QUALITY SYSTEMS: ANALYTIC PHASE PERFORMANCE SPECIFICATIONS & CALIBRATION

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--establishment and verification of performance specifications, and calibration and calibration verification procedures.

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:

- Establishment and verification of performance specifications
- Calibration and calibration verification procedures

Establishment and Verification of Performance Specifications

If your laboratory modifies an FDA-cleared or approved test system, or begins using a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures, Gram stain, or potassium hydroxide preparations), or if you use a test system in which performance specifications are not provided by the manufacturer you must, before reporting patient test results, establish the performance specifications for:

- Accuracy
- Precision
- Analytical sensitivity
- Analytical specificity to include interfering substances
- Reportable range of test results for the test system
- Reference intervals (normal values)
- Any other performance characteristic required for test performance.

To verify performance specifications, each laboratory that begins using any non-waived, unmodified, FDA-cleared or approved test system must, prior to reporting patient test results, demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for:

- Accuracy
- Precision
- Reportable range of test results for the test system

Be sure to verify that the manufacturer's reference intervals (normal values) are appropriate for your laboratory's patient population.

You must document all activities specified in this section.

Laboratories are not required to establish or verify performance specifications for any test system used by the laboratory before April 24, 2003.

To assist with compliance, CMS has published a brochure called Verification of Performance Specifications that can be viewed on-line at www.cms.hhs.gov/clia/downloads/6064bk.pdf.

Calibration and Calibration Verification Procedures
Calibration and calibration verification procedures are required to substantiate the continued accuracy of the test system throughout your laboratory's reportable range of test results.

Calibration
Your laboratory must perform and document calibration procedures for each applicable test system:

1. Following the manufacturer's instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer
2. Using the criteria verified or established by your laboratory
3. Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value
4. Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration
5. Whenever calibration verification fails to meet your laboratory's acceptable limits for calibration verification

Calibration Verification
Your laboratory must perform and document calibration verification procedures for each applicable test system:

1. Following the manufacturer's calibration verification instructions
2. Using the criteria verified or established by your laboratory, including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification
3. Using at least a minimal (or zero) value, a midpoint value, and a maximum value near the upper limit of the range to verify your laboratory's reportable range for the test system
4. At least once every six months and whenever any of the following occur:
   - A complete change of reagents for a procedure is introduced, unless your laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes.
   - There is major preventive maintenance or replacement of critical parts that may influence test performance.
   - Control materials reflect an unusual trend or shift, or are outside of your laboratory's acceptable limits.
   - Your laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

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.)