

CLIA Corner

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In this issue of the CLIA Corner we address:

- ***Part 2: Personnel Policies for Individuals Directing or Performing Non-waived Tests; including Primary Source Verification.***

Background

The Centers for Medicare & Medicaid Services (CMS) issued a Survey & Certification memorandum titled “Personnel Policies for Individuals Directing or Performing Non-waived Tests” (Ref: S&C: 16-18-CLIA) dated April 1, 2016 (revised on May 3, 2016). This memorandum allows CMS CLIA surveyors to accept primary source verification (PSV) documentation as evidence of laboratory compliance with the personnel requirements. In addition, this memorandum also answered questions and gave clarification on other commonly asked CMS personnel policies. Part 2 of the CLIA Corner will address these questions.

What are the Provider Performed Microscopy (PPM) Personnel Qualifications?

- **Laboratory Director:** must be a Doctor of Medicine (MD); Doctor of Osteopathy (DO); Doctor of Podiatric Medicine (DPM), Doctor of Dental Surgery (DDS), or a midlevel practitioner as defined in §42 CFR 493.2 (nurse midwife, nurse practitioner, physician assistant) and must be licensed by the State in which the laboratory is located, if required by that State.
- **Testing Personnel:** must be a Doctor of Medicine (MD); Doctor of Osteopathy (DO); Doctor of Podiatric Medicine (DPM), Doctor of Dental Surgery (DDS), or a midlevel practitioner as defined in §42 CFR 493.2 (nurse midwife, nurse practitioner, physician assistant) and must be licensed by the State in which the laboratory is located, if required by that State. Only these individuals are qualified to perform PPM testing; otherwise, routine moderate complexity personnel and other applicable requirements apply and the laboratory must obtain a certificate of accreditation or compliance.

Does CLIA accept professional certification and state licensure when qualifying testing personnel?

CMS Central Office (CO) continues to receive inquiries from CLIA surveyors as to whether the laboratory can present an individual’s professional certification, such as medical technology certification or nursing licenses, as the only type of documentation to meet the CLIA personnel requirements. This type of documentation **IS NOT** considered sufficient evidence of meeting the personnel qualifications. More detailed information, such as degrees, transcripts, or PSV documents verifying degrees and transcripts, are required.

One exception to this exists where professional certification is required by the CLIA regulations: cytologists and cytology general supervisor positions require American Society of Clinical Pathology (ASCP) certification, **in addition** to documentation of their highest level of academic achievement in education, training, and experiential requirements.

What are the CLIA requirements for foreign trained personnel?

The CLIA regulation and interpretive guidelines at §42 CFR 493.2 state, “Individuals who have degrees from foreign institutions must have an evaluation of their credentials to determine the equivalency of their education to an education obtained in the United States (U.S.). The equivalency evaluations should be on a course-by-course basis and may be performed by a nationally recognized organization. These may include such organizations as the National Association Credential Evaluation Services, Inc. (NACES) (<http://www.naces.org>) and the Association of International Credential Evaluators, Inc. (AICE) (<http://www.aice-eval.org>).”

CLIA clarifies in S&C 16-18-CLIA letter that foreign trained physicians (M.D., D.O., DDS) who are licensed to practice in the State in which the laboratory is located do not need to produce educational equivalencies. A valid State license is sufficient proof of academic achievement. **However**, moderate and high complexity testing personnel who attended a foreign school would still need to have foreign equivalencies done. Per the SOM, Chapter 6, Section 6122 states “personnel employed in laboratories subject to CLIA that perform tests of moderate and/or high complexity must meet the specific education, training, and experience requirements. Individuals who attended foreign schools **MUST** have an evaluation of their credentials determining equivalency of foreign to United States education.”

How does CMS verify a home schooling degree?

There is no standardized approach to home schooling across the country. Should a surveyor be presented with a home school diploma, in general, they would accept the home school diploma at face value and focus on the employee’s training and competency. At this time, CMS is not aware of any primary source verification company that verifies home school programs.

Are primary source verification companies able to verify military training?

Primary source verification companies are able to verify most military schooling and training. If the PSV company is unable to provide verification of the successful completion of “an official U.S. Military medical laboratory procedures training course of at least 50 weeks duration and that the applicant has held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician),” (§493.1423(b)(3) for moderate complexity testing and §493.1489(b)(4)(ii) for high complexity testing), the laboratory must present documentation that the testing personnel has the qualifications to meet the CLIA personnel requirements.

Does CLIA accept Regents Bachelor’s Degree (RBD) when qualifying testing personnel?

An RBD is a baccalaureate degree program designed for adult students. The basic principle is that credit is awarded for what students know regardless of how that knowledge was obtained. In other words, students may earn college-equivalent credit for work and life experiences that can be equated to college courses. It is designed to provide students with a comprehensive general education. Many times, no specific courses are required for graduation, allowing students to design their own programs of study. This degree is usually awarded by a Board of Regents of an accredited institution. CLIA regulations require that a bachelor’s degree be from an accredited institution. The RBD may meet this requirement. However, CLIA also requires that the bachelor’s degree be in a “chemical, physical, biological, or clinical laboratory science, or medical technology...” The RBD without the designation of one of the above majors does not meet this requirement, as it is a general education degree.

In conclusion, CLIA S&C letters are an extremely useful resource for surveyors and laboratories, as they clarify the CLIA regulations and CMS policies and procedures. Hopefully Parts 1 and 2 of the CLIA Corner have clarified the use of primary source verification processes and other personnel regulations. All of the CLIA S&C letters are available to the public at: <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions.html>. Once you are on the website, perform a search for “CLIA” and all of the current S&C letters pertaining to CLIA will populate. Happy reading!