

personnel have the necessary education and training or experience required for test performance.

#### Testing Personnel Qualifications (High Complexity)

*Comment:* Numerous commenters believed an associate degree in laboratory science or medical laboratory technology should be the minimum education requirement. Several commenters suggested recognizing associate degrees in fields other than clinical laboratory science or medical laboratory technology, with others suggesting equivalent requirements be established for the associate degree.

*Response:* Currently, the qualification requirements for high complexity testing personnel contain provisions that prospectively require high school graduates to obtain an associate degree. As mentioned above, in evaluating the comments received concerning high complexity testing personnel, we sought the advice of the CLIAC about the appropriateness of the qualifications required. The CLIAC recommended that the associate degree be established as the minimum education requirement and, in addition, that equivalent academic requirements be established for the associate degree. In this regulation, we are adding a provision to qualify individuals who have completed specific college courses but do not have an associate degree or who have an associate degree that is not in medical laboratory technology or a laboratory science. As previously mentioned, we have defined requirements equivalent to the associate degree (60 semester hours that must include 24 semester hours of medical laboratory technology courses or 24 semester hours of science courses that include six semester hours of chemistry, six semester hours of biology and twelve semester hours of courses in chemistry, biology or medical laboratory technology, or any combination); individuals qualifying under the equivalency provisions also must have completed either an accredited clinical laboratory or medical laboratory training program (which may be included in the 60 semester hours) or three months of documented training in each specialty in which the individual performs high complexity testing. The laboratory training may be acquired before, during or after completing the academic requirements.

*Comment:* Many commenters recommended recognizing medical laboratory technicians without an associate degree. Commenters also recommended qualifying individuals, including certified laboratory assistants, who received training in an accredited

hospital or technical school training program. A large number of commenters suggested qualifying individuals with military training.

*Response:* We agree with the commenters that, in addition to the revisions made to the general supervisor requirements, revisions are needed in the qualification requirements for high complexity testing personnel to recognize individuals who have completed a nondegree clinical laboratory training program and, therefore, have equivalent training. Therefore, we are adding to the high complexity testing personnel requirements, a provision to qualify individuals who, on or before April 24, 1995 have completed a 50-week U.S. military medical laboratory training program or have graduated from a medical laboratory or clinical laboratory training program accredited by the Accrediting Bureau of Health Education Schools, Commission on Allied Health Education Accreditation or other organization approved by HHS.

*Comment:* A number of commenters recommended that the regulations be revised to qualify all currently employed high complexity testing personnel. Other commenters said currently employed high school graduates, who were trained on the job, should be allowed to continue performing high complexity testing but only under supervision.

*Response:* We agree with the CLIAC recommendation that the regulations should be revised to alleviate the impact on currently employed personnel. We also believe that high school graduates with appropriate training, who were performing high complexity testing on or before April 24, 1995 have obtained sufficient work experience to allow them to continue performing testing with supervisory oversight. Therefore, we are revising the regulations to allow these individuals to continue performing high complexity testing even after September 1, 1997 (the current limit) and do not require that they obtain additional training or education. However, performance of any high complexity testing by these individuals must be in accordance with the supervision requirements discussed below.

*Comment:* A few commenters agreed with the responsibility requirements for high complexity testing personnel, while numerous commenters disagreed. The majority of the commenters who disagreed were opposed to requiring onsite supervision when individuals who do not have an associate degree perform high complexity testing.

*Response:* As previously mentioned above under the discussion of qualifications of the general supervisor, in the regulation published in the **Federal Register** on January 19, 1993, we changed the requirement for onsite supervision to only require 24-hour review of any high complexity testing performed by personnel who do not have an associate degree and who were performing high complexity testing on or before January 19, 1993. The onsite supervision requirement was retained only for those high school graduates, or equivalent, who began performing high complexity testing after January 19, 1993. In this regulation, we are not changing the requirements for onsite supervision or 24-hour review. However, we believe individuals who have completed accredited or U.S. military laboratory training programs or have qualifications equivalent to the associate degree and have appropriate laboratory training are qualified to perform high complexity testing without supervision. Therefore, we are revising the qualification requirements for high complexity testing personnel to allow individuals having these qualifications to perform high complexity testing without onsite supervision or 24-hour review.

### III. Other Revisions

We are making the following technical changes in addition to those discussed above:

- We are making minor editorial changes to improve clarity and remove redundancies. This includes removing §§ 493.610, 493.614, 493.618, 493.622, 493.626, 493.629, 493.630, 493.631, 493.632, 493.633 and 493.634.
- We are revising the definition of "certificate of registration" in § 493.2 to exclude reference to laboratories that are exempt from CLIA requirements because they are licensed by a HCFA-approved laboratory licensure program: these laboratories are not required to obtain a registration certificate.
- From the definition of "physician" in § 493.2 we are deleting the phrase "or equivalent degree" as there are no degrees equivalent to doctor of medicine, osteopathy or podiatric medicine.
- To §§ 493.35(d)(2) and 493.37(b)(2) we are adding a requirement that a laboratory seeking a certificate of waiver must permit announced inspections by HHS (as well as unannounced) because it was inadvertently omitted from the January 19, 1993 rule.
- In §§ 493.35(d)(2)(iv), 493.49(b)(2)(iv), 493.1776(a)(4) and 493.1776(b)(4)(iv), we indicate that we will collect information during