019

Document your compliance with this training update by taking the quiz in the MTS system.

Non-Technical SOP

Title	**College of American Pathologists (CAP) Terms of Accreditation**
Prepared by	Leslie Barrett Date: 6/17/2019
Owner	Cynthia Bowman-Gholston Date: 6/17/2019

Local Approval		
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		
Local Issue Date:	Local Effective Date:	

TABLE OF CONTENTS

1. PURPOSE

This document describes the requirements for compliance with the College of American Pathologists (CAP) Laboratory Terms of Accreditation.

2. SCOPE

This policy applies to all CAP accredited laboratory sites as well as those seeking initial CAP accreditation.

3. RESPONSIBILITY

Responsible Party	Task
Laboratory Director	• Approves the initial document and any revisions. • Ensures the terms and obligations required for accreditation by the College of American Pathologists are met and remain in compliance.
Laboratory Director or Designee	• Recurring review of this document • The implementation, coordination, management and oversight of each CAP accreditation term and obligation listed.

4. DEFINITIONS

College of American Pathologists (CAP) Accreditation Program: The CAP Laboratory Accreditation Program is an internationally recognized program that helps laboratories achieve the highest standards of excellence to positively impact patient care. The Centers for Medicare and Medicaid Services (CMS) have granted the CAP Laboratory Accreditation Program deeming authority to inspect and grant certifications for individual laboratory operations.

CAP Certification Mark: The logo symbolizing CAP accreditation achievement.

College of American Pathologists (CAP): A medical society of physicians and laboratory personnel throughout the world, fostering and advocating excellence in the practice of pathology and laboratory medicine.

Laboratory Director: The person whose name is on the CLIA certificate.

Proficiency Testing Program: Proficiency Testing (PT) is the process used to demonstrate a laboratory's ability to provide accurate and reliable results in its patient testing system by testing "unknown" samples from an approved PT provider. The process incorporates elements of pre-analytical, analytical, and post-analytical phases.

Quality Management Plan: A strategy for systematic monitoring of the ongoing and overall quality of the total testing process (pre-analytic, analytic and post-analytic phases). It is the process through which problems or errors are identified, corrective action implemented and the effectiveness of the corrective action is later evaluated and monitored.

5. POLICY

CAP accredited laboratories will comply with the terms and obligations set forth by the College of American Pathologists which includes the following:

- Compliance with all applicable federal, state, and local laws.
- Notification to the CAP office within two working days, whenever the laboratory finds itself the subject of an investigation by a government entity or other oversight agency, or the subject of adverse media attention related to laboratory performance. This

notification must include all complaint investigations conducted or warning letters issued by any oversight agency (e.g., CMS, State Department of Health, The Joint Commission, FDA, OSHA, AABB).

NOTE: Refer to appendix A *Notification of Federal and State Agency Laboratory Performance Investigations, Complaints or Adverse Media*

- Notification to the CAP if the laboratory becomes the subject of a validation inspection (e.g., CMS, State).
- Notification to the CAP if the laboratory discovers actions by laboratory personnel that appear to violate federal, state, or local laws or regulations that govern laboratories.
- Complying with Quest Diagnostics Duty to Report Policy and posting required signage (CAP Poster and Quest Diagnostics CheQline posters) so that employees understand their available options to communicate concerns to management or the CAP about quality and safety issues. Corrective or preventative actions taken in response to quality and safety issues are incorporated into the laboratory's Quality Management Plan.
- Providing an inspection team comparable in size and scope to that required for its own inspection if requested by the regional and/or state commissioner at least once during the two-year accreditation period.
- Participation in a CAP accepted proficiency testing program for each analyte as applicable.
- Notification to the CAP office in writing of changes in location, ownership, or directorship no later than 30 days prior to the change(s). In the case of unexpected changes, notification must occur no later than two days afterwards.
- Notification to the CAP office when there are additions or deletions in the laboratory's test menu. For additions, notify CAP of additions prior to starting new patient testing.
- Authorizing the CAP to release inspection and proficiency testing data to the appropriate regulatory or oversight agencies.
- Conducting an interim self inspection, documenting the correction of identified deficiencies, and the review of these findings by responsible personnel.
- Accepting and adhering to the *Certification Mark Terms of Use/Agreement for CAP Accredited Mark and Design*, if the laboratory is using or will use the CAP Certification Mark of accreditation.
- Submitting only documents and other materials to the CAP that have been de-identified of all protected health information (PHI) in accordance with the requirements of the Health Insurance Portability and Accountability Act (HIPAA) of 1996 unless the PHI is critical to the supporting documents (e.g., patient complaints).
- Cooperating in any CAP investigation or inspection.
- Refraining from copying or distributing the CAP Checklists or any content thereof except for use by inspectors in conducting a CAP inspection and by the laboratory in preparing for such an inspection.
- Adhering to CAP personnel qualification requirements for all personnel engaged in the pre-analytic, analytic and post-analytic phases of testing. (See the CAP website for specific requirements based on test complexity and job function.)
- Maintaining the necessary documentation to confirm that each employee's qualifications meet the CAP requirements.

