



Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 16-18- CLIA
REVISED 05.03.16

DATE: April 1, 2016

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Personnel Policies for Individuals Directing or Performing Non-waived Tests
Revised due to typographical error under citation of §493.1443(b)(3)

Memorandum Summary

This policy memorandum supersedes S&C-10-07-CLIA “Consolidation of Personnel Policies for Individuals Directing or Performing Non-waived Tests under the Clinical Laboratory Improvement Amendments (CLIA).”

- CLIA surveyors will now accept Primary Source Verification (PSV) as evidence of compliance with the personnel qualifications mandated in Subpart M of the Clinical CLIA Regulations.
- If there are required elements in the personnel regulations that the PSV company does not verify, it is the laboratory director’s (LD) responsibility to ensure that these personnel qualifications are met by other means.
- CLIA personnel regulations and the policy on mandatory citations are not changing.
- Laboratories may choose to submit primary source verification for LD qualifications.
- Bachelor’s and Associate’s degrees in nursing meet the requirement for earning a degree in a biological science for, respectively, high complexity testing personnel and moderate complexity testing personnel.

Background

The Centers for Medicare & Medicaid Services (CMS) CLIA surveyors are required to make compliance determinations regarding whether individuals in prescribed positions meet the CLIA personnel qualification and responsibility requirements stated in 42 CFR, Part 493, Subpart M. This includes the positions of LD, clinical consultant (CC), technical supervisor and consultant (TS, TC), general supervisor (GS), testing personnel (TP), cytology general supervisor (CGS), and cytotechnologist (CT). The process for verification of personnel qualifications requires surveyors to observe direct evidence of academic achievement.

A laboratory is considered to be non-compliant if: a required position is not filled, if an individual does not meet the required qualifications based on education, training and experience for that position, or if an individual does not fulfill the responsibilities of the position.

PSV is the process of confirming an applicant's credentials by verifying that a degree, certificate, or diploma was received; that licenses were granted; and, by confirming reported work history, such as company names and locations, dates, and positions held. Verifications are obtained either directly from an institution, former employers, or their authorized agents.

In the past, CMS has required surveyors to verify educational qualifications by reviewing direct evidence of academic achievement, e.g. a diploma or transcript. This required the laboratory to collect and maintain paper documentation on its personnel in addition to maintaining paper records on large numbers of point-of-care testing personnel that perform testing throughout a medical facility.

CMS has had many requests from laboratories, accreditation organizations, and other health care facilities to accept PSV of education, training, experience, and licensure in laboratory services in order to demonstrate compliance with regulatory requirements. Meetings were held with representatives of several PSV companies to review their processes and the documentation that results from a primary source verification. Effective immediately, CMS surveyors will accept PSV documentation as evidence of laboratory compliance with the personnel requirements stated in 42 CFR, Part 493, Subpart M. It should be noted that the PSV company is **NOT** responsible for determining whether a given individual meets the personnel requirements under CLIA; PSV companies merely confirm that the asserted training, degrees and credentialing have been achieved or conferred. It is always the responsibility of the laboratory to ensure that its personnel meet the CLIA requirements, and CMS, its agents and accreditation organizations retain full authority to determine compliance with those requirements. The PSV report is one tool that can be used by the surveyor and laboratory to determine if the applicant meets the personnel requirements. The laboratory is responsible for ensuring that individuals' qualifications meet the personnel requirements.

General Guidance

- **CLIA personnel regulations and the policy on mandatory citations are not changing.** By allowing the use of PSV companies, CMS is giving laboratories another means of verifying and documenting the qualifications of its laboratory personnel.
- CMS is not issuing standards to be applied to PSV companies – laboratories will need to judge the services offered by PSV companies for themselves. CMS is merely permitting surveyors to use PSV reports when they compare employees' qualifications against the regulatory personnel requirements. As needed, surveyors will continue to ask LDs to provide additional documentation on their employees' qualifications when they find the PSV reports inadequate to confirm compliance.
- The use of a PSV report as evidence of meeting CLIA personnel qualifications is **optional** for the laboratory. Surveyors will continue to accept direct observation of documents, and the laboratory may also achieve compliance through a combination of the two.

