QUALITY SYSTEMS: ANALYTIC PHASE
MAINTENANCE & FUNCTION CHECKS & TEST RECORDS

Introduction to Quality Systems

CLIA Facts 14: General Laboratory Practices contains an introduction to the quality systems concept. This fact sheet will discuss two components of the analytic phase of testing--maintenance and function checks, and test records.

Analytic Phase

The analytic phase includes the resources used and the processes that occur during laboratory testing. These resources and processes are:

- Procedure manual
- Test systems, equipment, instruments, reagents, materials, and supplies
- Establishment and verification of performance specifications
- Calibration and calibration verification procedures
- Maintenance and function checks
- Test records
- Comparison of test results
- Corrective actions
- Control procedures (quality control)

The analytic phase is divided into five fact sheets. Specialty-specific control procedures (quality control) are addressed in additional separate fact sheets for each testing specialty.

Let's continue with the next two components of the analytic phase:

- Maintenance and function checks
- Test records

Maintenance and Function Checks

For unmodified manufacturer's equipment, instruments, or test systems, your laboratory must perform and document the following:

1. Maintenance as defined by the manufacturer, and with at least the frequency specified by the manufacturer.
2. Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing begins.

For equipment, instruments, or test systems developed in-house, commercially available and modified by your laboratory, or without maintenance and function check schedules provided by the manufacturer, your laboratory must do the following:

1. Establish a maintenance schedule that ensures equipment, instrument, and test systems provide accurate and reliable test results and test result

reporting Perform and document the maintenance activities.

2. Define a function check schedule that ensures equipment, instrument, and test systems provide accurate and reliable test results and test result reporting. Perform and document function checks, including background or baseline checks. Function checks must be within your laboratory's established limits before patient testing begins.

Test Records

Your laboratory must maintain either paper or electronic records that include the following:

1. The positive identification of the specimen
2. The date and time the specimen was received by your laboratory
3. The condition and disposal of specimens that are not acceptable
4. The records and dates of all specimen testing, including the identity of the person who performed the test(s)
5. Records of patient testing, including instrument printouts which must be retained, if produced

Quality Assessment of the Analytic Phase

Your laboratory must establish and follow written policies and procedures to actively monitor, assess, and correct problems identified in the analytic phase. This quality assessment must include:

- Reviewing the effectiveness of corrective actions taken to resolve problems
- Revising appropriate policies and procedures to prevent problems from recurring
- Discussing the reviews with appropriate staff
- Documenting all quality assessment activities

Resources

- View the current laboratory requirements of Part 493, including the relevant Subpart K, at www.phppo.cdc.gov/clia/regs/toc.aspx
- Appendix C of the State Operations Manual (CMS Pub. 7) can be viewed online at: www.cms.hhs.gov/clia/03_interpretive_guidelines_for_laboratories.asp. (This document is the CMS Surveyor Procedures and Interpretive Guidelines.)