



ADDITIONAL PATHWAYS TO QUALIFY AS GENERAL SUPERVISOR/ TESTING PERSONNEL FOR HIGH COMPLEXITY

On April 24, 1995, CMS published a regulation to recognize alternate pathways for individuals to qualify as a general supervisor for high complexity testing to avoid adversely affecting many individuals currently acting as general supervisors. The regulation also modified the requirements for high complexity testing personnel to reduce unnecessary on-site supervision requirements of certain qualified individuals.



General Supervisor
Previously, at least an associate degree in a laboratory science or in medical laboratory technology from an accredited institution, and two years laboratory training or experience in high complexity testing

was required to supervise high complexity testing. The regulation added more flexibility to the academic requirements by establishing equivalency options for the associate degree.

Individuals who do not have an associate degree can qualify as the general supervisor, provided they have 60 semester hours or equivalent from an accredited institution. The hours must include either 24 semester hours of medical technology courses or 24 semester hours of science courses (including 6 hours of chemistry, 6 hours of biology, and 12 hours of courses in chemistry, biology, or medical laboratory technology, or any combination).

In addition, these individuals must have completed either an accredited clinical laboratory or medical laboratory training program (this training program may be included

in the total 60 semester hours required), or have three months of documented training in each specialty in which the individual performs high complexity testing. All individuals using this pathway to qualify as a general supervisor, including individuals who do not have a degree or who have a bachelor's degree that is not in a science, must have at least two years of laboratory training or experience in high complexity testing.

The regulation grandfathers individuals who were serving as a general supervisor of high complexity testing on or before September 1, 1992, but who do not have an associate degree or the equivalent, provided they have completed an accredited clinical laboratory training program. The individual must have completed, on or before April 24, 1995, 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, the Commission on Allied Health Education, or other organizations approved by the Department of Health and Human Services (HHS). Individuals with this type of training must have two years of training or experience in high complexity testing to qualify as a general supervisor.

Finally, all high school graduates or equivalent who, on or before September 1, 1992, were serving as a general

supervisor and have at least 10 years of laboratory training or experience in high complexity testing, including at least six years of supervisory experience in high complexity testing between September 1, 1982 and September 1, 1992, are qualified as general supervisor under CLIA.

Testing Personnel

The regulations require on-site supervision or 24-hour review (by the general supervisor) of the performance of high complexity testing by qualified high school graduates. High school graduates who were performing high complexity testing prior to January 19, 1993, are subject to the 24-hour review of test results requirement, whereas all others are required to have on-site supervision.

The regulation allows those high school graduates who have graduated from an approved or accredited medical laboratory or clinical laboratory training program, or completed a 50-week U.S. military medical laboratory training program to perform high complexity testing without on-site supervision or the 24-hour review of test results. The regulation also specifies that the following individuals can perform high complexity testing:

- Individuals who have completed college courses as defined for academic equivalency to an associate degree in laboratory science or medical laboratory technology.
- Individuals who have completed a non-degree clinical laboratory training program on or before April 24, 1995, including the 50-week U.S. military medical laboratory training program, or have graduated from a medical or clinical laboratory training program accredited by the Accrediting Bureau of Health Education Schools, the Commission on Allied Health Education, or other organizations approved by HHS.
- Individuals with a high school diploma who were performing high complexity testing on or before April 24, 1995. These individuals may continue to perform high complexity testing and are not required to obtain additional formal training or education (under the original CLIA rules these individuals were required to obtain an associate degree by September 1, 1997). Individuals who began performing high complexity testing AFTER April 24, 1995, were only allowed to continue to do so until September 1, 1997. Those individuals were required to obtain an associate degree or meet other requirements listed above by that date to continue performing high complexity testing. The supervision requirements discussed earlier apply to high school graduates.