- Laboratories electing to use the PSV option must maintain either paper or electronic reports from the PSV company.
- If there are required elements in the personnel regulations that the PSV company does not verify, it is the LD's responsibility to ensure that these personnel qualifications are met by other means. Each LD should collect and maintain documentation and records as may be necessary to provide any information that is not included in the PSV report.
- If the surveyor identifies potentially serious isolated or pervasive test quality problems that may be attributed to unqualified or untrained individuals performing or directing the laboratory's testing, the surveyor may request such documentation as may be necessary for the surveyor to confirm compliance with the personnel requirements.
- When there is a change in the LD for an accredited laboratory, the accreditation organization is responsible for checking credentials of the new LD. The State Agency is not responsible for verifying the LD credentials under this circumstance. See State Operations Manual (SOM), Chapter 6, Section 6006.7.
- Certain laboratory positions are **NOT** evaluated by the surveyor; examples include phlebotomists who do not perform testing, or individuals who do reagent preparation, specimen preparation, microbiology plating, etc., but no actual testing.
- Surveyors may not require an individual to test for and obtain a General Education Degree (G.E.D.). If records for a high school diploma or G.E.D are not available and a high school diploma or G.E.D. is required, **this individual is unqualified.**
- If a high school is closed, it is possible for the individual to solicit documentation from the local school board or State Board of Education to verify graduation.

Qualification Guidance

The LD qualifications are reviewed for all new laboratory applications (form CMS-116) prior to acceptance for enrollment in CLIA for provider-performed microscopy (PPM), accreditation, and compliance certificates, and when there is a change in laboratory director for a registration, compliance, or PPM certificate. Laboratories may choose to submit primary source verification for this requirement. When initially surveying the laboratory, surveyors evaluate the qualifications of the LD, TS or TC, CC, GS, CT, CGS, and a sample of TP. Surveyors are NOT required to evaluate qualifications for every TP. For subsequent surveys, surveyors evaluate all changes to personnel (for the positions of LD, TS or TC, CC, GS, CT, CGS) that have occurred since the previous survey, in addition to another sample of TP. The surveyor does not have to look for records on each TP.

It is important to note that not all personnel qualifications will be verifiable by a PSV company. Based on our current understanding, PSV companies do not verify transcripts. Laboratories need to be aware that, even if they choose to use PSV, personnel may still need to produce documentation that cannot be verified by PSV companies for those positions in which a transcript is necessary to qualify the individual. Ultimately, the LD is responsible for making sure that personnel qualifications are met for each position and that there is available evidence of the qualifications.

Provider Performed Microscopy (PPM) Personnel Qualifications

To obtain a certificate of PPM, the laboratory director must be an (Doctor of Medicine: MD, Doctor of Osteopathy: DO, Doctor of Podiatric Medicine: DPM, Doctor of Dental Surgery: DDS), or midlevel practitioner, as defined at §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 can perform PPM tests; otherwise, routine moderate complexity personnel and other applicable requirements apply and the laboratory must obtain a certificate of accreditation or compliance.

Professional Certification and State Licensure Requirements

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: CT and cytology CGS 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.

When the CLIA regulations specify that the individual must possess a license for any personnel in Subpart M (e.g., laboratory director, testing personnel), **if required by the State**, such as a physician (M.D., D.O., DDS) Midlevel practitioner (as defined at 42 CFR §493.2), testing personnel or otherwise, the laboratory need only produce a copy of the individual's State license or a report from a PSV company verifying the State license. No further academic documentation, such as diploma or transcripts, is required.

For individuals not required to be licensed under CLIA's express cross reference to state law in Subpart M, academic credentials, such as degrees, transcripts, or PSV documents, are required. Qualifications need only be provided at the highest level of academic achievement **applicable to CLIA** for the position held by the individual. It is not necessary to review a high school diploma, for example, of an individual whose position requires an advanced degree.

Bachelor Degree in Nursing

A bachelor's degree in nursing meets the requirement of having earned a bachelor's degree in a biological science for high complexity testing personnel. The laboratory may show a PSV report verifying that a bachelor's degree in nursing was earned, a diploma with the type of degree earned, or transcripts as evidence of meeting the education personnel requirement.

