

Understanding CLIA Roles and Responsibilities within the Clinical Laboratory

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Disclosures

Relevant Financial Relationship(s):

Nothing to Disclose

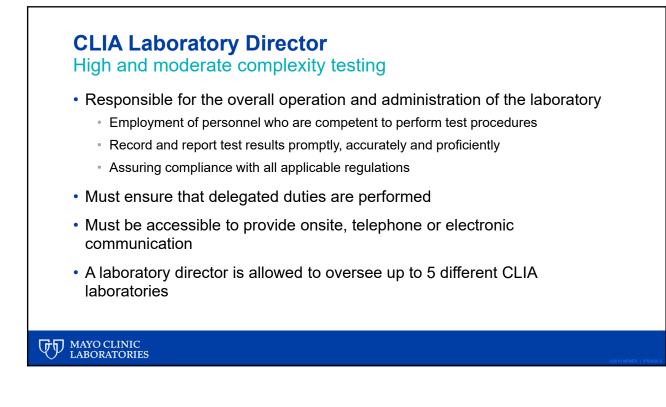
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Learning Objectives Define CLIA roles and appropriately assign responsibilities. Identify methods of delegating responsibilities. Review supervisor competency requirements.

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CLIA Role	High Complexity	Moderate Complexity	
CLIA Laboratory Director	X	X	
Technical Supervisor	X		
Technical Consultant		X	
Clinical Consultant	X	X	
General Supervisor	X		



Technical Supervisor High complexity testing

- The Technical Supervisor role is applicable only to laboratories that perform high complexity testing
- Responsible for the technical and scientific oversight of the laboratory
- Is not required to be on-site at all times testing is performed; however must be available to the laboratory on an as needed basis to provide supervision

Technical Supervisor Responsibilities

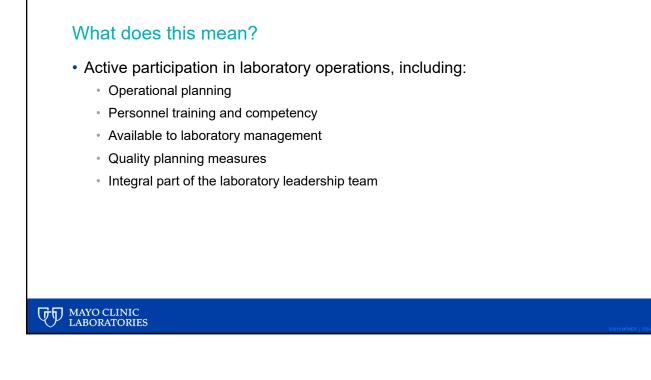
- All duties must be delegated from the CLIA laboratory director
 - · Appropriate test selection, with adequate method verification
 - Development of SOPs and maintenance records, including Quality Assurance, Quality Control and personnel documentation
 - Supervising enrollment in CMS approved proficiency testing programs
 - · Ensuring Proficiency Testing samples are tested and reviewed by appropriate staff
 - Carrying out corrective actions recommended by CLIA Lab Director, Consultant, Proficiency Testing, CLIA or other regulatory/accrediting bodies

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Technical Supervisor Responsibilities cont.

- Ensuring and supervising the development of effective quality assessment and quality control programs
- Documenting remedial actions and identifying systems for maintenance by keeping appropriate documentation on test systems
- · Overseeing laboratory personnel performance and competency
- · Planning for training or continuing education needs





What does this mean?

- You <u>must</u> maintain responsibility, including oversight and final sign off of all Technical Supervisor requirements
 - You can assign someone to do the work, but you must have oversight
- If responsibilities are delegated, the delegation must be in writing
 - Delegated person must meet Technical Supervisor qualifications
 - Technical Supervisor will still maintain oversight of delegated duties



General Supervisor

High Complexity testing

- The General Supervisor role is applicable only to laboratories that perform high complexity testing
- Day-to-day supervision of test performance by testing personnel
- Monitoring the laboratory processes to ensure that acceptable levels of analytic performance are maintained, to include review of qualify control, instrument and equipment maintenance, and other qualify assurance activities

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General Supervisor Responsibilities

- All duties must be delegated from the CLIA laboratory director or Technical Supervisor
 - Assures that all remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications
 - Ensures that patient test results are not reported until all corrective actions have been taken and the test system is properly functioning
 - Provides orientation to all testing personnel
 - Annually evaluating and documenting the performance of all testing personnel
- · Delegated person must meet General Supervisor qualifications
- Delegation <u>must</u> be in writing

Technical Consultant

Moderate complexity testing

- The Technical Consultant role is applicable only to laboratories that perform moderate complexity testing
- Responsible for the technical and scientific oversight of the laboratory
- Is not required to be on-site at all times testing is performed; however must be available to the laboratory on an as needed basis to provide supervision

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Technical Consultant Responsibilities

- All duties must be delegated from the CLIA laboratory director
 - · Appropriate selection of test methodology for the clinical use of the test results
 - Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system
 - Enrollment and participation in a CMS approved proficiency testing program
 - Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process

Technical Consultant

Responsibilities cont.

