Checklist Updates from the Laboratory Accreditation Program Audioconference

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The Commission of Laboratory Accreditation of the College of American Pathologists (CAP) sponsored an audioconference on the topic of CAP Checklist Updates. This presentation was given by Stephen J. Sarewitz, MD, FCAP. The objectives of the audioconference were to:

- ♦ List important topics from the Lab General, Hematology, and Microbiology checklists,
- ♦ Describe current and recent updates to the LAP inspection checklists including a rational for the changes, and
- ♦ Use the checklists to improve laboratory quality.

The following is a brief synopsis of his presentation.

CAP Administrative Requirements addresses the "Terms of Accreditation" by asking if the lab has a policy that addresses compliance with these terms; if the lab notifies CAP when being investigated by a government entity or adverse media attention related to lab performance; or if the lab notifies CAP when there is a change in lab testing menu, change in location, ownership, and directorship.

Competency assessment requirements for CAP differ from CLIA. CAP requires competency documentation for all waived tests. CAP also requires competency assessment in specimen collection (if collected by laboratory personnel) and critical result reporting, which CLIA does not. Centers for Medicare and Medicaid Services (CMS) has recommended CAP develop procedures to systematically evaluate compliance. In the first year of new personnel, competency must be assessed no later than 6 months after an individual starts a testing procedure, and then assessed again at one year. From then on, it can be done annually. In the future, laboratories can expect inspectors to spend more time reviewing personnel records. Bottom line as Dr. Sarewitz said, is to be certain the personnel files contain documentation for education, training, and certification under CLIA regulations.

New for 2009 is the two identifiers requirement for all primary containers of in-patient and out-patient specimens (attached at time of collection). The largest change anticipated in 2010 may be the format of the checklist. The familiar "question" format will be changed to statements. Rather than asking "Does the lab have a quality management plan?", a statement will be made "The lab has a quality management plan" in which the inspector will evaluate. The purpose of the change is that people find statements easier to interpret. There will also be changes to font and formatting. Additional fields will appear intended to make the checklist more user friendly and provide examples.

Future plans beyond 2010 will include a new numbering system using invariant numbers with alphabetical prefixes. "Single checklist" databases will be developed. This will enable checklists to be customized to fit the organization of each laboratory by linking common sections for PT, QC, instrument maintenance list, to the checklist items specifically applicable to each section of the laboratory.

Dr. Sarewitz elaborated on the contents of each specialty's procedure manual, that contents must reflect CLIA as applicable. NPHL will reserve these topics for future newsletter articles. Further details on Dr. Sarewitz's teleconference can be found at **www.cap.org**