QUALITY SYSTEMS: POST-ANALYTIC PHASE

Introduction to Quality Systems

CLIA Facts 14: General Laboratory Practices contains an introduction to the quality systems concept. This fact sheet will discuss the post-analytic phase of testing.

Post-analytic Phase

The post-analytic phase refers to the process that occurs after testing is complete--the test report.

Test Report

Your 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:

- Results reported from calculated data
- Results and patient-specific data electronically reported to network or interfaced systems
- 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

Test report information maintained as part of the patient's chart or medical record must be readily available to your laboratory staff and to CMS or a CMS agent upon request.

The test report must include the following:

- Positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number
- The name and address of the laboratory where the test was performed
- The test report date
- The test performed
- Specimen source, when appropriate
- The test result and the units of measurement and/or interpretation
- Any information regarding the condition and disposal of specimens that were not acceptable

Pertinent "reference intervals"' or "normal" values, as determined by your laboratory, must be available to the person who ordered the tests and the individual responsible for using the test results.

You must, upon request, make available to clients a list of test methods employed by your laboratory and the performance specifications established or verified as required. In addition, information that may affect the interpretation of test results, for example test interferences, must be provided upon request. Pertinent updates on testing information must be provided to clients whenever changes occur that affect the test results or interpretation of test results.

You may release test results only to authorized persons, the individual responsible for using the test results, and the laboratory that initially requested the test.

Your laboratory must immediately alert the individual or entity requesting the test and the individual responsible for using the test results when any test result indicates an imminent life-threatening condition (panic or alert values).

When your laboratory cannot report patient test results within its established time frames, you must determine,

based on the urgency of the patient test requested, the need to notify the appropriate individuals of the delayed testing.

If your laboratory refers patient specimens for testing:

- Your laboratory must not revise results or information directly related to the interpretation of results provided by the testing laboratory.
- Your laboratory may permit each testing laboratory to send the test result directly to the authorized person who initially requested the test. You 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 your laboratory of the name and address of each laboratory location where the test was performed.

All test reports or records of the information contained in the test reports must be maintained by your laboratory in a manner that permits easy identification and retrieval.

When errors in the reported patient test results are detected, you must do the following:

- Promptly notify the authorized person ordering the test and the individual using the test results of reporting errors
- Issue corrected reports promptly to the authorized person ordering the test and the individual using the test results
- Maintain duplicates of the original report, as well as the corrected report

Test Report Quality Assessment

Your laboratory must establish and follow written policies and procedures to actively monitor, assess, and correct problems identified in the post-analytic phase. Quality assessment of the test report 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.)