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CENTERS for MEDICARE & MEDICAID SERVICES

Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-10-07-CLIA
EXPIRED EFFECTIVE: December 6, 2024

DATE: **March 26, 2025**

ORIGINAL POSTING DATE: **November 6, 2009**

TO: **State Survey Agency Directors**

FROM: **Director, Quality, Safety & Oversight Group (QSOG)**

SUBJECT: ***EXPIRED:*** Consolidation of Personnel Policies for Individuals Directing or Performing Non- waived Tests under the Clinical Laboratory Improvement Amendments (CLIA)

Memo Expiration Information:
Expiration Date: ***December 6, 2024***
Expiration Information: ***Refer to QSO-25-10-CLIA: Advanced Copy –Revisions to State Operations Manual (SOM), Appendix C – Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services***

Memorandum Summary

EXPIRED AS OF JANUARY 17, 2025. FOR CURRENT GUIDANCE REFER TO QSO-25-10-CLIA: SOM, Appendix C – Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services –Presently CLIA-related personnel policies and procedures are dispersed throughout the regulations, State Operations Manual (SOM), Interpretive Guidelines, training presentations and in other less formal venues. This memo attempts to consolidate and clarify them for the surveyor's use and understanding.

Introduction

State survey agencies are required to make compliance determinations as to 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 laboratory director (LD), clinical consultant (CC), technical supervisor and consultant (TS, TC), general supervisor (GS), testing personnel (TP), cytology general supervisor (CGS), and cytology technologist (CT).

A laboratory is not considered in compliance 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 meet the responsibilities of the position. If these criteria are not met, the laboratory is subject to a mandatory condition-level citation.

General Surveyor Guidance

- Qualification determinations must be done at the highest level of academic achievement.
- The LD's qualifications are reviewed by the State Agency 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 director for a compliance or PPM certificate.
- When the director changes for an accredited laboratory, the accreditation organization is responsible for checking credentials. See SOM, Chapter 6, Section 6006.7.
- When surveying the laboratory initially, evaluate the qualifications of the LD, TS or TC, CC, GS, CT, CGS, and a sample of TP.
- For subsequent surveys, evaluate any new or changed personnel since the previous survey and another sample of TP, if the staffing warrants.
- Request appropriate documents to be provided within a reasonable timeframe (the time it takes to complete the survey or within 1 week afterwards). These will include: diplomas, certificates, licenses, degrees, transcripts, training, experience, continuing education (CE), competency assessment, duties and responsibilities.
- Certain positions are NOT evaluated by the surveyor; for example, phlebotomists who do not perform testing or individuals who do reagent preparation, specimen preparation, microbiology plating, etc., but no actual testing.
- Surveyors cannot require an individual to test for and obtain a General Education Degree (G.E.D.) if a high school diploma or G.E.D. is required and records for a high school diploma are not available, or the individual hasn't attained a high school diploma. This individual is determined to be unqualified, however.
- Agency evaluations, except for foreign credentials, are not acceptable to determine if an individual's qualifications meet CLIA.
- 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.

Professional Certification and State Licensure Requirements

We continue to receive inquiries as to whether the laboratory can present the surveyor an individual's professional certification, such as MT (ASCP) or nursing licenses, as the only type of documentation to meet the CLIA requirements. This information is not considered sufficient evidence. Therefore, more detailed information, like degrees and transcripts, is required.

One exception to this exists where professional certification is required by the regulations; i.e., cytotechnologist (CT) and cytology general supervisor (CGS) positions require American Society of Clinical Pathology (ASCP) certification, in addition to documentation of their highest level of academic achievement in educational, training, and experiential requirements.

When the CLIA regulation specifies that the individual must possess a license, if required by the State, such as a physician (Doctor of Medicine: MD, Doctor of Osteopathy: DO, Doctor of Podiatric Medicine: DPM, Doctor of Dental Surgery: 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 as proof of academic achievement. No further academic documentation is required.

Survey Efficiency and Scope of Personnel Record Reviews

The survey process makes provisions for surveyors to verify qualifications at the highest level of academic achievement for the individuals in the required personnel categories.

The regulation considers each personnel category's academic achievement, training, and experience necessary to meet the respective CLIA personnel requirements for the regulated position in which the individual currently functions. Thus, the surveyor will request an academic diploma or degree and/or transcript(s) that were earned by the individual at his or her highest level of academic achievement and will verify the individual's specific laboratory training and experience for that position. It is not necessary to review a high school diploma, for example, of an individual whose position requires an advanced degree.

