IOWA | State Hygienic Laboratory

CLIA CORNER

State Hygienic Laboratory at The University of Iowa First Quarter 2025

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- **Moderate and high complexity laboratory director qualifications (UPDATED 08/2025); and**
- **Moderate and high complexity laboratory director responsibilities**

On 12/28/2024, the new Clinical Laboratory Improvement Amendments (CLIA) personnel regulations took effect. In this edition of the CLIA Corner, we are going to review the CLIA qualifications and responsibilities for moderate and high complexity laboratory directors. UPDATE: On 06/23/2025, The Centers for Medicare & Medicaid Services (CMS) released a revised memo with additional updates to the CLIA regulations and interpretive guidelines, which can be found here: QSO-25-10-CLIA REVISED. In addition, CMS released memo QSO-25-21-CLIA, which describes CLIA enforcement discretion and provides clarification on personnel regulations as a result of the most recent revision of the CLIA regulations and interpretive guidelines.

Moderate Complexity Laboratory Director

With the updated CLIA personnel regulations and interpretive guidelines, there are now 12 pathways for an individual to qualify as a moderate complexity laboratory director.

1. **Be a doctor of medicine (MD), doctor of osteopathy (DO) licensed to practice medicine or osteopathy in the State in which the laboratory is located**; **AND**

⇒ Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology.

2. **Be a MD, DO, or doctor of podiatric medicine (DPM) licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located**; **AND**

⇒ Have laboratory training or experience consisting of at least one year directing or supervising non-waived laboratory testing; **OR**

⇒ Have at least 20 continuing education (CE) credit hours in laboratory practice that cover the laboratory director responsibilities defined in § 493.1407.

3. **Hold an earned doctoral degree in a chemical, biological, or clinical/medical laboratory science or medical technology from an accredited institution**, **AND**

⇒ Be certified and continue to be certified by a board approved by HHS; **AND**

⇒ Have at least 1 year experience directing or supervising nonwaived laboratory testing.

4. **Hold an earned doctoral degree**; **AND**

⇒ Have at least 16 semester hours of doctoral level coursework in biology chemistry, medical technology (MT), clinical laboratory science (CLS), or medical laboratory science (MLS); **AND**

⇒ Be certified and continue to be certified by a board approved by HHS; **AND**

⇒ Have at least 1 year experience directing or supervising nonwaived laboratory testing.

Moderate Complexity Laboratory Director, continued:

5. **Hold an earned doctoral degree; AND**

⇒ Have an approved thesis or research project in biology/chemistry/MT/CLS/MLS related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; **AND**

⇒ Be certified and continue to be certified by a board approved by HHS; **AND**

⇒ Have at least 1 year experience directing or supervising nonwaived laboratory testing.

6. **Have earned a master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution**; **AND**

⇒ Have at least 1 year of laboratory training or experience, or both, in nonwaived testing; **AND**

⇒ Have at least 1 year of supervisory laboratory experience in nonwaived testing; **AND**

7. **Meet bachelor's degree equivalency; AND**

⇒ Have at least 16 semester hours of additional *graduate* level coursework in biology, chemistry, MT, CLS or MLS; **AND**

⇒ Have at least 1 year of laboratory training or experience, or both, in nonwaived testing; **AND**

⇒ Have at least 1 year of supervisory laboratory experience in nonwaived testing; **AND**

8. **Meet bachelor's degree equivalency**; **AND**

⇒ Have at least 16 semester hours in a combination of *graduate* level coursework in biology, chemistry, MT, CLS or MLS ***and*** an approved thesis or research project in biology/chemistry/MT/MLS/MLS related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; **AND**

⇒ Have at least 1 year of laboratory training or experience, or both, in nonwaived testing; **AND**

⇒ Have at least 1 year of supervisory laboratory experience in nonwaived testing; **AND**

9. **Have earned a bachelor's degree in a chemical, biological science, CLS, MLS, MT from an accredited institution**, **AND**

⇒ Have at least 2 years of laboratory training or experience, or both, in nonwaived testing; **AND**

⇒ Have at least 2 years of supervisory laboratory experience in nonwaived testing; and

10. **Have at least 120 semester hours, or equivalent, from an accredited institution that, at a minimum, includes**:

⇒ 48 semester hours of MLS or medical laboratory technology (MLT) courses; **AND**

⇒ Have at least 2 years of laboratory training or experience, or both, in nonwaived testing; **AND**

⇒ Have at least 2 years of supervisory laboratory experience in nonwaived testing; and

11. **Have at least 120 semester hours, or equivalent, from an accredited institution that, at a minimum, includes**:

⇒ 48 semester hours of science courses that include:

- 12 semester hours of chemistry, which must include general chemistry and biochemistry or organic chemistry,
- 12 semester hours of biology, which must include general biology and molecular biology, cell biology or genetics; and
- 24 semester hours of chemistry, biology, MLS or MLT in any combination; **AND**

⇒ Have at least 2 years of laboratory training or experience, or both, in nonwaived testing; **AND**

⇒ Have at least 2 years of supervisory laboratory experience in nonwaived testing; **AND**

12. **An individual is considered qualified if they were qualified and serving as a laboratory director of a moderate complexity CLIA certified laboratory prior to 12/28/2024 and have done so *continuously* since 12/28/2024.**

High Complexity Laboratory Director

With the updated CLIA regulations and interpretive guidelines, there are now six pathways to qualify as a high complexity laboratory director.

