



MEETING PERSONNEL STANDARDS FOR HIGH COMPLEXITY

In 2003, the final CLIA regulations were published. Changes included were designed to streamline the regulatory process. In most cases, testing is now classified as waived or non-waived. The only requirements that still make a distinction between high complexity and moderate complexity are the personnel standards.

The amount of education and/or experience required for laboratory personnel depends on the complexity of the testing performed in your laboratory. Laboratories performing high complexity testing should make sure that they employ individuals qualified to fill the required positions for high complexity - laboratory director, technical supervisor, general supervisor, clinical consultant, and testing personnel. Please note that some states also require that laboratory personnel are licensed by the state.

Laboratory Director

The laboratory director is responsible for the overall operation of the laboratory and the competency of all laboratory personnel. The director should also ensure that all tests are performed according to applicable requirements, that quality control (QC) and quality assessment (QA) programs are established, and that the laboratory is enrolled in a CMS-approved proficiency testing program. Some responsibilities of the laboratory director can also be delegated, in writing, to other qualified individuals.

The laboratory director can be a physician certified in anatomic or clinical pathology. Physicians with one year of laboratory training during their residency or at least two years of clinical experience directing or supervising high complexity testing can also serve as the director.

In addition, an individual with a doctoral degree in a chemical, physical, or biological science who is also board certified* can serve as director. Beginning

February 24, 2003, all new PhD directors of high complexity testing must be certified by an approved board. PhD directors who are not board-certified but were directing (or have previously directed) high complexity testing before February 24, 2003, may continue to serve as director under a grandfather clause. Another grandfather clause specifies that, if prior to February 28, 1992, any individual was qualified under state law or Medicare lab regulations as the director he or she may continue to serve as the laboratory director.

Technical Supervisor

The technical supervisor is responsible for overseeing the technical and scientific aspects of the laboratory. It is not necessary for the technical supervisor to be on-site or full-time, but the person should be accessible to laboratory staff. The director may function as the technical supervisor, thereby eliminating the need to hire an additional individual, provided the director meets the qualifications.

For all specialties/subspecialties except for histocompatibility and cytogenetics, the technical supervisor can be a physician certified in anatomic and clinical pathology. Licensed MDs and DOs can act as technical supervisors provided they have the necessary training or experience.

For the subspecialties of bacteriology, mycobacteriology, mycology, virology, or parasitology, a physician with one year of training or experience in high complexity microbiology, which includes six months of experience in the appropriate subspecialty, could serve as technical supervisor. The requirements for chemistry, diagnostic immunology, hematology, and radiobioassay are the same; however, there is no minimum six-month subspecialty requirement.

Individuals with a doctoral, master's, or bachelor's degrees in a chemical, physical, biological, or laboratory

science and the appropriate experience can serve as the technical supervisor.

For the subspecialties of bacteriology, mycobacteriology, mycology, virology, and parasitology individuals with a master's degree, as specified, and two years of laboratory training or experience in high complexity microbiology testing with a minimum of six months in the appropriate subspecialty can act as a technical supervisor. An individual with a bachelor's degree, as specified, and four years of laboratory training or experience in high complexity microbiology testing with a minimum of six months in the appropriate subspecialty can act as a technical supervisor.

For diagnostic immunology, chemistry, hematology, and radioassay the education, training, and experience requirements are the same for an individual with a master's or bachelor's degree; however, there is no six-month subspecialty requirement.

Some specialties such as immunohematology have more specific requirements not discussed in this fact sheet. You may refer to the CLIA regulations for detailed information on these requirements.

Clinical Consultant

The clinical consultant is responsible for determining the appropriateness of tests ordered and interpreting test results. This function must be filled by a licensed physician or an individual with a doctoral degree who is board certified. The laboratory's director can also be the clinical consultant provided the director is a physician, or has a doctoral degree and board certification.

General Supervisor

The general supervisor provides on-site supervision of testing personnel. The laboratory director and/or qualified technical supervisor can also serve as the general supervisor. Individuals with a doctoral, master's, or bachelor's degree in a chemical, physical, biological, or laboratory science and one year of training or experience in high complexity testing, or individuals with an associate's degree in laboratory science and two years laboratory training or experience can serve as general supervisor.

In 1995, CMS published regulations establishing equivalency requirements for the associate degree individual and established other pathways for individuals to qualify as the general supervisor. These requirements are the subject of *CLIA Facts 25: Additional Pathways to Qualify as General Supervisor/Testing Personnel for High Complexity*.

Testing Personnel

At a minimum, individuals with a high school diploma who were performing high complexity testing on or before April 24, 1995 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 by that date to continue performing high complexity testing. The supervision requirements discussed below apply to high school graduates.

The work of high school graduates employed prior to January 19, 1993, should be reviewed by a qualified general supervisor within 24 hours. High school graduates who are employed after January 19, 1993, must have on-site supervision. Individuals who have completed an accredited or 50-week U.S. military medical laboratory training program, or who have academic qualifications equivalent to the associate degree are qualified to perform high complexity testing without on-site supervision or a 24-hour review of test results. Individuals who began performing high complexity testing after April 24, 1995 must have, at a minimum, an associates degree or equivalent.

The equivalency requirements for the associate degree testing personnel are addressed in *CLIA Facts 25: Additional Pathways to Qualify as General Supervisor/Testing Personnel for High Complexity*.