

COLA Technical Bulletin

2024-10: New Laboratory Director Qualification Requirements

URGENT

On **December 28, 2024**, significant changes to the Personnel section (Subpart M) of the CLIA regulations will take effect. The final rule relating to these changes was published in the [Federal Register](#) on December 28, 2023.

COLA Technical Bulletin 2024-7 reviewed some of the impending changes to Subpart M. **Significant changes relating to Laboratory Director qualifications will take effect by the end of this year.** COLA is sharing this urgent Technical Bulletin to ensure that laboratories are aware and can take appropriate measures to remain in compliance.

New 20 CE Credit Hour Requirement

All laboratory directors, regardless of their qualification pathway and the complexity of the laboratory they direct, are now required to have at least 20 CE credit hours in laboratory practice that cover laboratory director responsibilities. The **only** exceptions are physicians board-certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology.

This 20 CE requirement is **in addition to** the required education and experience described in Subpart M. That is, a non-pathologist physician must have the required year(s) of experience in directing or supervising nonwaived testing in addition to completing 20 CE credit hours in laboratory director responsibilities.

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The new qualifying pathways for the role of Laboratory Director are listed in the following sections below.

Laboratory Director Qualifications: Moderate Complexity

1. Licensed MD/DO/DPM, **AND** certified in anatomic or clinical pathology
2. Licensed MD/DO/DPM
AND laboratory training or experience consisting of 1 year directing or supervising non-waived tests
AND have earned at least 20 CE credits in laboratory practice addressing director responsibilities



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3. Doctoral degree in a laboratory science*
AND current board certification by a board approved by HHS
AND have 1 year of experience directing or supervising non-waived testing
AND have earned at least 20 CE credits in laboratory practice addressing director responsibilities
4. Master's degree in a laboratory science*
AND 1 year of non-waived laboratory training or experience
AND 1 year of experience supervising non-waived testing
AND have earned at least 20 CE credits in laboratory practice addressing director responsibilities
5. Bachelor's degree in a laboratory science*
AND 2 years of non-waived laboratory training or experience
AND 2 years of experience supervising non-waived testing
AND have earned at least 20 CE credits in laboratory practice addressing director responsibilities

Laboratory Director Qualifications: High Complexity

1. Licensed MD/DO/DPM, **AND** certified in anatomic or clinical pathology
2. Licensed MD/DO/DPM
AND laboratory training or experience consisting of 2 years of directing or supervising high complexity testing
AND have earned at least 20 CE credits in laboratory practice addressing director responsibilities
3. Doctoral degree in a laboratory science*
AND current board certification by a board approved by HHS
AND have 2 years of experience directing or supervising high complexity testing
AND have earned at least 20 CE credits in laboratory practice addressing director responsibilities

*Where the requirements state a degree in "laboratory science," acceptable degrees are biological, chemical or laboratory science degrees. A degree in physical science is no longer considered acceptable as a degree in a laboratory science. In some cases, COLA may request transcripts to evaluate the curriculum. For degrees other than biology, chemistry or laboratory science, specific semester hours of applicable coursework or an approved thesis or research project related to laboratory science is required.

NOTE: An individual is considered qualified as a laboratory director under these sections if they were qualified and serving as a laboratory director in a CLIA-certified laboratory as of December 28, 2024, **and remained continuously employed in their position at the laboratory since December 28, 2024.**

