CLIA Corner

State Hygienic Laboratory at The University of Iowa

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Iowa CLIA Surveyors: Nancy Grove, BS, MT(ASCP) & Kristine Rotzoll, BS, MT(ASCP)

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Quality Assessment Introduction

The Clinical Laboratory Improvement Amendments (CLIA) interpretive guidelines defines quality assessment (QA) as an ongoing review process that encompasses all facets of the laboratory's technical and non-technical functions and all locations where testing is performed. QA extends to the laboratory's interactions with and responsibilities to patients, physicians, and other laboratories ordering tests, and the other non-laboratory areas or departments of the facility of which it is a part.

Subpart K of the CLIA regulations is divided into four quality systems: general laboratory, preanalytic, analytic, and postanalytic. Laboratories performing nonwaived testing must establish and follow policies and procedures that implement and monitor all four quality systems. The laboratory's QA process must include a component that ensures continuous improvement of the laboratory's performance and services through ongoing mechanisms to monitor, assess, and when indicated, correct problems. The QA policies and procedures should include: a review of the effectiveness of corrective action taken to resolve problems, the revision of policies and procedures necessary to prevent recurrence of problems, and the discussion of the QA reviews with the appropriate staff. CLIA does not define the specific QA monitors or the frequency for monitoring. It is the laboratory's responsibility to have a written comprehensive QA plan that covers the four quality systems, and then follow the written plan. This edition of the CLIA Corner will focus on the general laboratory quality system, and give examples of possible QA monitors.

First CLIA Quality System - General Laboratory

The laboratory's QA policies and procedures should include reviews of the following areas of patient testing:
Confidentiality of patient information: The laboratory must ensure confidentiality of patient information throughout all phases of the testing process that are under the laboratory's control. The laboratory must have systems in place to monitor visitor access to the laboratory areas where patient information may easily be viewed (e.g. drawing areas, computer terminals, facsimile machines, and worksheets.) There must be safeguards in place to ensure confidentiality of patient information and test reports, unauthorized personnel should not be able to gain access to laboratory information systems or patient test reports. Example: Monitor which individuals have access to the laboratory information system and if the access is necessary for each individual's specific job responsibilities.

Specimen identification and integrity: The laboratory must ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. The laboratory must have systems in place to monitor positive patient identification of specimen collection, labeling, accessioning, processing, storing, testing and reporting of results. Example: Monitor the frequency of mislabeled or unlabeled specimens.

Complaint investigations: The laboratory must ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate. Example: Monitor the type and number of complaints received by the laboratory; document the investigation and resolution of the complaint.

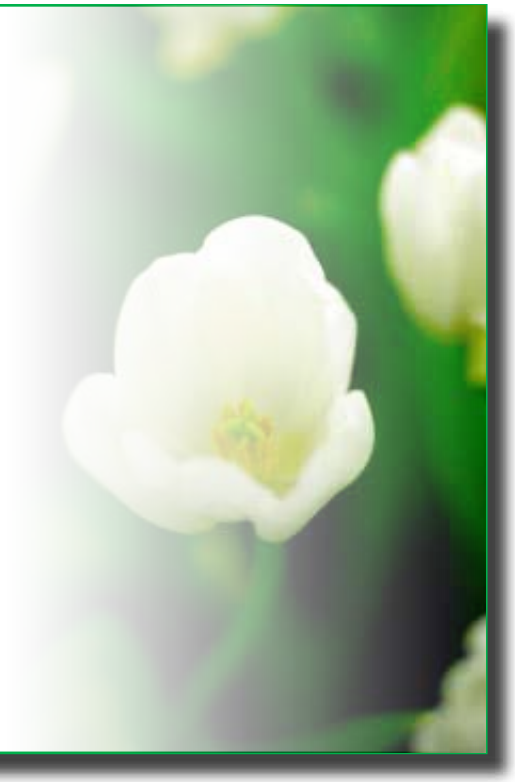
Communications: The laboratory must have a system in place to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results. Example: Monitor the receipt of unacceptable specimens; assess if there is a breakdown in communication between the laboratory and the specimen collection site. If the assessment reveals that a particular individual or site continually submits unacceptable specimens, education and training may be indicated and should be provided.

Personnel competency assessment policies: The laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency (as specified in Subpart M of the CLIA regulations.) Example: Monitor and evaluate personnel for consistency in slide reviews (e.g. urine sediment and manual differentials) to ensure all personnel report microscopic morphology data in the same manner.

Proficiency testing (PT): The laboratory must review and evaluate PT results including all results not graded by the proficiency testing company. The laboratory must also verify the accuracy at least twice annually for all non-regulated proficiency testing analytes. Example: Monitor and self-evaluate all non-graded proficiency testing results. (PT companies may not grade results if there are less than ten participants in a particular peer group or there is less than 80% consensus between the referee laboratories.)

Correction Process

When the laboratory discovers an error or identifies a potential problem, actions must be taken to correct the situation. It is the laboratory's responsibility to identify, investigate, and resolve the error or problem. All pertinent laboratory staff must be involved in the assessment process. The laboratory must then develop policies and procedures to prevent recurrence of the problem. New policies developed due to QA monitors must be written, as well as, communicated with the laboratory personnel and all others necessary staff. Over time, the laboratory must monitor the corrective action(s) taken to ensure that the recurrence of the original error or problem has been prevented.



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WE MOVED!
NEW ADDRESS:

Iowa CLIA Laboratory Program
State Hygienic Laboratory
UI Research Park-Coralville
Iowa City, IA 52242
Email your questions, comments or suggestions to Nancy Grove
nancy-grove@uiowa.edu or
Kristi Rotzoll
kristine-rotzoll@uiowa.edu

Be sure to catch upcoming issues of CLIA Corner for information on other quality systems; preanalytic, analytic, and postanalytic!