An associate's degree in nursing meets the requirement of having earned an associate's degree in a biological science for moderate complexity testing personnel. The laboratory may show a PSV

report verifying that an associate's degree in nursing was earned, a diploma with the type of degree earned, or transcripts as evidence of meeting the education personnel requirement.

Foreign Trained Personnel

Surveyors are not to review foreign academic credentials, but, instead, should point individuals with foreign credentials to SOM, Chapter 6, Section 6122 and CLIA Interpretive Guidelines at §42 CFR 493.2 (generally instructing such individuals to seek the services of a foreign credential evaluation agency). Allowing laboratories to make use of PSV when confirming personnel qualifications does not change this policy regarding how one should document a foreign degree's equivalency.

Foreign trained personnel that have a PhD equivalent must hold current HHS approved board certification or meet the regulation at 42 CFR §493.1405(b)(3) or 42 CFR §493.1443(b)(3)

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.

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.”

Each person examining cytology slide preparations must (1) meet the qualifications of §493.1449(b) or (k), or (2) possess a current license as a cytotechnologist issued by the State in which the laboratory is located, if such licensing is required, and meet one of several sets of requirements. One set of requirements states that on or before September 1, 1994 cytotechnologists examining cytology slide preparations must have full-time experience of at least two years or equivalent examining cytology slide preparations within the preceding five years in the United States under the supervision of a physician qualified under §493.1449(b) or (k)(1), and on or before September 1, 1995, have met the requirements in §493.1483(b)(1) or (2).

Federal Laboratories

The regulation at §493.3(c) states that “laboratories under the jurisdiction of an agency of the Federal Government are subject to the rules of this part, except that the Secretary may modify the application of such requirements as appropriate.” Therefore, with respect to the employment of physicians and similar medical and scientific professionals in federal laboratories, the Secretary's noted discretion in applying CLIA regulations to federal laboratories would offer other federal agencies a means for adopting hiring criteria that only require possession of a valid license in one state in order to work in any federally operated laboratory.

Home Schooling

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.

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.

Regents Bachelor's Degree (RBD)

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.

Mandatory Citations

Noncompliance with personnel regulations must be cited at the condition level if not met; i.e., the individual does not meet the required education, training, or experience, the position is not filled, or the corresponding responsibilities of that position are not met at the time of survey. See attached list of mandatory citations. As indicated in the list, **both the condition level AND standard level deficiencies must be cited.**

Competency Assessment

The current CLIA guidelines for competency assessment is attached. Personnel competency is addressed in the CLIA regulations for the laboratory director responsibilities at §493.1407, for moderate complexity, and §493.1445 for high complexity as well as for the TC and TS, §493.1413 and §493.1451, respectively.

Documented competency assessment is required for individuals fulfilling the following personnel responsibilities outlined in Subpart M of the CLIA regulations: CC, TC, TS, GS and TP. Clinical consultants, technical consultants, technical supervisors, and general supervisors who perform testing on patient specimens are required to have the six required procedures in their competency assessment in addition to a competency assessment based on their federal regulatory responsibilities. If the CC, TC, TS, or GS are **not** performing any testing on patient specimens, their competency should be based only on their federal regulatory responsibilities.

If the LD is the only individual testing and reporting test results, the LD must establish and document a minimal level of proficiency in order to ensure that they maintain the required competency for accurate and reliable testing and reporting.

Contact: Questions related to this memorandum may be submitted to:
LabExcellence@cms.hhs.gov

Effective Date: Immediately. The information contained in this memorandum is current policy and is in effect for all laboratory facilities. The State Agency should disseminate this information within 30 days of the date of this memorandum.

/s/
Thomas E. Hamilton

Attachment(s): 1. Practical Application of the Personnel Qualification Determinations
2. Mandatory Citations Personnel
3. Competency Assessment Guidelines

cc: Survey and Certification Regional Office Management

Attachment 1

Practical Application of the Personnel Qualification Determinations

Surveyors are instructed to cite the most appropriate mandatory deficiency(s) if the laboratory does not meet the personnel requirements for the CLIA position categories which are included on Forms CMS-1557 and CMS-209. Some examples are included here, though this is not an exhaustive list.

Example 1: A CLIA surveyor is evaluating a sample of TP qualifications in a moderate complexity laboratory and is presented with a home school diploma as evidence of compliance. What would the surveyor do?

