QUALITY SYSTEMS: ANALYTIC PHASE PROCEDURE MANUAL & TEST SYSTEMS

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--procedure manual and test systems.

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 of instruments
- 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 start with the first two components of the analytic phase:

- Procedure manual
- Test systems, equipment, instruments, reagents, materials, and supplies

Procedure Manual

Your laboratory should have written procedures for all tests, assays, and examinations your laboratory performs, and they should be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace your laboratory's written procedures for testing or examining specimens.

The procedure manual must include the following, when applicable to the test procedure:

- Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in the Specimen Collection, Handling, and Referral section of *CLIA Facts 15: Pre-analytic Phase*
- Instructions for microscopic examinations, including the detection of inadequately prepared slides
- Step-by-step instructions, including test calculations and interpretation of results
- Instructions for preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing
- Calibration and calibration verification procedures
- The reportable range for test results as established or verified by your laboratory
- Control procedures
- Corrective action to take when calibration or control results fail to meet your laboratory's criteria for acceptability
- Limitations of the test methodology, including interfering substances
- Reference intervals (normal values)
- Imminently life-threatening test results (panic or alert values)
- Pertinent literature references
- Your laboratory's system for entering results in the patient record and reporting patient results--include, when appropriate, the protocol for reporting imminent life threatening results (panic or alert values)

- Description of what to do if your laboratory is unable to perform testing

You may use manufacturer's instructions (package inserts) or operator manuals, when applicable, to meet the requirements above. Any of the items not provided by the manufacturer, however, must be provided by your laboratory.

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. Your laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in CLIA Facts 13: Facility Administration.

Test Systems, Equipment, Instruments, Reagents, Materials, and Supplies

Test systems selected by your laboratory must be performed following the manufacturer's instructions and in a manner that provides test results within your laboratory's stated performance specifications.

Criteria for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting must be defined and consistent with the manufacturer's instructions. The following conditions must be monitored and documented, if applicable:

- Water quality
- Temperature
- Humidity
- Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports

You should label reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, with the following:

- Identity and when significant, titer, strength, or concentration
- Storage requirements
- Preparation and expiration dates
- Other pertinent information required for proper use

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

Components of reagent kits of different lot numbers must not be interchanged unless otherwise specified by the manufacturer.

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.)