# QUALITY SYSTEMS: GENERAL LABORATORY PRACTICES

In 2003 the CLIA'88 requirements were revised. Changes include a new format, new terminology, and updated requirements.

Subparts J, K, and P of the Code of Federal Regulations, Part 493 have been combined into two new subparts. Subpart J is now Facility Administration for Non-waived Testing and Subpart K is Quality System for Non-waived Testing.

**What is "Quality System"?**
Quality system is a new term that refers to all of your laboratory's policies, processes, procedures, and resources needed to achieve quality testing. Processes that were previously referred to as patient test management, quality control, and quality assurance are now collectively part of your laboratory's overall quality system.

**Introduction to Quality Systems**
If your laboratory performs non-waived testing, you must establish, maintain and implement written policies and procedures that monitor all phases of the total testing process (pre-analytic, analytic, and post-analytic) as well as general laboratory practices.

The various components of your laboratory's quality systems are used to meet CLIA requirements and should be appropriate for the specialties and subspecialties of testing you perform, the services you offer, and the clients your lab serves.

**Quality Assessment (QA)**
Quality assessment is the new term for quality assurance. The QA requirements have not changed, but they now appear in each applicable section of the regulations rather than in a separate section. This emphasizes the need to assess quality throughout the total testing system by incorporating these practices into the daily routine of your laboratory.

Each phase of your laboratory's path of workflow (general, pre-analytic, analytic, and post-analytic) should include a quality assessment component that ensures continuous improvement of your laboratory's performance and services. This is accomplished through ongoing monitoring that identifes, evaluates, and resolves problems. Make sure all these phases are addressed in your QA Plan.

**General Laboratory Practices**
General laboratory practices include those processes that are not particular to a specific phase of testing. These include the following:

- **Confidentiality of Patient Information**
  You must ensure confidentiality of patient information throughout all phases of the testing process that are under your laboratory's control.
- **Specimen Identification and Integrity**
  Your laboratory should have written policies and procedures that ensure positive identification and the integrity of a patient's specimen from the time it's collected (or received) through the completion of testing and reporting of results. It's necessary to ensure laboratory staff adhere to these policies.
- **Complaint Investigations**
  Your laboratory must have a process in place to ensure it documents all complaints and problems reported. You are required to conduct investigations of complaints, when appropriate.
- **Communications**
  Your laboratory is required to identify and document problems that occur as a result of a breakdown in communication between the laboratory and the person authorized to order or receive test results.

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

- **Evaluation of Proficiency Testing Performance**
  Your laboratory staff should review and evaluate proficiency testing results. In addition, you must verify the accuracy of the following:
  - Any regulated analyte or subspecialty that is not evaluated or scored by a CMS-approved proficiency testing program.
  - Any analyte, specialty, or subspecialty assigned a proficiency testing score that does not truly represent your laboratory's test performance (for example, when the proficiency testing program is unable to score the test due to lack of satisfactory agreement on scoring, or your laboratory receives a zero score for nonparticipation or late return of results).

  At least twice annually, your laboratory must verify the accuracy of any non-waived test or procedure you perform that is unregulated, or for which there are no compatible proficiency testing samples offered by a CMS-approved proficiency testing program. Remember to document all proficiency testing evaluation and verification activities.

**Quality Assessment of General Laboratory Practices**
Your laboratory must establish and follow written policies and procedures to actively monitor, assess, and correct problems identified in each of the general laboratory practices specified above. 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
- View the CMS Surveyor Procedures and Interpretive Guidelines at www.cms.hhs.gov/clia/03_interpretive_guidelines_for_laboratories.asp (The text written in italics that follows the regulation offers interpretation of the regulation and assistance with compliance.)