Answer: Surveyor would accept the diploma at face value and focus on the testing personnel's training and competency.

Example 2: A CLIA surveyor is evaluating a sample of TP qualifications in a high complexity laboratory and is presented with proof of a medical technology degree from an accredited institution. Does this degree satisfy the personnel requirement or are transcripts needed?

Answer: Yes, a medical technology degree from an accredited institution is sufficient. A PSV report verifying a medical technology degree from an accredited institution would also meet the requirement.

Example 3: If a laboratory is applying for a CLIA certificate and the LD is not board certified, but is board eligible, what evidence is needed for CMS to issue a Certificate of Registration?

Answer: If an LD is only eligible to be board certified, the PSV Company may not be able to verify eligibility status. The LD would need to provide the documentation of training and experience required by the board to be eligible to take such examinations.

Example 4: A laboratory is hiring a military trained medical laboratory technician. What evidence is needed for the laboratory to maintain compliance with CLIA personnel qualifications?

Answer: Primary source verification companies are able to verify most military schooling and training. If the PSV company cannot verify 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), the laboratory must present documentation that the testing personnel has the qualifications to meet the requirement.

Example 5: A CLIA surveyor evaluating qualifications of a nurse performing moderate complexity laboratory is presented with a nursing license as evidence of compliance. What would the surveyor do?

Answer: CLIA surveyors **do not** accept nursing licenses as evidence of compliance. An associate's or bachelor's degree in nursing meets the requirement of having earned a degree in a biological science for moderate complexity testing personnel. The laboratory must provide the surveyor with a PSV report verifying the type of degree earned, a diploma showing the type of degree earned, or transcripts as evidence of meeting the personnel requirement.

Example 6: A CLIA surveyor is evaluating a sample of TP qualifications in a high complexity laboratory and is presented with a report from a primary source verification company. The report verifies that the TP has a degree in Medical Technology from an accredited university and that the TP has worked for 3 years as a medical technologist at a hospital. Does this report satisfy the personnel requirement or are transcripts needed?

Answer: Yes, the PSV company report is sufficient; no further evidence is needed.

Example 7: A CLIA surveyor is evaluating a sample of TP qualifications in a high complexity laboratory located in a state that requires licensure for medical technologists. The surveyor is presented with a PSV company report that verifies the TP's State license as evidence of meeting the personnel requirement. Does the surveyor also need to see further evidence of education, such as degrees or transcripts?

Answer: No. It is acceptable for the laboratory to present the surveyor with a PSV report verifying State licensure. The State license would also be acceptable. For laboratories in states that require licensure, no further academic documentation, such as diploma or transcripts, is required.

Example 8a: A CLIA surveyor is evaluating LD qualifications in a high complexity laboratory located in a state that requires licensure. The surveyor is presented with a PSV report verifying the LD's State license as evidence of meeting the personnel requirement. Does the surveyor also need to see further evidence of education, such as degrees or transcripts?

Answer: No. It is acceptable for the laboratory to present the surveyor with only a PSV report verifying State licensure. The State license would also meet the requirement. For laboratories in states that require licensure, no further academic documentation, such as diploma or transcripts, is required.

Example 8b: A CLIA surveyor is evaluating LD qualifications in a high complexity laboratory located in a state that requires licensure. The LD is a foreign trained physician. The surveyor is presented with a PSV company report verifying the LD's State license as evidence of meeting the personnel requirement. Does the LD also need to produce foreign educational equivalencies?

Answer: No. It is acceptable for the laboratory to present the surveyor with only a PSV report verifying State licensure. The State license would also meet the requirement. Foreign trained physicians (MD, DO, DPM or DDS) who are licensed to practice medicine in the State in which the laboratory is located do not need to produce educational equivalencies. The state license is also sufficient proof of academic achievement.

Example 9: A CLIA surveyor is evaluating TP qualifications in a high complexity laboratory. The surveyor is presented with a bachelor's of science in nursing diploma as evidence of compliance. Does this satisfy the personnel requirement?

Answer: Yes. A bachelor's degree in nursing meets the requirement of having earned a bachelor's degree in a biological science for high complexity testing personnel. The laboratory must show a PSV report verifying the degree, a diploma showing the type of degree earned, or transcripts as evidence of meeting the personnel requirement.

