

COLA Technical Bulletin

2024-7: Upcoming Changes to CLIA Personnel Regulations

On December 28, 2023, CMS published a final rule including several changes to the CLIA regulations regarding the qualifications and responsibilities of clinical laboratory personnel. These changes were made to address obsolete regulations and update the regulations to incorporate technological changes. The final rule, including the changes to the Personnel section (Subpart M) of the CLIA regulations, is available for review in the [Federal Register](#); changes to Subpart M will take effect on **December 28, 2024**.

COLA is sharing this Technical Bulletin to make laboratories aware of these changes in advance of the effective date.

Changes to Personnel Regulations

Degrees

Throughout the revised personnel regulations, CMS clarifies that degrees in physical science are too broad as to be acceptable without further examination of the specific course credits earned in the degree program. Degrees in chemical, biological, clinical or medical laboratory science or medical technology from accredited institutions are listed as acceptable; other degrees must be assessed for semester hours of biology, chemistry and so on.

In part due to the variability in degree program titles and coursework, CMS has included information in this final rule about coursework that is equivalent to associate, bachelor's, master's and doctoral degrees in acceptable laboratory-related fields. Please see 42 CFR Part 493 [CMS-3326-F] using the link provided in the Reference section of this bulletin for more information about these coursework equivalencies, including required semester hours for each subject.

The new regulations also clarify that doctoral degrees do not include doctors of medicine (MD), doctors of osteopathy (DO), doctors of podiatry, doctors of veterinary medicine (DVM) or honorary degrees. A Doctorate in Clinical Laboratory Science (DCLS) degree is considered an acceptable doctoral degree in this new final rule.

Beginning with the effective date of this final rule, a degree in nursing is not an acceptable degree to qualify an individual as high complexity testing personnel. Nursing degrees will only be able to qualify for personnel positions listed in subpart M when a nursing degree is specifically listed in the regulatory qualifications for the position.

Laboratory Director Onsite Visits

The final rule requires that the laboratory director must be onsite at the laboratory at least twice annually, with at least 4 months between the minimum two visits. The laboratory must retain documentation of these visits, including evidence of performing activities that are part of the laboratory director's responsibilities.



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20 CE Credit Hours: Laboratory Director Responsibilities

With this update to the regulations, any individual wishing to qualify as Laboratory Director for a moderate or high complexity laboratory, **regardless of their educational background and experience**, must have at least 20 CE credit hours in laboratory practice that cover laboratory director responsibilities. This is **in addition to** the required years of experience directing or supervising nonwaived laboratory testing; the number of years of experience required varies based on the degree held, and this experience requirement is unchanged in the final rule. The **only** exceptions to the 20 CE credit hours requirement are physicians who are board-certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology.

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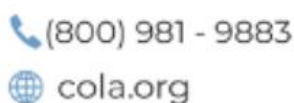
Under the new regulations, individuals who have an associate degree in medical laboratory technology, medical laboratory science, or clinical laboratory science may now qualify as Technical Consultants (TC) in moderate complexity laboratories, provided that they have at least **4 years** of laboratory training or experience in nonwaived testing in the designated specialty or subspecialty areas of service.

Technical Supervisor

The qualifications for the Technical Supervisor (TS) of a high complexity immunohematology laboratory have been modified to align with requirements for the TS in other specialties. That is a minimum of a bachelor's degree in a chemical, physical or biological, clinical or medical laboratory science, or medical technology from an accredited institution (or have completed coursework that is equivalent to an acceptable degree, as described in §493.1449) **and** at least 4 years of laboratory training or experience in high complexity testing for immunohematology.

Competency Assessment

The final rule will allow individuals with applicable associate degrees and experience (i.e., individuals who qualify as TC under the new regulations) to perform competency assessments for both moderate and high complexity testing.



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Blood Gas Testing

CMS does not consider a degree in respiratory therapy (RT) or cardiovascular technology to be equivalent to a biological or chemical science degree. However, an individual may qualify as TC for blood gas analysis if they have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution **and** have at least 2 years of laboratory training or experience, or both, in blood gas analysis.

Note: Laboratory personnel employed in their position on the effective date of the final rule, December 28, 2024, will continue to qualify as long as they remain continuously employed in that role.

For More Information

This Technical Bulletin is a brief overview of the most significant changes to the personnel regulations that will take effect on December 28, 2024. This document is not intended to replace the CLIA regulations as written in the Federal Register. Please refer to the linked document in the reference section to read the complete text of the revised regulations, along with a discussion of the rationale behind the decisions made by CMS.

COLA will be releasing an updated Accreditation Manual later this year which will include criteria additions and revisions in response to the final rule.

Reference

<https://www.federalregister.gov/documents/2023/12/28/2023-28170/clinical-laboratory-improvement-amendments-of-1988-clia-fees-histocompatibility-personnel-and>