6. RELATED DOCUMENTS

- *Policy for the Documentation of Testing Personnel Qualifications in PeopleSoft*™
- Quality Management Plan, QA procedure
- Quest Diagnostics Compliance Policies and Procedures:
  - Cooperation with Government Inspections and Inquiries
  - Duty to Report
  - Licenses and Accreditation
  - Privacy of Protected Health Information (PHI)
    Legal / Compliance Policies/Procedures & Supporting Documents

7. REFERENCES

- College of American Pathologists Laboratory Accreditation Program (cap.org)
- Code of Federal Regulations, Title 45, § 164.514(b)
- Quest Diagnostics *Policy for Compliance with the College of American Pathologists (CAP) Terms of Accreditation* QDNQA726

8. DOCUMENT HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes SGAHQDNQA726v2.3		

9. ADDENDA

A. Notification of Federal and State Agency Laboratory Performance Investigations, Inspections, Complaints or Adverse Media

Appendix A

Notification of Federal and State Agency Laboratory Performance Investigations, Inspections, Complaints or Adverse Media

Actions the Lab must take for both the immediate or routine notification to the appropriate Corporate Departments when such events occur

I. DEFINITIONS

Adverse Media Attention: Any mention of a Laboratory Performance issue that appears in the media including, but not limited to, newspaper articles and news reports on TV, internet or radio (local or national)

Condition Level Deficiency: A type of deficiency cited by CMS when a laboratory has non-compliance with one or more condition level requirements. Condition level requirements are any of the requirements identified as "conditions" in the CLIA regulations. The deficiency letter usually identifies “condition level requirement(s) not met”.

Corporate Departments: Quest Diagnostics Medical Regulatory Affairs (MRA), Legal, National Quality Assurance (NQA), Environmental Health and Safety (EHS).

Immediate Notification: Notification to the required Corporate Departments on the same business day or if after hours on the next business day.

Non-Routine Inspection: Any inspection that is not part of the license renewal process, e.g., a communication based on a patient complaint to an agency referenced above.

Routine Inspection: Any inspection (announced or unannounced) that is conducted by a state, federal, accrediting or other regulatory agency for the purpose of license or accreditation renewal.

UCO: Business Unit Compliance Officer

Unsuccessful Proficiency Test: Failure of 2 out of 3 proficiency testing events from any proficiency testing agency.

II. ROUTINE NOTIFICATIONS

- On the day of an unannounced routine inspection or when notified by the regulatory agency, if advanced notice is received, the lab must notify NQA (for laboratory performance) or EHS (for safety).
- Results of the routine inspection must be sent to NQA (for laboratory performance) or EHS (for safety) as applicable.

III. NON-ROUTINE INVESTIGATIONS, NOTIFICATIONS OR COMPLAINTS

A. Notification Process

IF	THEN
Written Notification is received from an agency identified below* …	Follow these steps…..

