

# CLIA Corner

State Hygienic Laboratory at The University of Iowa

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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, other laboratories which order 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 to follow the written plan. This edition of the CLIA Corner will focus on the quality system—analytic and give examples of possible QA monitors.

## **Third CLIA Quality System – Analytic Testing**

The analytic system is related to the direct testing of patient specimens and should include processes to monitor, assess and, when indicated, correct problems related to the following areas:

### **Test procedures**

- The laboratory must have a written procedure manual for all tests, assays and examinations performed by the laboratory; and the manual must be available to all testing personnel.
- For specific procedure manual requirements see Subpart K standard 493.1251(b)(1) – (b)(14) (D 5403).
- Procedures and changes in procedures must be approved, signed and dated by the current laboratory director before use.

QA Examples:

- Are the procedures up to date and do they include the most current information?

- Have all changes been approved by the laboratory director prior to use?
- Do all personnel have access to the procedures?

### **Accurate and reliable test systems, equipment, instruments, reagents, materials and supplies**

- The laboratory must define criteria for selection and implementation of test systems, equipment or methods.
- Testing must be performed following the manufacturer's instructions including all recommendations, suggestions and requirements in package inserts and/or instrument operator manuals.
- When equipment is retired, maintain records and the procedure for the test system for a minimum of two years.

#### QA Examples:

- Has the laboratory reviewed and removed all discontinued procedures?
- Does the laboratory have the most current manufacturer's package inserts available and is the laboratory following all the requirements and recommendations?

### **Specimen and reagent storage condition**

- Ensure storage conditions are met for reagents and equipment.
- Ensure that reagents, solutions, culture media, control materials, calibration materials and other supplies are not used when they have exceeded their expiration date.

#### QA Examples:

- How does the laboratory monitor for expired reagents?
- Are temperature charts reviewed periodically? When temperatures are out of range is corrective action taken and documented?

### **Establishment and verification of performance specifications**

- Each laboratory that introduces an unmodified, FDA-cleared or approved test system must demonstrate: accuracy, precision, reportable range and reference intervals (normal values).
- Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval must demonstrate: accuracy, precision, analytical sensitivity, analytical specificity, reportable range, reference intervals (normal values) and any other performance characteristic required for test performance.
- Ensure the laboratory director reviews and approves the results of the verification or establishment process (validation studies) before reporting patient test results.
- Ensure training has been performed and documented for all testing personnel.

#### QA Examples:

- Has testing personnel been trained on all new test systems? Where are the training documents located (e.g. in personnel files, with validation or installation records, etc.)?
- Has the director approved, signed, and dated the documentation of the test system's verification or establishment process, as well as the procedure for the new test or test system prior to patient testing?

### **Maintenance and function checks**

- Ensure maintenance and function checks are performed according to the manufacturer's requirements and recommendations.
- When the manufacturer does not define maintenance and/or function checks, the laboratory must develop and follow their own procedures or protocols.

#### QA Examples:

- Review function check procedures and records (e.g. centrifuge speed and timer checks, blood bank re-

frigorator and freezer alarm checks, etc.) to determine whether the laboratory is following its established policy.

- Are maintenance records being reviewed periodically (daily, monthly, quarterly, etc.)? Does the laboratory take and document corrective action when maintenance is not performed?

### **Calibration and Calibration verification**

- Follow manufacturer's calibration requirements. If there are no manufacturer's requirements, the laboratory must establish its own calibration schedule.
- Perform and document calibration verification procedures for all applicable test systems.

QA Example:

- What mechanism does the laboratory have to ensure calibration and calibration verification procedures have been performed and are acceptable?

### **Control Procedures**

- The laboratory must have control procedures that monitor the accuracy and precision of the complete analytic process.
- Review and evaluate control results for acceptability and, as appropriate, for shifts and trends.

QA Examples:

- How does the laboratory monitor and review quality control results?
- How does the laboratory monitor the effectiveness of corrective action taken for control failures?

### **Comparison of test results**

- If the laboratory performs the same test using different methods or instruments, or at multiple sites – at least twice annually, the laboratory must evaluate the test results between the different methods, instruments, or testing sites. Establish an acceptable comparison range and ensure the test values fall within the established range.
- The laboratory must monitor and evaluate test results for inconsistencies with patient information, and for correlation between test results (e.g. hemoglobin and hematocrit values; blood urea nitrogen and creatinine comparisons; histopathology and cytology discrepancies.)

QA Example:

- How does the laboratory ensure that comparison studies are being performed on multiple analyzers?

### **Test Records**

- The laboratory must monitor test records for completeness and accuracy.
- The laboratory must maintain an information or record system that includes the following:
  - a) positive identification of the specimen,
  - b) date and time of specimen receipt into the laboratory,
  - c) documentation of unacceptable specimens, and
  - d) date(s) of specimen testing, including the identity of the testing personnel.

QA Examples:

- How does the laboratory monitor unacceptable specimens? Is there a trend in the reason for the unacceptable specimens? How is corrective action documented?
- Do testing records (including microbiology) reflect all patient testing performed and the dates of their performance?



## ***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 other 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.

*Watch for the next issue of the CLIA Corner for information on the remaining quality system: post-analytic!*

## ***NEW Name, Address and Website for State Hygienic Laboratory (SHL)***

Since moving into its new building in November 2010, the Hygienic Laboratory returned to using its official name as established by Iowa Code: State Hygienic Laboratory at the University of Iowa. With recent changes to the United States Postal Service mail delivery, the mailing address for SHL is now the following:

***State Hygienic Laboratory  
University of Iowa Research Park  
2490 Crosspark Road  
Coralville, IA 52241-4721***

Visit our redesigned website at: [www.shl.uiowa.edu](http://www.shl.uiowa.edu).

## ***Contact Information:***

***If you want to be added to our e-mailing list, need a change of address, or have a question or topic suggestion for the CLIA Corner you can contact either Kristi Rotzoll at [kristine-rotzoll@uiowa.edu](mailto:kristine-rotzoll@uiowa.edu) or Nancy Grove at [nancy-grove@uiowa.edu](mailto:nancy-grove@uiowa.edu).***