Introduction to Quality Assessment

In an effort to increase the laboratory’s awareness of the importance of quality assessment, the 2012 Management Bulletin will begin a four part series on quality assessment. This edition will focus on defining important quality assessment terms and introducing the four CLIA Quality Systems.

What’s in a Name?

Quality Improvement? Quality Assurance? Quality Assessment? Confused? No worries, they are all the same thing. The CLIA Final Rule effective April 23, 2003, officially changed the term to Quality Assessment.

The Definition

The Clinical Laboratory Improvement Act (CLIA) interpretative 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.

In simpler terms, QA is a coordinated system designed to identify, evaluate and resolve problems.

The Rule

Subpart K of the CLIA regulations (Sec. 493.1200 Introduction) states each laboratory that performs nonwaived testing must establish and maintain written policies and procedures that implement and monitor quality systems for all phases of the total testing process.

As defined by CLIA the Quality Systems are:

1. General Laboratory Systems
2. Preanalytic
3. Analytic
4. Postanalytic

Each of the laboratory’s quality systems must include an assessment component that ensures continuous improvement of the laboratory’s performance and services through ongoing monitoring that identifies, evaluates and resolves problems.

Quality System: General Laboratory

The first of the four quality systems is General Laboratory Systems. General Laboratory Systems encompasses the general operation functions of laboratory testing that are not specific to any one specialty or subspecialty. The laboratory’s QA policies and procedures should include reviews of the following areas of patient testing:

1. Confidentiality of Patient Information:
   The laboratory must ensure confidentiality of patient information throughout all phases of the total testing process that are under the laboratory’s control.

2. Specimen Identification and Integrity:
   The laboratory must establish and follow written policies and procedures that 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.
3. **Complaint Investigation:**
   The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate.

4. **Communications**
   A system must be in place to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized individual who orders or receives test results.

5. **Personnel Competency Assessment**
   The laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

6. **Evaluation of Proficiency Testing Performance (PT)**
   The laboratory must review and evaluate PT results including all results not graded by the PT provider. The laboratory must also verify the accuracy at least twice annually for all non-regulated PT analytes.

**Quality System: Preanalytic**

Preanalytic Systems is the second of the four quality systems. Preanalytic Systems includes those systems that occur before a procedure or test is performed. The laboratory must establish and follow written policies and procedures for ongoing process to monitor, assess, and when indicated, correct problems identified in the following areas:

1. **Test Request:**
   - The laboratory must have a written or electronic requisition for patient testing from an authorized person. If the laboratory accepts verbal requests, written or electronic authorization must be received within 30 days.
   - The test requisition must contain the following:
     - Name and address or other suitable identifiers of the authorized person requesting the test, or
     - Name and address of the laboratory submitting the specimen
     - Patient name or unique identifier
     - Patient sex and age or date of birth
     - Test(s) to be performed
     - Specimen source when applicable
     - Date and, if appropriate, time of collection
     - Any additional information relevant or necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.
   - If the laboratory transcribes or enters test requisitions or authorization information into a records system or a laboratory information system (LIS), the laboratory must ensure the information is transcribed or entered accurately.

2. **Specimen Submission, Handling and Referral:**
   - The laboratory must establish and follow written procedures for the following:
     - Patient preparation
     - Specimen collection
     - Specimen labeling
     - Specimen storage and preservation
     - Conditions for specimen transportation
     - Specimen processing
     - Specimen acceptability and rejection
     - Specimen referral
   - The laboratory must document the date and time it receives a specimen.
   - The laboratory must refer specimens for testing only to a CLIA-certified or CMS-approved laboratory.
   - If the laboratory accepts referral specimens, written instructions must be available to clients and must include the items listed above in this section.

**Quality System: Analytic**

Analytic Systems is the third quality system. Analytic Systems activities are 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:

1. **Test Procedures**
   - A written procedure manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by laboratory personnel.
2. 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.

3. Establishment and Verification of Performance Specification
   - Each laboratory that introduces an unmodified, FDA-cleared or approved test system must demonstrate: accuracy, precision, reportable range and reference intervals.
   - 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, reportable range, reference intervals 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 results.
   - Ensure training has been performed and documented for all testing personnel.

4. Maintenance and Function Checks
   - Ensure maintenance and function checks are performed according to the manufacturer’s requirements and recommendation.
   - When the manufacturer does not define maintenance and/or function checks, the laboratory must develop and follow their own procedures or policies.