Step	Action
1	Clearly document the date and time the communication was received.
2	Notify the Laboratory Director (or designee if the laboratory director is unavailable) immediately and provide him/her with the original document to initiate the investigation following the internal local process which includes the notification of all relevant personnel.
	The Laboratory Director or designee shall:
3	Immediately contact the appropriate Corporate Departments and forward a copy of the document via email, facsimile or overnight delivery service to the appropriate Corporate Departments.
4	Identify and note the time period to file a response.
5	Begin the internal investigation.
6	Set up conference call with MRA to review the issues and consult with the business unit to provide advice and instruction on the steps to be taken to respond to the communication.
7	Draft the initial response to the communication.
8	The final written response must be reviewed and approved by the business unit Laboratory Director and appropriate Corporate Departments (Medical Regulatory Affairs and EHS, NQA or Legal as necessary), **prior** to submission to the agency (see documentation requirements below).

* AABB, CAP, CMS, DEA, FDA, JC, NRC (Nuclear Regulatory Commission), OSHA (Occupational Safety and Health Administration), State or Local Agencies

IF	THEN
Verbal Notification is received from an agency…	Follow these steps…..

Step	Action
1	Speak professionally and courteously to the agency representative.
2	Clearly document the date and time the communication was received.
3	Take a detailed written message including: o Correct spelling of the agency and representative's name; o Exact title and contact information including address and telephone number of person to whom you are speaking; o Your name and phone number
4	Repeat the agency representative's telephone number back to the agency representative to be sure that the telephone number is correct.
5	Ask the agency representative when would be a good time for the Laboratory Director or designee to return the call.

Step	Action
6	Do not offer or respond to requests for information prior to conducting an internal investigation.
7	Notify the Laboratory Director immediately and provide him/her with the original information and follow the internal local process which includes the notification of all relevant personnel.
	The Laboratory Director or designee shall:
8	Return the call to the agency.
9	Immediately contact the appropriate Corporate Departments and forward a copy of the document via email, facsimile or overnight delivery service to the appropriate Corporate Departments.
10	Identify and note the time period to file a response.
11	Begin the internal investigation.
12	Set up conference call with MRA to review the issues and consult with the business unit to provide advice and instruction on the steps to be taken to respond to the communication.
13	Draft the initial response to the communication.
14	The final written response must be reviewed and approved by the business unit Laboratory Director and appropriate Corporate Departments (Medical Regulatory Affairs and EHS, NQA or Legal as necessary), **prior** to submission to the agency (see documentation requirements below).

IF	**THEN**
On site contact is made from an agency …	Follow these steps…..
Step	**Action**
1	In the event the employee is not familiar with the agency representative request and verify proper identification and ask the persons to sign the visitor's log.
2	Speak professionally and courteously to the agency representative.
3	Escort the visitors to a private area (e.g., Conference Room).
4	Notify the Laboratory Director immediately and provide him/her with any written documents received from the agency representative.
5	Follow internal processes for the notification of all relevant personnel.
6	The Laboratory Director or designee shall immediately contact the appropriate Corporate Departments and forward a copy of any written documents via email, facsimile or overnight delivery service to the appropriate Corporate Departments.
7	Cooperate with the inspector/agency representative request for information *Note: if there is any question regarding inspector requests please contact MRA immediately.*
8	Provide summary updates to MRA and where possible, include MRA by conference in the closing summation with the inspector /agency representative.
9	Set up a follow-up conference call with MRA and NQA to review the findings / issue(s) and consult with the business unit to provide advice and instruction on the any steps that may be needed to respond.
10	The final written response must be reviewed and approved by the business unit Laboratory Director and appropriate Corporate Departments (Medical Regulatory Affairs and EHS, NQA or Legal as necessary), **prior** to submission to the agency.

B. Documentation
    1. Submission of Responses to State, Federal or Accrediting Agency:
        - Each page of each document submitted in response to an agency must have "Confidential & Proprietary" clearly noted on the paper.
        - All documents and other materials submitted must be de-identified of all protected health information (PHI) in accordance with the requirements of the Health Insurance Portability and Accountability Act (HIPAA) of 1996 unless the PHI is critical to the supporting documents (e.g., patient complaint).
        - All written response documents must be sent to the state, local, federal or accrediting agency using a tracking mechanism (e.g., Federal Express, Certified Return Receipt and/or Electronic filing).
        - If response is sent via e-mail, paper copy should be sent via overnight mail as well. A copy of the response must also be copied to Medical Regulatory Affairs.