Example 10: A CLIA surveyor is evaluating TP qualifications in a high complexity laboratory. The surveyor is presented with a PSV report verifying that the TP received a bachelor's degree from an accredited university in 2008. Is this sufficient evidence of meeting the personnel requirement?

Answer: No. Regulation §493.1489(b)(1) states that high complexity testing personnel will have earned a "...bachelor's degree in a chemical, physical, biological, or clinical laboratory science, or medical technology..." The documentation in the PSV report did not state the type of BS degree earned. The surveyor would need to look for additional evidence of the type of bachelor's degree earned, a diploma showing the type of degree earned, or transcripts. Just having evidence of a BS degree does not meet the personnel requirement.

Attachment 2

Personnel Mandatory Citations

Requirement	Cite the Standard at least:	Cite the Condition at least:
Laboratory Director (LD) High complexity	D6078	D6076
Technical Supervisor (TS) High complexity	D6111	D6108
Clinical Consultant (CC) High complexity	D6135	D6134
General Supervisor (GS) High complexity	D6143	D6141
Cytology General Supervisor (CGS) High Complexity	D6155	D6153
Cytotechnologist (CT) High Complexity	D6164	D6162
Testing Personnel (TP) High complexity	D6171	D6168
Laboratory Director (LD) Moderate complexity	D6003	D6000
PPM Laboratory Director	D5981	D5980
PPM Testing Personnel Moderate complexity	D5991	D5990
Technical Consultant (TC) Moderate complexity	D6035	D6033
Clinical Consultant (CC) Moderate complexity	D6057	D6056
Testing Personnel (TP) Moderate complexity	D6065	D6063

Attachment 3

Competency Assessment Guidelines

Technical consultant, clinical consultant, technical supervisor, general supervisor

Documented competency assessment is required for individuals fulfilling the following positions listed on Laboratory Personnel Report (Form CMS-209): clinical consultant (CC), technical consultant (TC), technical supervisor (TS), and general supervisor (GS). The laboratory must have policies and procedures to assess competency based on the position responsibilities listed in Subpart M and these assessments must be performed at a frequency determined by the laboratory. Cite D5209 (§493.1235). It is mandatory for clinical consultants, technical consultants, technical supervisors, and general supervisors who perform testing on patient specimens to have the six required procedures of competency assessed at intervals specified in the regulations in addition to a competency assessment based on their federal regulatory responsibilities. Note: The individual named on the CMS-209 must be the individual who is actually responsible for the functions of the position for CLIA purposes, whether that individual is an employee or a contracted consultant, and must meet the regulatory qualifications for the position.

Testing personnel

All testing personnel must be listed on the CMS-209 and must undergo documented competency assessment using the 6 procedures denoted under the technical consultant/supervisor's responsibilities for all testing performed. Depending on the situation, non-compliance can be cited at general lab systems (D5209), lab director (D6030/§493.1407 or D6103/§493.1445) or technical consultant/supervisor (D6046-6055, D6121-D6129).

Testing personnel in laboratories with a PPM certificate

Testing personnel, including mid-level practitioners, in PPM laboratories are required to undergo competency assessment. The requirements for performing the assessment and its frequency are determined by the regulations. If it is necessary to cite non-compliance, use D5209 or the appropriate D-tag under the technical consultant responsibilities (D6046-6055).

Other staff

Personnel performing pre-analytic and post-analytic activities are not required to be listed on the CMS-209. Surveyors do not normally check for documented competency evaluation on these individuals. However, if you discover problems in the laboratory and you find that a factor in these problems is poor performance of incompetent staff, cite D6030 or D6103 (lab director).

Quality assessment

Problems in competency assessment that are not picked up and/or corrected by QA should be cited at D5291.

Discussion: Regular competency assessment is an important element of assuring that all personnel are capable of performing their duties correctly. In situations in which more than one citation may be used, choose the one that is most applicable to the situation. For example, if the assessments of testing personnel do not include all six required procedures, cite the Technical Consultant (D6046-D6052) or Technical Supervisor (D6120-D6126). **KEY POINT: Use the most appropriate citation for non-compliance with competency assessment requirements, depending on the situation. Use the citation that will best allow the laboratory to understand the problem and correct it.**