

S&C-16-18-CLIA Personnel Policies for Individuals Directing or Performing Non-waived Tests Frequently Asked Questions

Q1. What is Primary Source Verification (PSV)?

A1. PSV is the process of confirming an individual'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.

Primary source verification can be achieved through several methods, including, but not limited to, directly contacting the organization from which the credential was issued. This may be done through methods such as documenting a telephone conversation with the issuing source, or by facsimile, email, or letter. A secure online database may also be used to determine the validity of the credentials.

Q2. Why do employers use PSV?

A2. Employers began using PSV to verify credentials from the "primary source," such as universities or other institutions, to prevent fraudulent representation of individuals' qualifications and experience. Fraudulent credentials can be created easily with commonly available computer software.

Q3. Are laboratories required to use PSV?

A3. No. The use of a PSV report as evidence of meeting the Clinical Laboratory Improvement Amendments of 1988 (CLIA) personnel qualifications is optional for laboratories.

Laboratories have two ways to demonstrate compliance with personnel regulations. (A combination of the two methods may be used.)

1. Utilize a PSV report
2. Continue to accept direct observation of source documents

If there are required elements in the personnel regulations that the PSV organization does not verify, **it is the Laboratory Director's (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.**

Q4. What kind of organizations can perform PSV?

A4. PSV organizations may include, but are not limited to, organizations that confirm an individual's credentials by verifying that a degree, certificate, or diploma was received, or that a license was granted, or by confirming reported work history, such as company names and locations, dates, and positions held. **CMS is not issuing standards to be applied to PSV**

organizations. 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.

Q5. Is an organization that only collects diplomas and transcripts from qualifying individuals considered to be performing PSV?

A5. Organizations that merely collect documentation directly from the qualifying individual are not considered to be performing PSV. However, if those organizations confirm an individual's credentials by verifying, directly from an institution or the institution's authorized agents, that a degree, certificate, diploma, or other credential was received, then they are considered to be performing PSV.

Q6. Must a PSV organization be certified by a Credential Verifying Organization (CVO) Certification Program?

A6. A Credentials Verification Organization (CVO) Certification Program evaluates credentials verification operations and the processes that a PSV organization uses to provide its services to its clients. CVO certification is generally available to organizations that conduct credentials verification, report the credentialing information to clients and have systems in place to protect the confidentiality and integrity of the information. CMS has not issued standards or specific requirements for either a PSV or a CVO. It is the responsibility of the LD to ensure that personnel qualifications are met for each position and that there is sufficient evidence of the qualifications.

Q7. Will RO/SA surveyors accept all PSV documentation?

A7. Laboratories electing to use the PSV option must maintain either paper or electronic reports from the PSV organization.

When surveyors find a PSV report that is inadequate to confirm compliance with the personnel requirements, they will ask LDs to provide additional documentation on their employees' qualifications.

Q8. If the high school degree has been verified by a PSV organization, does anyone need to keep a copy of the actual high school diploma?

A8. No. If there is documentation on a report from a PSV company that they have verified that a high school diploma was awarded, the laboratory need only keep the PSV report showing that the requirement has been met. If there isn't verification on the PSV report of the diploma being awarded, then the laboratory would need to keep a copy of the diploma to demonstrate compliance.

CLIA does not dictate what documentation the PSV organization needs to keep. It is ultimately the Laboratory Director's (LD) responsibility to choose a PSV company for their laboratory, based on their own criteria.

Q9. What is the CMS policy on nursing degrees and the CLIA personnel requirements?

A9. As stated in S&C 16-18 CLIA, "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."

In addition to academic qualifications, CLIA requires training and competency assessment for all laboratory personnel.

Q10. Why did CMS change the policy on accepting nursing degrees to meet the CLIA personnel requirements with the release of S&C 16-18-CLIA?

A10. S&C 16-18-CLIA does not reflect new CLIA policy or a change in CLIA policy regarding the recognition of bachelor's and associate's degrees in nursing meeting the requirement for earning a degree in a biological science for, respectively, high complexity testing personnel and moderate complexity testing personnel. S&C 16-18-CLIA merely clarifies existing policy and practice.

Q11. Are laboratories required to allow nurses to perform moderate and high complexity testing?

A11. No. Laboratories can, and already do, adopt stricter standards than the CLIA regulations require. For example, some laboratories require more experience, specialty certification, more advanced degrees, etc. In addition, state law may also impose stricter standards than the CLIA regulations require.

Q12. Is a bachelor's degree in nursing considered a degree in biological science for the purpose of meeting the TC qualification at 42 CFR §493.1411(b)(4)(i) for moderate complexity testing?

A12. Yes, an individual holding a bachelor's degree in nursing, possessing a current license issued by the state in which the laboratory is located (if such licensing is required), **and having at least 2 years of laboratory training or experience, or both in non-waived testing, in the**

designated specialty or subspecialty areas of service for which the technical consultant is responsible, can meet the qualification for moderate complexity TC.

Q13. Can a bachelor's degree in nursing meet the requirement 42 CFR §493.1405(b)(5)(i) for LD (moderate complexity)?

A13. In order to qualify under §493.1405(b)(5)(i) as a LD for moderate complexity testing, the individual must possess a current license issued by the state in which the laboratory is located (if such licensing is required); must have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; must have at least 2 years of laboratory training or experience, or both in non-waived testing; and must have at least 2 years of supervisory laboratory experience in non-waived testing.