    2. Retention of Documents:
        - All copies of documents created as part of the internal investigation, including e-mails and signed responses, will be retained by the laboratory.
        - Corporate Medical Regulatory Affairs maintains, at a minimum, copies of all communications, either submitted to or received from the agency or other relevant documents.
        - Documents will be retained in compliance with the *Records Retention* procedure.

C. Follow-Up Communication
    - If follow-up communication is received from the agency, immediate notification to the Corporate Departments is also required following the process described in this SOP, even if the agency findings were unsubstantiated.

IV. PROCESS FOR ADVERSE MEDIA:

A. As a condition of accreditation with the College of American Pathologists, a laboratory must notify the CAP Office whenever it finds itself the subject of **adverse media attention related to laboratory performance**. Notification must occur no later than 2 working days after the laboratory learns of any adverse media attention.
B. MRA monitors "Media Clips" provided by the Communications Department for any adverse media.
C. The Laboratory Director, or designee, has a system to monitor local media to identify any adverse media attention related to laboratory performance (other types of media attention, even if adverse, are not included in this policy, see Communications Media Policy).

Following are the steps and actions to be taken.

IF	THEN
The Laboratory identifies or obtains knowledge of adverse media attention related to laboratory performance	The Laboratory Director, or designee, (from any Quest Diagnostics CAP accredited laboratory), will provide immediate notification to MRA.

IF	THEN
MRA either identifies from the Media Clips provided by the Communications Department or is informed of any adverse media by a BU	MRA reviews information to assess reporting requirements, if any.
If notification is required to CAP	▪ MRA will provide the notification to CAP no later than 2 working days after the laboratory learns of the adverse media. ▪ MRA notifies CAP of adverse media via email or letter and, where possible, sends a copy of the media to CAP by email or overnight mail.
Follow-up activities are required by CAP	MRA will work with the Laboratory and Legal, using the complaint investigation process, to ensure required actions are taken and, where required, send a response to CAP.

V. SUPPLEMENTARY NOTIFICATION

A. Certain state and federal investigations/inspections may require CAP notification. Notification by the Laboratory to the CAP is **required** if the laboratory is subject to a non-routine investigation, inspection or complaint related to pre-analytical, analytical or post-analytical laboratory performance by a government entity or accrediting agency or if the laboratory experiences adverse media attention related to pre-analytical, analytical or post-analytical laboratory performance.
B. MRA will assist the Laboratory in preparation for this reporting.

Notification of Federal and State Agency Laboratory Performance Investigations, Inspections, Complaints or Adverse Media ☎ Phone Call 💻 Email		**Immediate Notification (24 hours)** **Routine Notification (within 72 hours)**	
	Medical Regulatory Affairs	**National Quality Assurance (AP or CP)**	**Environmental Health & Safety**
Routine Laboratory Licensure Inspections (CAP, AABB, State, JC, COLA, FDA, NRC, DEA, CMS)		☎💻	
NON-Routine Laboratory Agency Investigation or Inspection (CMS, CAP, AABB, State, JC, COLA, FDA, NRC, DEA, etc. - On-site, Written, Oral, Notice, Complaint)	☎💻	☎💻	
Adverse Media	☎💻		
Accidental or Intentional internal or external PT referral or communication	☎		
ANY Condition Level Deficiency	💻	💻	
ANY Unsuccessful Proficiency Test (2 of 3 event failures)	💻	💻	
Routine Laboratory Licensure Agency Inspection Reports		💻	
FDA Blood Bank Reportable		💻	
Any Inspection from OSHA , EPA, DOT or FAA (Written Complaints, Notices, Investigations)	💻		☎💻
NOTE: The CAP must be notified of any complaint investigation, adverse media, non-routine inspection or warning letter from an oversight agency within two working days (AABB, State, JC, COLA, FDA, NRC, DEA, CMS, OSHA, FAA, DOT, EPA, etc.)			