

*Response:* Although physicians with certain training or experience are qualified to serve as directors of laboratories performing high complexity testing, the notice of proposed rulemaking only included proposed revisions to the qualification requirements by which an individual with a doctoral degree may serve as a director of a laboratory that performs high complexity testing.

*Comment:* We received numerous comments on the qualification requirements for directors of laboratories performing histocompatibility testing. The majority of this group of commenters, which included the American Society of Histocompatibility and Immunogenetics (ASHI), and the American Board of Histocompatibility and Immunogenetics (ABHI), were in support of requiring specific histocompatibility training and experience for directors of laboratories performing histocompatibility testing. Specifically, they were in favor of requiring individuals with a doctoral degree to either meet the histocompatibility technical supervisor requirements specified in the former regulations at § 493.1449(o) and be certified by ABHI; or be serving or have served as a director of a histocompatibility laboratory and meet the histocompatibility technical supervisor requirements at § 493.1449(o). Opposing comments expressed concern that ASHI's proposal would exclude qualified individuals currently serving as directors of laboratories performing histocompatibility testing and is unnecessarily restrictive in an effort to protect the employment of those individuals who possess ABHI certification.

*Response:* We do not agree that the qualifications for directors of laboratories performing histocompatibility testing, which is categorized as high complexity testing, need to be revised to include specific histocompatibility training and education requirements. We note the revisions suggested by ASHI would establish higher director qualification requirements for individuals having a doctoral degree than for physicians who direct laboratories performing histocompatibility testing. In addition, these suggested changes to the qualifications for directors of laboratories performing histocompatibility testing would be inconsistent with the former qualifications required to direct laboratories performing other testing specialties. Although the commenters maintained that histocompatibility is

highly complex and requires specialized skills for direction, other specialty areas (for example, cytogenetics and pathology) are also complex and require specialized technical expertise. Under the CLIA regulations, the requirements for specialty training and experience are included under the qualification requirements for the technical supervisor, which vary depending on the specialty of service. The December 28, 2001 proposed regulation did not include technical supervisor requirements, and we are not making any changes to the former requirements for technical supervisors.

In addition, several commenters mistakenly thought that having the director meet the histocompatibility technical supervisor requirements would eliminate the need for two individuals. Two individuals are only needed when a particular individual is unable to meet both the laboratory director and histocompatibility technical supervisor qualification requirements.

Finally, while regulations specify the minimum requirements for compliance, accreditation organizations may establish higher requirements for laboratory accreditation.

*Subpart P—Quality Assurance for Moderate Complexity (Including the Subcategory), High Complexity Testing, or Any Combination of These Tests*

Following publication of the February 28, 1992 final rule with comment period, we received approximately 25 comments in reference to subpart P. The comments were in response to the requirements for enforcement of a written quality assurance policy. The laboratory's policy was required to address the ongoing and overall monitoring and evaluation of the quality of the total testing process and the laboratory's policies and procedures, identifying and correcting problems to ensure the accurate, reliable, and prompt reporting of test results, and to ensure the adequacy and competency of the staff. Over half of the comments received agreed with most of the requirements. Approximately 25 percent of the comments disagreed with some of the requirements or offered specific revised language.

Specific comments and responses regarding subpart P are set forth below.

*Comment:* One commenter suggested that the CLIA regulation specify who has primary responsibility for QA activities by adding a statement, for example, "The laboratory director is responsible for ensuring that a quality assurance program is established and maintained."

*Response:* We agree with the commenter. A requirement already appears at §§ 493.1407(e)(5) and 493.1445(e)(5), moderate complexity and high complexity laboratory director responsibilities, respectively, and states "The laboratory director must ensure that the quality control and quality assessment programs are established and maintained to ensure the quality of laboratory services provided and to identify failures in quality as they occur." In addition, we are now providing an introduction at § 493.1200, subpart K that provides an overview of what quality systems include, the importance of ongoing assessment of these systems, and the laboratory's responsibility for establishment and maintenance of appropriate policies and procedures. The term "quality assurance" is synonymous with the term "quality assessment." In addition, we are also making conforming changes ("assessment" replaces "assurance") where appropriate.

*Comment:* One commenter suggested adding text at § 493.1709, Comparison of test results, that would acknowledge the role the manufacturer may have in verifying the accuracy and reliability of test results at least twice a year. Other commenters suggested language to clarify that tests not included under subpart I, performed by the laboratory at various (multiple) testing sites, must also be evaluated twice a year.

*Response:* Manufacturers are not precluded from providing services to laboratories to assist in verification of the accuracy and reliability of test procedures. However, it is ultimately the responsibility of the laboratory to develop and implement protocols for the biannual evaluation and comparison of test results obtained using the different methodologies and instruments employed by the laboratory and various testing sites the laboratory may have (for example, central laboratory, satellite laboratories, point-of-care testing). In addition, the laboratory must, twice a year, verify the accuracy of any test it performs that is not listed in subpart I. Therefore, we believe the requirements, formerly at § 493.1709 (now at §§ 493.1281 and 493.1236), clearly state the testing that must be evaluated and the requirements remain unchanged.

*Comment:* We received a comment agreeing with the requirement at § 493.1707, Proficiency testing assessment. The commenter stated that all proficiency testing (PT) results that were not correct should be investigated. Another commenter stated that all regulated analytes must be graded or the PT program must notify HHS and the