



MEETING PERSONNEL STANDARDS FOR MODERATE 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 training or experience required for laboratory personnel depends on the complexity of the testing performed in your laboratory. Labs performing moderate complexity testing should make sure they employ individuals qualified to fill the required positions for moderate complexity -- laboratory director, technical consultant, clinical consultant, and testing personnel. A qualified individual may hold more than one of these positions. Please note that some states require laboratory personnel to be licensed by the state.

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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, quality control (QC) and quality assessment (QA) programs are established, and the laboratory is enrolled in a CMS-approved proficiency testing program.

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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 one year of clinical experience directing or supervising moderate complexity testing can also serve as the director.

Physicians without one year of experience directing a moderate complexity laboratory can qualify as a director by taking 20 continuing medical education (CME) credits of training on the responsibilities of the laboratory director. Continuing education credits can be obtained through a variety of sources, including www.labuniversi-ty.org.

An individual with a doctoral degree in a chemical, physical, biological, or laboratory science and board certification* or one year of experience directing or supervising non-waived testing can also qualify as lab director. An individual with a master's degree in a chemical, physical, biological, or lab science or medical technology with one year of training or experience and one year supervisory experience in non-waived testing can serve as the director.

Two years of training or experience and two years of supervisory experience in non-waived testing are required for individuals with a bachelor's degree (chemical, physical, biological, or laboratory science or medical technology).

If an individual was qualified as the director prior to February 28, 1992, under state law or Medicare lab regulations he or she may continue to serve as the laboratory director. In addition, some responsibilities of the lab director can be delegated in writing to other qualified individuals.

Technical Consultant

The technical consultant is responsible for technical and scientific oversight of the laboratory. It is not necessary for the technical consultant to be on-site but the individual should be accessible by phone or other electronic means. The director may function as the technical consultant provided he/she meets the qualifications. To qualify, the physician should have at least one year of training or experience in non-waived testing in the specialty or subspecialty of service provided.

Due to the complexity of CLIA and the time commitment required to comply, some physicians with office laboratories hire an outside, part-time technical consultant to establish and monitor the QA, QC, and patient test management systems required by CLIA. Individuals with master's or bachelor's degrees in laboratory science and one or two years of experience respectively in non-waived testing in the designated specialty or subspecialty of testing, may serve as technical consultant.

Clinical Consultant

The clinical consultant is responsible for determining the appropriateness of tests ordered and test result interpretation. This function must be filled by a licensed physician or an individual with a doctoral degree who is board certified. The lab director can also be the clinical consultant provided the director is a physician or board-certified PhD.

Testing Personnel

At a minimum, testing personnel should have a high school diploma or equivalent (GED) and documented training appropriate to the testing being performed.

For example, the laboratory director should document training in specimen collection, labeling, and preparation; laboratory procedures; preventive maintenance, troubleshooting, and calibration; QC procedures; factors influencing test results; and validation of patient results with QC prior to reporting.