One must also consider the test complexity/categorization and specialty and subspecialty of the non-waived tests performed by the laboratory when making personnel qualification determinations because many of the positions in these areas have unique qualification and experiential requirements.

If the surveyor identifies serious isolated or pervasive test quality problems that may be attributable to unqualified or untrained individuals performing or directing the laboratory's testing, the surveyor may expand the request for documentation, as necessary.

Provider Performed Microscopy (PPM) Personnel Qualifications

To obtain a certificate of PPM, the director must be an M.D., D.O., DDS or midlevel practitioner, as defined at 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.

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 (Survey Report Form: CLIA) and CMS-209 (Laboratory Report Form). Some simple examples are included here.

Example 1: A dentist (DDS) is previously listed on Forms CMS-1557 and CMS-209 as moderate complexity TC via §493.1409 & 493.1411. This dentist earned a master's degree in chemistry in accordance with §493.1411(b)(3)(i) and a bachelor's degree in medical technology in accordance with §493.1411. The laboratory is now upgrading its CLIA certificate to include high complexity tests within the specialty of pathology and the subspecialty of oral pathology. The DDS will now serve as either: LD, CC, TS, or TP. The surveyor must also verify if the DDS obtained board certification with the American Board of Oral and Maxillofacial Pathology or other board certifications to complete the qualification determination.

Example 2: A phlebotomist never obtained a high school diploma or a G.E.D. and does not perform any laboratory testing; therefore, there are no qualification requirements prescribed by CLIA and this individual's credentials are not evaluated during the CLIA survey.

Example 3: A phlebotomist performs moderate complexity bleeding time tests, so it is necessary to determine if this person meets the applicable CLIA moderate complexity testing personnel qualification requirements at the highest level of academic achievement.

Foreign Trained Personnel

Surveyors are requested to not review foreign academic credentials, but instead, to recommend that the individual obtain the services of a nationally recognized foreign credential evaluation agency to determine equivalency. (See SOM, Chapter 6, Section 6122 and Interpretive Guidelines at 42 CFR 493.2)

Mandatory Citations

These circumstances 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.

Competency Assessment

The current CLIA policy for competency assessment is attached. Personnel competency is addressed in CLIA for the 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. Competency is not assessed for solo practitioners.

We request that you address any further questions on this topic to Janet Perryman-Butler at: janet.perrymanbutler@cms.hhs.gov.

Effective Date: 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.

Training: The information contained in this announcement should be shared with all survey and certification staff including managers and surveyors and their manager. The policies and procedures will be formalized in the appropriate sections of the Interpretive Guidelines.

/s/
David R. Wright
Director, Quality, Safety & Oversight Group

Resources to Improve Quality of Care:

Check out CMS's new Quality in Focus interactive video series. The series of 10-to-15 minute videos are tailored to provider types and aim to reduce the deficiencies most commonly cited during the CMS survey process, like infection control and accident prevention. Reducing these common deficiencies increases the quality of care for people with Medicare and Medicaid.

Learn to:

- Understand surveyor evaluation criteria
- Recognize deficiencies
- Incorporate solutions into your facility's standards of care

See the Quality, Safety, & Education Portal Training Catalog, and select Quality in Focus

cc: Survey and Certification Regional Office Management

Attachments: Mandatory Citations Personnel
Competency Assessment Guidelines Final

Personnel Mandatory Citations

Requirement:	Cite the Std. at least:	Cite the Cond. 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 moderate complexity	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

Competency Assessment Guidelines

Technical consultant, clinical consultant, technical supervisor, general supervisor

Documented competency assessment is required for the following named positions on the Form CMS-209: technical consultant, clinical consultant, technical supervisor, general supervisor. 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). Exception: If the laboratory director is filling multiple positions, competency evaluation is not feasible. For example, the laboratory director may also fill the position of technical consultant or clinical consultant, if qualified.

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 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 criteria 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 PPMP certificate

Testing personnel in PPMP laboratories are required to undergo competency assessment. (Exception: In certain circumstances it is not feasible to perform competency assessment, for example, a solo practitioner.) The requirements for performing the assessment and its frequency are determined by laboratory policy and procedure. If it is necessary to cite non-compliance, use D5209.

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 elements, cite the Technical Consultant.

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.