



Clinical Laboratory Improvement Amendments (CLIA)

Laboratory Director Responsibilities

What Are My Responsibilities As A Laboratory Director

NOTE: Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988 establishing quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. The final CLIA regulations were published in the Federal Register on February 28, 1992. The requirements are based on the complexity of the test and not the type of laboratory where the testing is performed. On January 24, 2003, the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare & Medicaid Services (CMS) published final CLIA Quality Systems laboratory regulations that became effective April, 24, 2003.



IS IT SUFFICIENT THAT I MEET THE EXPERIENCE, EDUCATIONAL, AND TRAINING REQUIREMENTS FOR A LABORATORY DIRECTOR UNDER CLIA?

No, in addition you must meet the regulatory responsibilities outlined below. You must demonstrate active involvement in the laboratory's operation and be available to the laboratory staff, as needed.

WHAT ARE MY OVERALL RESPONSIBILITIES?

As laboratory director, you are responsible for the overall operation and administration of the laboratory, including the employment of competent qualified personnel. Even though you have the option to delegate some of your responsibilities, you remain ultimately responsible and must ensure that all the duties are properly performed and applicable CLIA regulations are met. It is your responsibility to ensure that your laboratory develops and uses a quality system approach to laboratory testing that provides accurate and reliable patient test results.

WHAT IS THE QUALITY SYSTEM APPROACH?

In the quality system approach, the laboratory focuses on comprehensive and coordinated efforts to achieve accurate, reliable, and timely testing services. The quality system approach includes all of your laboratory's policies, processes, procedures, and resources needed to achieve consistent, high quality testing services. Integral to the quality system approach is **quality assessment**, which involves the following activities:

- *ongoing monitoring of each testing process used in your laboratory in order to identify errors or potential problems that could result in errors;*
- *taking corrective action; and*
- *evaluating the corrective actions taken, to make sure that they were effective and will prevent recurrence.*

WHAT ARE THE RESPONSIBILITIES FOR WHICH I MUST MAINTAIN DIRECT OVERSIGHT AND CANNOT DELEGATE TO OTHERS?

As laboratory director, you must ensure that:

- testing systems in the laboratory provide quality services in all aspects of test performance, i.e., the preanalytic, analytic, and postanalytic phases of testing and are appropriate for your patient population;
- physical and environmental conditions of the laboratory are adequate and appropriate for the testing performed;
- the environment for employees is safe from physical, chemical, and biological hazards and safety and biohazard requirements are followed;
- a general supervisor (high complexity testing) is available to provide day-to-day supervision of all testing personnel and reporting of test results as well as provide on-site supervision for specific minimally qualified testing personnel when they are performing high complexity testing;
- sufficient numbers of appropriately educated, experienced, and/or trained personnel who provide appropriate consultation, properly supervise, and accurately perform tests and report test results in accordance with the written duties and responsibilities specified by you, are employed by the laboratory;
- new test procedures are reviewed, included in the procedure manual and followed by personnel; and
- each employee's responsibilities and duties are specified in writing.

IN ADDITION TO LABORATORY DIRECTOR, WHAT ARE THE REQUIRED PERSONNEL POSITIONS FOR NONWAIVED TESTING NAMED IN THE CLIA REQUIREMENTS?

Moderate complexity testing

Technical consultant
Clinical consultant
Testing personnel

High complexity testing

Technical supervisor
Clinical consultant
General supervisor
Testing personnel

NOTE: The responsibilities for a technical consultant for moderate complexity and a technical supervisor for high complexity testing are the same. The responsibilities for a clinical consultant for moderate complexity and high complexity testing are also the same. The personnel *qualifications* for these positions may *be different* due to the need for specialized education, training and/or experience to address the higher level of test complexity.

MAY I ASSUME THE RESPONSIBILITIES OF OTHER POSITIONS REQUIRED IN THE CLIA REQUIREMENTS?

As director, you may assume the responsibilities for any position named in the CLIA requirements, such as clinical consultant, technical consultant (moderate complexity testing) or technical supervisor and general supervisor (high complexity testing), as long as you meet the personnel qualification requirements of education, experience, and training for the position in order to fulfill the responsibilities.

IF I CHOOSE NOT TO PERFORM THE RESPONSIBILITIES OF POSITIONS OTHER THAN DIRECTOR, MUST I DESIGNATE SEPARATE INDIVIDUALS FOR CLINICAL CONSULTANT, TECHNICAL CONSULTANT OR TECHNICAL SUPERVISOR, AND GENERAL SUPERVISOR?

You may choose separate individuals for each position or have individuals serve in multiple positions, as long as those individuals can fulfill the responsibilities and meet the personnel qualifications for the positions they are filling.

WHICH RESPONSIBILITIES MAY I DELEGATE AND TO WHOM?

As laboratory director, you may share some dual responsibilities with the *clinical consultant*; therefore, you may delegate, in writing, the responsibilities for ensuring:

- test reports include pertinent information for test interpretation, and
- availability for consultation concerning test results and the interpretation of those results as they relate to specific patient conditions.

As laboratory director, you share some dual responsibilities with the ***technical consultant*** (moderate complexity) or ***technical supervisor*** (high complexity); therefore, you may delegate, in writing, the responsibilities for ensuring:

- appropriate test method selection;
- adequate method verification in order to determine the accuracy and precision of the test;
- enrollment of the laboratory in a CMS-approved proficiency testing (PT) program for the test performed;
- PT samples are tested in accordance with the CLIA requirements;
- PT results are returned within the time frames established by the PT program;
- PT reports are reviewed by the appropriate staff;
- corrective action plans are followed when PT results are found to be unacceptable or unsatisfactory;
- quality assessment and quality control programs are established and maintained;
- acceptable analytical test performance are established and maintained for each test system;
- remedial actions are taken and documented when significant deviations from the laboratory's established performance characteristics are identified, and patient test results are reported only when the system is functioning properly;
- personnel have been appropriately trained and demonstrate competency prior to testing patient specimens;
- policies and procedures are established for monitoring personnel competency in all phases (preanalytic, analytic, and postanalytic) of testing to assure the ongoing competency of all individuals who perform testing;
- remedial training or continuing education needs are identified and training provided; and
- an approved procedure manual is available to all personnel.