1. **Be a MD or DO licensed to practice medicine or osteopathy in the State in which the laboratory is located**; **AND**

⇒ Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology;

2. **Be a MD, DO, or DPM licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located**; **AND**

⇒ Have at least 2 years of experience directing or supervising high complexity testing; **AND**

3. **Hold an earned doctoral degree in a chemical, biological, CLS, MLS, or MT from an accredited institution**; **AND**

⇒ Be certified and continue to be certified by a board approved by HHS; **AND**

⇒ Have at least 2 years of laboratory training or experience, or both; **AND**

⇒ Have at least 2 years of laboratory experience directing or supervising high complexity testing.

⇒ *The laboratory director can obtain the 2 years of laboratory training and experience and 2 years of laboratory experience directing or supervising high complexity testing simultaneous. The interpretive guidelines clarify a total of two years of laboratory training or experience and laboratory experience direction or supervising high complexity testing.*

4. **Hold an earned doctoral degree**; **AND**

⇒ Have at least 16 semester hours of doctoral level coursework in biology, chemistry, MT, CLS, or MLS; **AND**

⇒ Be certified and continue to be certified by a board approved by HHS; **AND**

⇒ Have at least 2 years of laboratory training or experience, or both; **AND**

⇒ Have at least 2 years of laboratory experience directing or supervising high complexity testing.

⇒ *The laboratory director can obtain the 2 years of laboratory training and experience and 2 years of laboratory experience directing or supervising high complexity testing simultaneous. The interpretive guidelines clarify a total of two years of laboratory training or experience and laboratory experience direction or supervising high complexity testing.*

5. **Hold an earned doctoral degree; AND**

⇒ Have an approved thesis or research project in biology/chemistry/MT/MLS/MLS related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; **AND**

⇒ Be certified and continue to be certified by a board approved by HHS; **AND**

⇒ Have at least 2 years of laboratory training or experience, or both; **AND**

⇒ Have at least 2 years of laboratory experience directing or supervising high complexity testing.

⇒ *The laboratory director can obtain the 2 years of laboratory training and experience and 2 years of laboratory experience directing or supervising high complexity testing simultaneous. The interpretive guidelines clarify a total of two years of laboratory training or experience and laboratory experience direction or supervising high complexity testing.*

6. **An individual is considered qualified if they were qualified and serving as a laboratory director of a high complexity CLIA certified laboratory prior to 12/28/2024 and have done so *continuously* since 12/28/2024.**

What does CMS mean by served "continuously" as a laboratory director?

For a moderate or high complexity laboratory director to be considered "continuously" employed, the individual may not have more than 6 months of break in employment as a laboratory director for a two year period. For example, if an individual previously qualified as a moderate complexity laboratory director in 2020 but stepped down from their position and now would like to qualify as the laboratory director of a new facility, they do not meet the grandfather requirement and will need to be requalified under the new regulations.

What documentation will be accepted to meet the 20 CE credit hours?

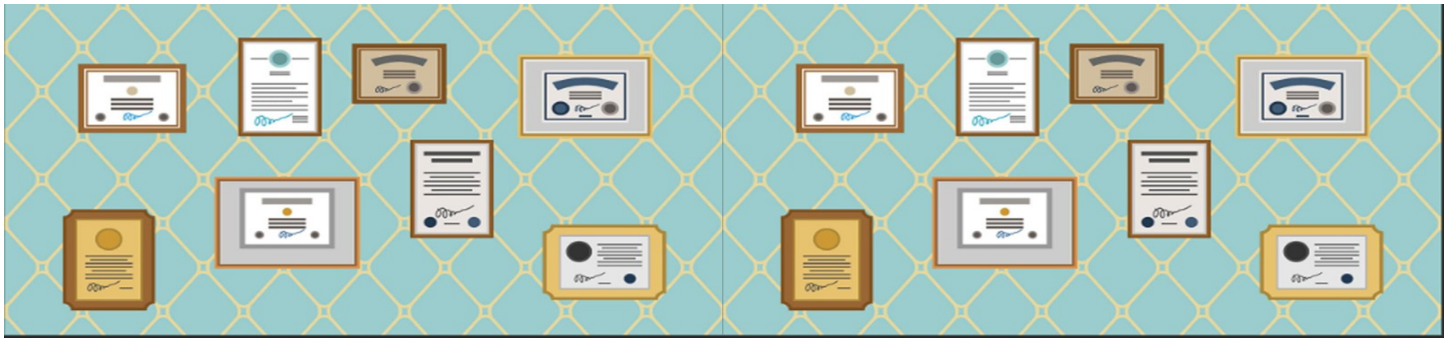
The 20 CE credit hours must be obtained prior to qualifying as a laboratory director. The CE credit hours must encompass preanalytic, analytic, and postanalytic phases of testing. Examples of CE courses can be found on the CMS website. Additional examples of CE courses would include PACE credits from attended presentations, or course hours obtained from on-line training. It is the laboratory director's responsibility to gather the 20 CE credit hour documentation. The courses **must** relate to the laboratory director responsibilities. A course related to laboratory payment or CPT coding would not count as a CE credit hour, as the course is not related to the laboratory director's responsibility.

