

for this final rule's personnel qualification requirements, and we are clarifying the training and experience requirements individuals must meet. 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. Individuals must, therefore, as of February 24, 2003, have at least 2 years of training or experience, or both; and 2 years of experience directing or supervising high complexity testing.

*Comment:* Several commenters (including one laboratory professional organization and one certification board) felt continuing education should be added as a requirement to the second proposed provision.

*Response:* We acknowledge that continuing education is important; however, the proposed rule did not include a continuing education component for this provision. In addition, when "grandfathering" individuals who are serving or who have served in a particular position, minimum qualification requirements are considered so as not to disenfranchise these individuals. Finally, while regulations specify minimum requirements, States, accreditation organizations, and certification boards may establish more stringent requirements.

*Comment:* The majority of the commenters were opposed to including the third provision (at proposed § 493.1443(b)(3)(iii)). While there was general agreement that training and experience is essential for direction of high complexity testing, a few commenters (including a certification board and a laboratory professional organization) noted that training and experience vary greatly and it would be inappropriate to use training and experience as sole criteria to qualify individuals with a doctoral degree to direct high complexity testing. CLIA also recommended that this provision be eliminated because it would not provide adequate documentation of the knowledge and skills needed for directorship of high complexity testing, lacks a mechanism to ensure continued competency, and is not commensurate with the high complexity laboratory director responsibilities. Several commenters noted that this proposed qualification pathway might result in an

increase in the quantity of individuals qualified to direct high complexity testing at the expense of quality, which is in part attributed to a competent workforce. Although a few commenters agreed with this proposed provision to provide qualification specifications based on training and experience in lieu of board certification, they suggested revisions to make the provision more stringent and felt continuing education should be added to ensure that individuals maintain competency.

*Response:* We agree with the comments expressing disagreement with the third proposed qualification pathway and are not including it in this final rule. Although high complexity procedures comprise less than 20 percent of the laboratory procedures categorized, these are the most complex tests requiring a broad-based knowledge and the highest skills to fulfill the director responsibilities (formerly at § 493.1445) and ensure quality testing. Therefore, we believe the knowledge and training of a high complexity laboratory director with a doctoral degree can best be demonstrated through board certification. In addition, in the former regulations, we provided phase-in qualification requirements that allow individuals with a doctoral degree to qualify based on training and experience in lieu of board certification until the specified expiration date. As mentioned earlier, on five separate occasions, we extended the phase-in provision to allow time for directors who were not board certified to complete the certification requirements and for HHS to review and approve certification boards. During the 10 years the phase-in provision has been in effect, HHS has approved five additional boards and we believe sufficient time has been provided for individuals to become aware of the board certification requirement. Moreover, recent efforts of certification boards have provided additional routes to certification, allowing more individuals to meet the certification requirements.

In this final rule, board certification will be required for an individual with a doctoral degree seeking to become a high complexity laboratory director on and after February 24, 2003. However, as previously mentioned, we are allowing individuals, who qualified under the phase-in provision and are now serving or have served as directors of laboratories performing high complexity testing, to continue to serve as laboratory directors.

*Comment:* A few commenters disagreed with requiring a doctoral degree as the minimum education requirement for directors of laboratories

performing high complexity testing. They suggested that individuals with an appropriate master's degree and progressive experience in the clinical laboratory (5 to 10 years) should be able to qualify.

*Response:* We believe the doctoral degree is an appropriate minimum education requirement for directors of laboratories performing high complexity testing. It is commensurate with the responsibilities of a high complexity laboratory director, as specified in the former regulations at § 493.1445, and consistent with the education requirements and responsibilities specified for the other laboratory personnel categories described in subpart M of the regulations.

*Comment:* Several commenters from local, county, and public health officials in a State disagreed with the doctoral degree requirement and cited the State Code that allows an individual with a baccalaureate or master's degree to direct a public health laboratory. The commenters noted that although the public health laboratories currently have a director who meets the CLIA regulations, many of these directors qualified under the former regulations at § 493.1443(b)(5), the "grandfather" provision that qualifies individuals if on or before February 28, 1992, they were qualified as a director under State law. Many of these directors will retire within 5 years.

*Response:* For the reasons stated previously, we believe the education requirements for directors of high complexity laboratories are appropriate and should not be lowered. In addition, as noted by the commenters, the February 28, 1992 final rule with comment period included a grandfather provision that qualified individuals that were serving as laboratory directors under State law on or before that date. We also provided a phase-in provision, which allows individuals with doctoral degrees time to obtain board certification by the specified expiration date. The phase-in provision was extended on multiple occasions and during this 10-year period HHS has approved five additional boards. We believe sufficient time has been provided for individuals to become aware of the requirements. In this regard, the State revised its statutes in a February 18, 1998 amendment and now requires any city or county public health laboratory and its personnel to comply with the CLIA regulations.

*Comment:* One commenter thought the proposed regulation would only allow physicians to serve as directors of laboratories performing high complexity testing.