Q 14. Does a Bachelor's degree in nursing meet the requirement for a degree in a biological science for those specialties/subspecialties that allow individuals with Bachelor's degrees to be Technical Supervisors, such as Bacteriology [§493.1449(c)(5)(i)] and Hematology [§493.1449(j)(5)(i)]?

A 14. Yes, for those specialties/subspecialties that allow individuals with Bachelor's degrees to be a Technical Supervisor, a bachelor's degree in nursing would meet the educational requirement for a bachelor's degree in a biological science for an individual seeking to qualify as a Technical Supervisor. Note that in order to fully meet the regulations, an individual must also meet the applicable licensing, training, and experience requirements for the position for which they seek to qualify.

For example, in order to qualify under §493.1449(c)(5)(i) as a TS for high complexity testing within the subspecialty of bacteriology, an individual must possess a current license issued by the state in which the laboratory is located (if such licensing is required); have earned a bachelor's degree in a chemical, physical, biological, or clinical laboratory science or medical technology from an accredited institution; and is **required to have at least 4 years of training or experience, or both, in high complexity testing within the specialty of microbiology, with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology.**

NOTE: Some specialties/subspecialties require higher educational qualifications. Individuals seeking to qualify for CLIA positions should consult the CLIA regulations for the exact requirements for the position(s) they seek to fill.

Q15. Does CLIA allow Nurse Practitioners, with a Master's degree in Nursing, and with the required experience, to qualify as moderate complexity lab directors under 42 CFR §493.1405(b)(4)?

A15. Yes. A master's degree in nursing meets the requirement of having earned a master's degree in a biological science. The regulation, §493.1405(b)(4), states that the individual must "have earned a master's degree in a chemical, physical, biological or clinical laboratory science

or medical technology from an accredited institution”; “have at least one year of laboratory training or experience, or both in non-waived testing”; and “have at least one year of supervisory laboratory experience in non-waived testing”. **All three parts of the requirement must be met for an individual to qualify under 42 CFR §493.1405(b)(4).**

Q16. Can you please clarify whether an associate degree in nursing has been determined to satisfy the requirements at §493.1489(b)(2)(i) specifying an associate degree in a laboratory science or medical laboratory technology for high complexity testing personnel?

A16. No, an associate degree in nursing does not meet the requirement for an associate degree in a laboratory science or medical laboratory technology found at §493.1489(b)(2)(i). However, an individual may qualify to perform high complexity testing by having education and training equivalent to that specified in §493.1489(b)(2)(i), including the semester hour requirements at §493.1489(b)(2)(ii)(A) and the laboratory training requirements at §493.1489(b)(2)(ii)(B).

Q17. Will a bachelor’s degree in respiratory therapy be deemed sufficient for testing personnel performing non-waived testing?

A17. For blood gas analysis, section 493.1489(b)(6) allows individuals that have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution to qualify as testing personnel performing non-waived testing, provided that they meet all other applicable requirements contained in the regulations.

Q18. In States with licensure for laboratory testing personnel, what evidence of qualifications should surveyors expect to see for individuals performing moderate complexity testing (42 CFR §493.1423)? Is the State licensure for testing personnel sufficient? Or should surveyors also require evidence of a high school diploma in addition to the State license for laboratory personnel?

A18. 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 (as defined at 42 CFR §493.2), 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, provided that the laboratory or PSV report also shows that the State licensure process requires verification that the individual meets the academic requirements specified in section 493.1423(b)(4)(i). No further academic documentation, such as diploma or transcripts, is required unless further documentation is requested.

Q19. A CLIA surveyor is evaluating LD qualifications in a high complexity laboratory. The surveyor is presented with a PSV report verifying the LD’s State license as a Doctor of Medicine licensed to practice medicine in the state in which the laboratory is located as evidence of meeting the personnel requirement at §493.1443(b)(1)(i). Does the surveyor also need to see further evidence of education, such as degrees or transcripts?

A19. No. It is acceptable for the laboratory to present the surveyor with only a PSV report verifying State licensure. Direct verification of the State license would also meet the requirement.

Q20. A CLIA surveyor is evaluating LD qualifications in a high complexity laboratory. The LD is a foreign trained physician. The surveyor is presented with a PSV company report verifying the LD's State license as a Doctor of Medicine licensed to practice medicine in the state in which the laboratory is located as evidence of meeting the personnel requirement at §493.1443(b)(1)(i). Does the LD also need to produce foreign educational equivalencies?

A20. No. It is acceptable for the laboratory to present the surveyor with only a PSV report verifying State licensure. Direct verification of the State license would also meet the requirement. Foreign trained physicians (MD, DO) who are licensed to practice medicine or osteopathy in the State in which the laboratory is located do not need to produce educational equivalencies to meet the requirement at §493.1443(b)(1)(i).

Q21. Are home school certificates or diplomas proof of High School education?

A21. There is no standardized approach to home schooling across the country as each state determines its own curriculum and documentation of completion requirements for a home school education. 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. It is ultimately up to the LD to make the determination if the laboratory accepts the home school diploma as evidence of meeting applicable personnel requirements.