

laboratories, if manufacturer instructions and laboratory specifications allow, performance of two control testing events per day can be eliminated for each hematology analyzer. Therefore, the aggregate savings may be significant, but we cannot estimate the impact.

#### Alternative Approaches

For these three changes, the aggregate impact will be a cost savings; however, we have insufficient information to estimate the reduced burden or savings in reduced analyst time, cost of reagents, and control materials associated with the reduced frequency of control material testing. We considered leaving the requirements for control procedures unchanged; however, based upon the current stability of the test systems used in these three areas, we have determined that few additional testing errors would be prevented by more frequent control testing.

#### 4. Completion of Laboratory Director Phase-in

We are completing the phase-in qualification requirement for high complexity laboratory director that allows individuals with a doctoral degree to qualify based on training and experience in lieu of board certification. With the implementation of this final rule, board certification will be required under one provision. However, under the second provision, we are allowing individuals, who qualified under the phase-in provision and who have served or are now serving as directors of laboratories performing high complexity testing and have at least 2 years of training or experience, or both, and 2 years of experience directing or supervising high complexity testing to continue to serve as laboratory directors. To ensure a smooth transition to the new provisions for directors of high complexity testing who are not board certified (but who have doctoral degrees), we will not be holding facilities out of compliance with the provisions of the rule concerning directors who are not board certified until the effective date of this new rule, to the extent the facilities are otherwise in compliance with the requirements for laboratory directors.

#### Rationale

Personnel qualifications are considered an essential benchmark of performance and requiring appropriate qualifications for the complexity level of testing performed by the laboratory is in the best interest of quality testing. High complexity testing requires more

extensive knowledge, training, and experience to perform the management and administrative duties necessary to ensure that personnel are competent, methodologies are appropriate, and the quality control and quality assessment programs are suitable for the testing performed. The high complexity laboratory director qualification requirements in this final rule balance the quality concerns with the need to ensure continued access to high complexity testing.

#### Methodology

To determine the impact of these laboratory director qualification requirements over time on laboratories performing high complexity testing, we estimated the number of high complexity laboratories potentially impacted and the number of qualified individuals available to serve as high complexity laboratory directors during the next 5 years.

#### Laboratory Demographics

Using the CMS OSCAR (2001) database, we have determined that approximately 8,000 of the 22,720 Certificate of Compliance (COC) laboratories (35 percent, or 4.7 percent of all CLIA laboratories) perform some high complexity testing. To determine the total number of Certificate of Accreditation (COA) laboratories that perform high complexity testing, we included the approximately 9,200 laboratories accredited by five of the CLIA-approved accreditation organizations (American Association of Blood Banks, American Osteopathic Association, American Society for Histocompatibility and Immunogenetics, College of American Pathologists, and Joint Commission on Accreditation of Healthcare Organizations). The majority of these laboratories are independent or hospital-based and are assumed to perform some high complexity testing. We also estimated that approximately 1,700 of the 6,881 COLA-accredited laboratories (25 percent) perform some high complexity testing. In addition, the number of high complexity laboratories in the two CLIA-exempt States, New York (540) and Washington (235), is approximately 775 laboratories (New York and Washington, personal communication, March 2002). Therefore, the total number of CLIA laboratories (including New York and Washington) performing some high complexity testing in the United States is estimated to be approximately 19,700 laboratories.

As previously mentioned and illustrated at Table 4, the percentages of

laboratories with each certificate type have remained stable over the past several years; however, the absolute numbers show trends toward lower complexity levels (waiver and PPM). While we expect this trend to continue in the future because of the widening availability of waived tests, we assume that COC laboratories switching to waiver and PPM certificates are those that perform only moderate complexity testing and the number of COC laboratories performing some high complexity testing will remain stable. In addition, we assume the number of accredited laboratories performing some high complexity testing will remain fairly stable, as has been the trend in the past several years.

#### High Complexity Laboratory Director Demographics

We also used the OSCAR (2001) database to identify the CLIA qualification requirements by which those individuals currently serving as laboratory directors of COC high complexity laboratories qualified. Using this data, we have calculated that 28 percent of these laboratories are directed by board-certified pathologists; 56 percent by licensed physicians with laboratory training or experience; 5 percent by individuals with doctoral degrees; 3 percent by individuals who have been serving as laboratory directors and were qualified as a laboratory director on or before February 28, 1992 (according to the March 14, 1990 final rule with comment period (55 FR 9538) published in the **Federal Register**); 7 percent by individuals who on or before February 28, 1992 were qualified under State law to direct a laboratory in the State in which the laboratory was located; and less than 1 percent by individuals who meet the qualifications currently at § 493.1443(b)(6) for the subspecialty of oral pathology.

We assume individuals currently serving as high complexity laboratory directors will retire at approximately the same rate as projected for the general population; that is, on average 3.8 percent per year for fiscal years 2001 through 2005 (U.S. Office of Personnel Management, Central Personnel Data Files, 2000). Therefore, we anticipate 3.8 percent of the approximately 19,700 high complexity laboratories (750) will need to hire a new laboratory director each year for the next 5 years. Pool of Individuals Qualified to Serve as High Complexity Laboratory Directors.

Using data (September 2000) from the American Board of Medical Specialties (ABMS), we estimated the total number of physicians that have 1 year of