For high complexity testing, the director or technical supervisor may delegate to a ***general supervisor***, in writing, the responsibilities for assuring:

- remedial actions are taken when test systems deviate from the laboratory's established performance specifications;
- patient test results are not reported until all corrective actions have been taken and the test system functions properly;
- orientation is provided to all testing personnel; and
- annual personnel performance evaluations and documentation of testing personnel performance competency.

HOW CAN I BE SURE OTHERS PERFORM THE DELEGATED RESPONSIBILITIES APPROPRIATELY?

Remaining actively involved in the operations of the laboratory is the best way to assure that others are performing the delegated duties appropriately. For example:

- Have a mechanism in place for effective communication among management and all personnel in the laboratory.
- Routinely review quality control and quality assessment activities to assure problems occurring within the laboratory are identified and corrected and the corrections are monitored for effectiveness and timeliness.
- If there are no apparent problems identified through the quality control or quality assessment programs for lengthy periods of time, investigate the possible need for more stringent or sensitive programs, as the current programs may not be appropriately identifying errors. You may find it necessary to make some changes in what you are monitoring. Once you have consistently achieved success with a quality assessment indicator, you may wish to move on to others.
- Make certain the quality assessment activities include a mechanism for resolution of any complaints received against the laboratory, either from the staff, public or clients of the laboratory.
- Make certain the quality assessment activities include a mechanism to address any breakdown in communication between the laboratory and persons authorized to order tests and receive test results.

- Review a sampling of PT results, ensure that PT samples are tested in the same manner as patient specimens and that the cause of PT failures are identified, corrected and documented.
- Ensure that laboratory staff and management are aware of CLIA requirements that preclude them from referring PT specimens to another laboratory or communicating about the results until after the date by which the laboratory must report PT results to the program for the testing event in which the samples were sent.
- Review a sampling of results obtained from procedures and their outcomes for verifying the accuracy of tests for which PT is not required.
- Review policies and procedures for personnel evaluation and a sampling of personnel evaluations.
- Review a sampling of the analytical performances of test systems for acceptability based on your laboratory's criteria.

**DOES THE MAXIMUM LIMIT OF DIRECTING
5 LABORATORIES APPLY IF SOME OF THE
LABORATORIES FOR WHICH I AM THE DIRECTOR
ONLY PERFORM WAIVED TESTS?**

No, the maximum limit of directing 5 laboratories (laboratories in this case means the number of certificates) is only applicable for laboratories performing nonwaived tests. However, the CLIA requirements have 3 exceptions for each certificate type that will allow one individual to direct multiple locations under one certificate. These 3 exceptions are:

- Laboratories that are not at a fixed location, that is, laboratories that move from testing site to testing site, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations may be covered under the certificate of the designated primary site or home base, using its address.
- Not-for-profit or Federal, State or local government laboratories that engage in limited (not more than a combination of 15 moderately complex or waived tests per certificate) public health testing, may file a single application.

- Laboratories within a hospital that are located at contiguous buildings on the same campus and under common direction may file a single application or multiple applications for the laboratory sites within the same physical location or street address.

IF I PERFORM BOTH MODERATE AND HIGH COMPLEXITY TESTING IN MY LABORATORY, DO ALL OF THE PERSONNEL NEED TO MEET THE QUALIFICATIONS FOR HIGH COMPLEXITY TESTING?

No, only those personnel that oversee or perform high complexity testing must meet the requirements for high complexity testing. Other personnel who meet the requirements for moderate complexity testing may oversee and/or perform moderate complexity tests.

WHAT ARE THE TOP TEN TIPS THAT I SHOULD CONSIDER AS A LABORATORY DIRECTOR?

The top ten tips you should consider as a laboratory director are:

1. Learn CLIA (www.cms.hhs.gov/clia); understand the laboratory director delegations and monitor them.
2. Review policies, procedures and processes; i.e., their quality system.
3. Review problem log and corresponding corrective actions. Learn from your/their mistakes.
4. Are the laboratory's panic values appropriate for the patient population?
5. Notify the State Department of Health and the accrediting organization, if applicable, of the change in laboratory director.
6. Review and evaluate the laboratory's quality assessment plan, indicators and monitor.
7. Review the laboratory's proficiency testing (PT) enrollment and performance, corrective actions for all missed challenges and speak to the staff about what constitutes intentional referral of PT.
8. Learn what equipment and test systems are used in the laboratory, the QC and validation protocols utilized and the tests' applicability to the patient population.

9. Understand the supervisory and testing personnel array for the laboratory; confirm their training and competency record and that there are adequate numbers of the right personnel for each discipline.
10. Ensure that the laboratory is customer focused.

WHERE CAN I FIND MORE INFORMATION AND GUIDANCE ON MY RESPONSIBILITIES ?

You can find more information in Appendix C of the State Operations Manual located on the CMS CLIA website at www.cms.hhs.gov/clia under “The Interpretive Guidelines for Laboratories”. You may also contact your local State Survey Agency or CMS–approved accreditation organization.

NOTE: This brochure is not a legal document. The official CLIA program provisions are contained in 42 CFR 493 of the regulations.

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