- Technical problems are resolved and assure remedial actions have been taken and the test system is functioning properly
- Identifying training needs and assuring that each individual performing testing receives regular in-service training and education. *NOTE: Trainers do not need to meet the qualifications of a Technical Consultant.*
- Evaluation and documentation of testing personnel competency at least semiannually during the first year the employee tests patient specimens and annually thereafter. *Direct observation must be performed by someone meeting Technical Consultant qualifications.*

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Clinical Consultant

High and moderate complexity testing

• Provides consultation regarding the appropriateness of testing ordered and the interpretation of teste results



Clinical Consultant Delegated duties

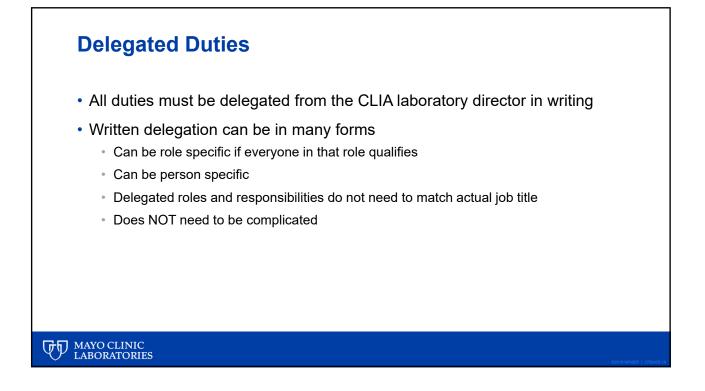
- All duties must be delegated from the CLIA laboratory director in writing
 - · Available to provide consultation to the laboratory's clients
 - Assist the laboratory's client in ensuring that appropriate tests are ordered to meet clinical expectations
 - Ensure that reports of test results include pertinent information required for specific patient interpretation
 - Ensure that consultation is available and communicated to the laboratory's clients on matters related to the qualify of the test results reported and the interpretation concerning specific patient conditions

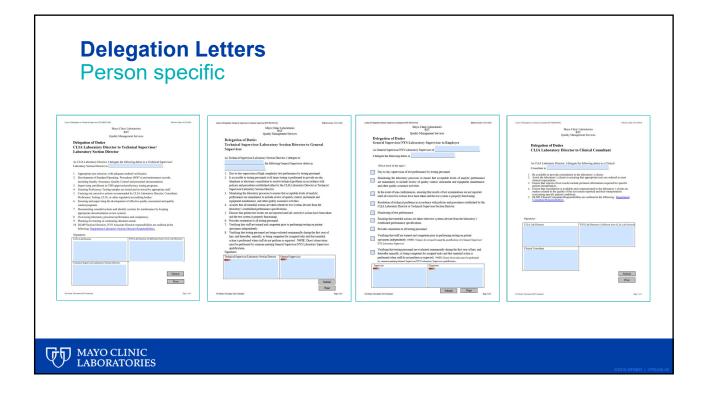
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How do I manage all of these responsibilities?

CLIA requirement	Laboratory	
Selection of Test methodology	Test Validation Process/Process Management	
Verification of Test procedures performed, including test performance characteristics (precision/accuracy)		
Enrollment in Proficiency Testing program		
Establishing a Quality Control program appropriate for testing performed		
Resolving technical problems and taking actions when test systems deviate	Event Management	
Ensuring patient test results are not reported until corrective actions are taken	Process Management	
Identifying training needs and assuring that personnel received appropriate training and education	Training Programs Each laboratory will have a specific training program established.	
Ensuring competency of all testing personnel, including all areas of competency assessment	Competency Assessment programs *Direct observation must be done by someone meeting General Supervisor qualifications. This cannot be delegated to someone that does not meet this qualification.	
Evaluating performance of individuals semiannually during the first year and at least annually thereafter		

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Competency Assessment Requirements

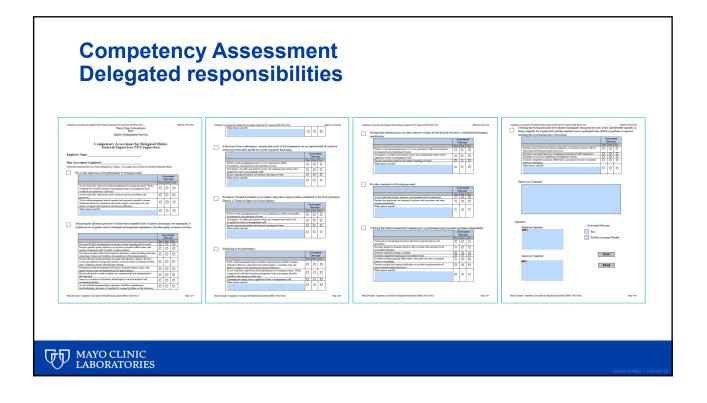
- Documented competency assessment is required for the following named positions:
 - Technical Supervisor
 - General Supervisor
 - Technical Consultant
 - Clinical Consultant
- The laboratory must have policies and procedures to assess competency based on the position responsibilities
- If they perform testing on patient specimens, they are required to have the six required procedures in their competency assessment in addition to a competency assessment based on their federal regulatory responsibilities

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Competency Assessment

- Should encompass assigned responsibilities
 - Include delegated responsibilities
- · Assessment should be completed annually
- Can be incorporated into annual performance appraisals/evaluations







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Heidi Miksanek June 12, 2019

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