

three proposed alternative qualification pathways were as follows:

- On or after January 1, 2003, be certified and continue to be certified by a board approved by HHS.
- Before January 1, 2003, must have served or be serving as a director of a laboratory performing high complexity testing and must have at least 2 years of laboratory training or experience, or both; and 2 years experience directing or supervising high complexity testing.
- Have at least 6 years of laboratory training or experience, or both, including 2 years of experience directing or supervising high complexity testing.

In this final rule, effective April 24, 2003, all laboratories must meet and follow the QC requirements. In addition, we are setting forth qualification requirements for an individual with a doctoral degree to serve as a director of a laboratory performing high complexity testing. Effective February 24, 2003, an individual with a doctoral degree may qualify to serve as a director of a laboratory that performs high complexity testing if he or she is certified and continues to be certified by a board approved by HHS; or before the effective date of this rule, has served or is serving as a director of a laboratory performing high complexity testing and has acquired at least 2 years of laboratory training or experience, or both, and 2 years of experience directing or supervising high complexity testing.

The qualification requirements for high complexity laboratory directors that are contained in this final rule will become effective February 24, 2003. To ensure a smooth transition to these new provisions, we will not be holding facilities out of compliance with the Board certified regulations of the former rule until the effective date of this new rule, to the extent the facilities are otherwise in compliance with the regulations for laboratory directors.

In addition, we are addressing the comments received in response to the February 28, 1992 final rule with comment period concerning part 493 of title 42 of the Code of Federal Regulations (CFR), subparts I, J, K, M, and P; comments received in response to the date-extension rules for certain provisions of subparts K and M; and comments to the December 28, 2001 proposed rule regarding qualification requirements for directors of laboratories performing high complexity testing.

## II. Highlights and Organization of Final Rule

This regulation contains revisions to part 493 of title 42 of the CFR. We have

renamed, reorganized, and consolidated similar requirements into one section, deleted duplicate requirements, and reworded numerous requirements to maintain and/or clarify their original intent, making the revised regulation easier to read and understand. In addition to specific changes to subparts I, J, K, M, and P, applicable technical and conforming changes were also made to other subparts.

The organization of this regulation now reflects the flow of a patient specimen through the laboratory, that is, from receipt of the specimen with the test request through test performance and test result reporting. In addition, this final rule more accurately describes the testing requirements and laboratory assessment activities.

In this final rule, the former Subpart I—Proficiency Testing Programs for Tests of Moderate Complexity (Including the Subcategory), High Complexity, or Any Combination of These Tests has been renamed Proficiency Testing Programs for Nonwaived Testing. In addition, in each specialty and subspecialty area of the subpart, we are restoring the requirement for the 80 percent agreement used by proficiency testing programs prior to the February 28, 1992 final rule with comment period.

The requirements formerly in Subpart J—Patient Test Management for Moderate Complexity (Including the Subcategory), High Complexity, or Any Combination of These Tests; Subpart K—Quality Control for Tests of Moderate Complexity (Including the Subcategory), High Complexity, or Any Combination of These Tests; and Subpart P—Quality Assurance for Moderate Complexity (Including the Subcategory) or High Complexity Testing, or Any Combination of These Tests, are consolidated and reorganized into a new Subpart J—Facility Administration for Nonwaived Testing, and Subpart K—Quality Systems for Nonwaived Testing.

As revised by this issuance, subpart J consolidates and clarifies the facility administration requirements for laboratories performing nonwaived testing. These include requirements for facility space, utilities and safety, transfusion services, and record and specimen retention. Also, subpart J now specifies that laboratories must comply with Federal, State, and local laboratory requirements. This will allow CMS to support a Federal, State, or local government that seeks to protect the public from actions it finds would be detrimental to public health. In addition, the requirements formerly at § 493.1111 (now at § 493.1242(c)) have

been revised to allow CLIA-certified laboratories to refer specimens to laboratories operated under the Veterans Administration (VA), the Department of Defense (DOD), and CLIA-exempt laboratories within a State whose licensure program has been granted approval under subpart E.

Requirements pertaining to the total testing process (preanalytic, analytic, and postanalytic) are now in subpart K. Specifically, subpart K has been revised to eliminate the QC requirements formerly at § 493.1202 and provisions pertaining to the FDA review and approval of manufacturers' test system QC for CLIA purposes as specified at § 493.1203 in the February 28, 1992 final rule with comment period. Also, subpart K is now structured to correlate with the movement of a specimen through the laboratory from acquisition to examination or testing, and reporting of results. The requirements were not substantively changed to correspond to the testing process, but we did eliminate redundant requirements and revise others for clarification.

In addition, subpart K now incorporates the requirements formerly in Subpart P—Quality Assurance; Moderate Complexity (Including the Subcategory) or High Complexity Testing, or Any Combination of These Tests. These requirements are now located under the appropriate sections in subpart K, that is, General Laboratory Systems, Preanalytic Systems, Analytic Systems, and Postanalytic Systems. We listed the quality assurance (renamed quality assessment (QA) to more clearly reflect the activities performed) activities for each phase of testing. For example, QA requirements for preanalytic activities, such as monitoring the medical necessity and completeness of test request information solicited and obtained by the laboratory, now appear at the end of the preanalytic section of subpart K under § 493.1249. We believe that integrating the QA requirements into the various phases of the testing process enhances the understanding of the vital and important role QA plays in ensuring that quality services are provided by the laboratory throughout the entire testing process. To further emphasize and clarify the essential components of a comprehensive QA program, we are reiterating in each assessment section the laboratory's responsibility to: (1) Establish and follow written policies and procedures for an ongoing mechanism to monitor and assess each of its activities; (2) take corrective actions, as necessary, based on these assessments; (3) review the effectiveness of the assessments and corrective actions