What records will be accepted to document the training or experience necessary to qualify a laboratory director?

Some examples of training or experience records include, but are not limited to: training and competency records from a previous or current employer; attestation statements of an individual's training and experience from a previous or current employer; log sheets initialed by the individual indicating attendance at a training session or in-service; and certificates from organizations providing training sessions, workshops, conferences, and specialty courses. Additionally, the CMS-209 Personnel form approved by a CLIA State Agency can be used to document training and experience. The training records must be generated by an individual other than the person attempting to meet CLIA personnel qualifications requirements. A curriculum vitae (CV) is not acceptable to document training or experience verification.

What are the HHS approved boards to qualify for a PhD?

- ABB – American Board of Bioanalysis
- ABB – Public Health Microbiology certification,
- ABCC – American Board of Clinical Chemistry.
- ABFT – American Board of Forensic Toxicology
- ACHI – American College of Histocompatibility and Immunogenetics
- ABMGG – American Board of Medical Genetics and Genomics
- ABMLI – American Board of Medical Laboratory Immunology
- ABMM – American Board of Medical Microbiology
- DMLI – Diplomate in Medical Laboratory Immunology, American Society of Clinical Pathology (ASCP) Board of Certification (BOC)
- NRCC – National Registry for Certified Chemists – Clinical Chemist or Toxicological Chemist certifications only



Moderate and High Complexity Laboratory Director Responsibilities

The laboratory director responsibilities are the same for both moderate and high complexity laboratory directors and include:

1. The overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations.
2. **Must be onsite at least once every 6 months, with at least 4 months between the minimum of two on-site visits.** Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed. The director must provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities.
3. Cannot direct more than five non-waived laboratories.
4. Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanayltic, analytic, and post analytic phases of testing.
5. Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed.
6. Provide a safe environment in which employees are protected from physical, chemical, and biological hazards.
7. Ensure that test methodologies selected have the capability of providing the qualify of results required for patient care.
8. Ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.

9. Ensure the laboratory personnel are performing the test methods as required for accurate and reliable results.
10. Ensure the laboratory is enrolled in an HHS-approved proficiency testing (PT) program for the testing performed.
11. Ensure the PT samples are tested as required under subpart H of this part.
12. Ensure the PT results are returned within the timeframes established by the PT program.
13. Ensure all PT reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.
14. Ensure an approved corrective action plan is followed when any PT result is found to be unacceptable or unsatisfactory.
15. Ensure that quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.
16. Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system.
17. Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified.
18. Ensure that patient test results are reported only when the system is functioning properly.
19. Ensure that reports of test results include pertinent information required for interpretation.
20. Ensure that consultation is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation concerning specific patient conditions.

Moderate and High Complexity Laboratory Director Responsibilities, continued:

21. Ensure that a general supervisor provides on-site supervision of high complexity test performance by testing personnel qualified under § 493.1489(b)(5). **(This responsibility applies only to high complexity laboratory directors)**.
22. Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in Subpart M.
23. Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.
24. Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.
25. Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.
26. Specify***, in writing***, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

What type of documentation is needed to verify the laboratory director's on-site visits?

Documentation of the laboratory director's on-site visits should demonstrate the laboratory is in continuous compliance with the CLIA regulations and interpretive guidelines. **The laboratory director's onsite visits cannot be delegated.** Examples of acceptable documentation include: logs indicating date and time of the director's visit; meeting minutes/summary of the visit; and/or notes of observations made during the visit. All documentation should be approved, dated, and signed by the laboratory director.

Which of the responsibilities can be delegated to other laboratory personnel?

- The moderate complexity laboratory director can delegate to the technical consultant, in writing, the following responsibilities: 7- 18 and 23 – 25.
- The moderate and high complexity laboratory director can delegate to the clinical consultant, in writing, responsibilities 19 and 20.
- The high complexity laboratory director can delegate to the technical supervisor, in writing, the following responsibilities: 7 – 18 and 23 – 25.
- The list of responsibilities that can be delegated to the general supervisor will be addressed in an upcoming CLIA Corner but can be found at in § 493.1463(b)(1) – (4).

The director must assign, in writing, the duties/responsibilities to each person involved in all phases of the testing process. The list of assigned duties must be current.

If you would like to be added to the CLIA Corner Google Group,

send an email to Kristi Rotzoll & Melinda Bochmann: SHL-CLIA@uiowa.edu