

requirement should be an associate degree with area of study not specified. Some commenters said that requirements equivalent to the associate degree should be established. Several commenters indicated that individuals having a bachelor of arts or education degree with a specified number of science courses should be qualified.

*Response:* We agree with the commenters who suggested the establishment of requirements equivalent to the associate degree with appropriate study in the sciences because we believe individuals who have completed the requisite courses and training are qualified to supervise high complexity testing. In this regulation, we are defining the following as equivalent to the academic requirements for an associate degree: 60 semester hours, which must include either 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. In addition, individuals must have completed either an accredited clinical laboratory or medical laboratory training program (which may be included in the 60 semester hours specified above) or three months of documented training in each specialty in which the individual performs high complexity testing. We are specifying the equivalent requirements for the associate degree under high complexity testing personnel, which are adopted by cross-reference to the general supervisor requirements. Therefore, individuals who do not have a degree or who have a bachelor's degree that is not in a science can now qualify as a general supervisor if they meet the equivalency requirements for an associate degree and have at least two additional years of laboratory training or experience in high complexity testing.

*Comment:* Many commenters recommended qualifying medical laboratory technicians without an associate degree to serve as general supervisor. Some commenters recommended qualifying individuals, including certified laboratory assistants, who received training in an accredited hospital or approved technical school training program. Other commenters recommended qualifying individuals with military training.

*Response:* We agree with the commenters that the regulations should recognize individuals who were serving as a general supervisor of high complexity testing on or before

September 1, 1992 (the effective date of the CLIA personnel regulations) but do not have an associate degree, or equivalent, provided they have completed an accredited clinical laboratory training program. We believe individuals having this training and experience have the appropriate qualifications to serve as a general supervisor. Therefore, we are adding a provision to the general supervisor qualification requirements to qualify individuals who, on or before September 1, 1992, were serving as a general supervisor of high complexity testing. The individual must 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. To help assure equivalency to other qualification pathways, individuals having this type of training are required to have two additional years of laboratory training or experience in high complexity testing in order to qualify as general supervisor. This additional training or experience may be acquired before or after completing the accredited or U.S. military medical laboratory training program.

*Comment:* Several commenters misread the regulations and thought that individuals qualified under regulations published March 14, 1990 (55 FR 9576) were required to obtain an associate degree.

*Response:* Individuals who qualified as general supervisors under the previous Federal regulations are qualified under these regulations and are not required to obtain an associate degree.

*Comment:* Some commenters recommended that all laboratory personnel currently employed as general supervisors be qualified through a "grandfather" provision.

*Response:* We agree with the commenters and the CLIA recommendation that regulations should include provisions to allow currently employed supervisors who have pertinent laboratory experience to continue their employment. We are adding a provision to the general supervisor requirements to qualify high school graduates, or equivalent, who, on or before September 1, 1992, were serving as a general supervisor and have at least ten years of laboratory training or experience in high complexity testing, including at least 6 years of

supervisory experience in high complexity testing within the last 10 years because we believe this amount of experience is appropriate to qualify individuals as general supervisors and is commensurate with the general supervisor responsibility requirements.

*Comment:* A few commenters agreed with the responsibilities for general supervisor, while a few commenters disagreed. Most of the commenters who disagreed with the responsibilities were opposed to requiring the general supervisor to be onsite when high complexity tests are performed by personnel who do not have at least an associate degree. Conversely, many commenters indicated that an individual with an associate degree should be allowed to perform high complexity testing only when a technologist or supervisor is onsite.

*Response:* In the revised regulation published in the **Federal Register** on January 19, 1993, we changed the requirement for onsite supervision to require 24-hour review of any high complexity testing performed by personnel who do not have at a minimum an associate degree and were performing high complexity testing on or before January 19, 1993. However, in the January 19, 1993 regulation, we retained the onsite supervision requirement 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 50-week U.S. military medical laboratory training programs or have academic qualifications equivalent to the associate degree are qualified to perform high complexity testing. Therefore, we are revising the regulations to qualify as high complexity testing personnel individuals having these qualifications. Individuals who qualify under these new provisions may perform high complexity testing without onsite supervision or 24-hour review.

We do not agree with the commenters that onsite supervision should be required for high complexity testing performed by individuals having an associate degree; such a requirement would be unnecessarily burdensome and could exacerbate personnel shortages and limit patient access to testing. It should be emphasized that these are minimum requirements that do not restrict laboratories from establishing their own policies requiring higher personnel qualifications. In all cases, the laboratory director is responsible for ensuring that all testing