5. Calibration and Calibration Verification
   - The laboratory must follow manufacturer’s calibration requirements. If there are no requirements, the laboratory must establish its own calibration schedule.
   - Perform and document calibration verification procedures for all applicable test systems.

6. Control Procedures
   - For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytical process.
   - The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified.

7. Comparison of Test Results
   - If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites.
   - The laboratory must monitor and evaluate test results for inconsistencies with patient information and for correlation between test results.

8. Test Records
   - The laboratory must maintain an information or record system that includes the following:
     - The positive identification of the specimen.
     - The date and time of specimen receipt into the laboratory.
     - The condition and disposition of specimens that do not meet the laboratory’s criteria for specimen acceptability.
     - The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).
   - Records of patient testing including, if applicable, instrument printouts must be retained.

**Quality System: Postanalytic**

Postanalytic Systems is the last of the four quality systems. Postanalytic Systems includes laboratory activities related to the result reporting process. The laboratory’s QA plan should include processes to monitor, assess and, if necessary, revise procedures in the following areas:
1. Test Report- Delivery
   - The laboratory must have adequate manual or electronic systems in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following:
     o Results reported from calculated data.
     o Results and patient-specific data electronically reported to network or interfaced systems.
     o Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

2. Test Report- Content
   - The test report must include the following:
     o Positive patient identification to include either the patient’s name and identification number, or a unique patient identifier and identification number.
     o Name and address of the laboratory location where the test was performed.
     o Test report date.
     o Test performed.
     o Specimen source, when appropriate
     o Test result, and if applicable, the units of measurement or interpretation, or both.
     o Disposition of unacceptable specimens.

3. Test Report- Information to be Available to Authorized Person
   - Reference intervals or normal values
   - List of test methods and, as applicable, the performance specification.
   - Information that may affect the interpretation of test results.
   - Pertinent updates on testing information must be provided to clients whenever changes occur that affect the test results or interpretation of test results.
   - Release of test information only to authorized individuals.

4. Test Report- Notification/Release of Test Results
   - Test results must be released only to authorized persons and, if applicable, the individual responsible for using the test results and the laboratory that initially requested the test.
   - The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminent life-threatening condition, or panic or alert values.
   - When the laboratory cannot report patient test results within its established time frames, the laboratory must determine, based on the urgency of the patient test(s) requested, the need to notify the appropriate individual(s) of the delayed testing.

5. Test Report- Test Referral
   - The referring laboratory must not revise results or information directly related to the interpretation of results provided by the testing laboratory.
   - The referring laboratory may permit each testing laboratory to send the test result directly to the authorized person who initially requested the test. The referring laboratory must retain or be able to produce an exact duplicate of each testing laboratory’s report.
   - The authorized person who orders a test must be notified by the referring laboratory of the name and address of each laboratory location where the test was performed.

6. Test Report- Retention and Retrieval
   - All test reports or records of the information on the test reports must be maintained by the laboratory in a manner that permits ready identification and timely accessibility.
   - Test report information maintained as part of the patient’s chart or medical records must be readily available to the laboratory.

7. Test Report- Corrected Reports
   - When errors in the reported patient test results are detected, the laboratory must promptly notify the authorized person ordering the test.
   - Issue corrected reports to the authorized person ordering the test, and if applicable, the individual using the test results.
- Maintain duplicates of the original report, as well as the corrected report.

8. Laboratory Information Systems (LIS) and Electronic Health Records (EHR)
- Monitor the patient information confidentiality and security.
- Monitor and evaluate the laboratory's backup system for requesting patient tests and reporting test results during scheduled and/or non-scheduled downtime of the LIS and EHR.
- Ensure that the laboratory makes the necessary updates or changes to the LIS or EHR when a new test or test method is introduced.
- Verify or validate the LIS and/or EHR when major updates or repairs are made to the system(s).
- Ensure that procedures are available to all operators.

**Correction Process**

For each of the four Quality Systems, CLIA regulations state the laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems when identified. All pertinent laboratory staff must be involved in the assessment process. In addition, the laboratory must document all assessment activities and monitor the corrective action(s) taken to ensure that the recurrence of the original error or problem has been prevented.

**Conclusion**

Quality assessment is an ongoing process. 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-general laboratory systems, preanalytical, analytical, and postanalytical- and then follow the written plan. When errors or potential problems are identified, corrective actions must be initiated.

Remember **identify**, **evaluate**, and **resolve** and your laboratory should be well on its way to establishing and utilizing effective quality assessment.

**Tracey Shives, BS, MT(ASCP)**

**References**