



Understanding CLIA Roles and Responsibilities within the Clinical Laboratory

Lisa Becker
Quality Management Coordinator
Mayo Clinic
Rochester, Minnesota



©2018 MFMER | 3793435-1

Disclosures

Relevant Financial Relationship(s):

Nothing to Disclose

Off Label Usage:

Nothing to Disclose



©2018 MFMER | 3793435-2

Learning Objectives

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

CLIA Roles

Varies by test complexity

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

**Note: It is possible to serve as a Technical Supervisor/Technical Consultant in one laboratory and Clinical Consultant in another or to fulfill multiple roles within the same laboratory.

CLIA Laboratory Director

High and moderate complexity testing

- Responsible for the overall operation and administration of the laboratory
 - Employment of personnel who are competent to perform test procedures
 - Record and report test results promptly, accurately and proficiently
 - Assuring compliance with all applicable regulations
- Must ensure that delegated duties are performed
- Must be accessible to provide onsite, telephone or electronic communication
- A laboratory director is allowed to oversee up to 5 different CLIA laboratories

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

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?

- Active participation in laboratory operations, including:
 - Operational planning
 - Personnel training and competency
 - Available to laboratory management
 - Quality planning measures
 - Integral part of the laboratory leadership team

What does this mean?

- You must 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 quality control, instrument and equipment maintenance, and other quality assurance activities

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 must 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

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.*

Clinical Consultant

High and moderate complexity testing

- Provides consultation regarding the appropriateness of testing ordered and the interpretation of test 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 quality of the test results reported and the interpretation concerning specific patient conditions

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	Event Management
Resolving technical problems and taking actions when test systems deviate	Process Management
Ensuring patient test results are not reported until corrective actions are taken	Training Programs <i>Each laboratory will have a specific training program established.</i>
Identifying training needs and assuring that personnel received appropriate training and education	
Ensuring competency of all testing personnel, including all areas of competency assessment	Competency Assessment programs <i>*Direct observation must be done by someone meeting General Supervisor qualifications. This cannot be delegated to someone that does not meet this qualification.</i>
Evaluating performance of individuals semiannually during the first year and at least annually thereafter	

Delegated Duties

- All duties must be delegated from the CLIA laboratory director in writing
- Written delegation can be in many forms
 - Can be role specific if everyone in that role qualifies
 - Can be person specific
 - Delegated roles and responsibilities do not need to match actual job title
 - Does NOT need to be complicated



Delegation Letters Person specific

The image displays four sample Delegation Letters from Mayo Clinic Laboratories, each titled "Delegation of Duties" and "Person specific".

- Letter 1: Delegation of Duties CLIA Laboratory Director to Technical Supervisor/Laboratory Section Director**
 - As CLIA Laboratory Director, I delegate the following duties to a Technical Supervisor/Laboratory Section Director:**
 1. Approve test methods, with adequate method validation.
 2. Development of Standard Operating Procedures (SOP) and maintenance records, including Quality Assurance, Quality Control and personnel documentation.
 3. Supervise activities as CMS approved proficiency testing program.
 4. Ensure Proficiency Testing samples are tested and received by appropriate staff.
 5. Carry out corrective actions recommended by CLIA Laboratory Director, Consultant, Proficiency Testing, CLIA or other regulatory accrediting bodies.
 6. Ensuring and supervising the development of effective quality assessment and quality control programs.
 7. Documenting harmful actions and identify systems for maintenance by keeping appropriate documentation on test systems.
 8. Overseeing laboratory personnel performance and competency.
 9. Planning for testing or maintaining classifier needs.
 10. ICMAP Section Director, NYS Associate Director responsibilities are outlined at the following: [Department Laboratory Section Director Responsibilities](#).
 - Signatures:**
 - CLIA Lab Director: [Signature]
 - NYS Lab Director (if different from CLIA Lab Director): [Signature]
 - Technical Supervisor/Laboratory Section Director: [Signature]
- Letter 2: Delegation of Duties Technical Supervisor/Laboratory Section Director to General Supervisor**
 - As Technical Supervisor/Laboratory Section Director, I delegate to [Name] the following General Supervisor duties:**
 1. Day-to-day supervision of high complexity test performance for testing personnel.
 2. It is acceptable for testing personnel at all times using a permit-to-work as an authorization or other device, constituting to transfer method, procedure, in accordance with policies and procedures established either by the CLIA Laboratory Director or Technical Supervisor/Laboratory Section Director.
 3. Monitoring the laboratory processes to ensure that acceptable levels of analytic performance are maintained in multiple areas of quality control, instrument and equipment maintenance, and other quality assurance activities.
 4. Assure that all method activities on this laboratory test system adhere to the laboratory's established performance specifications.
 5. Ensure that patient test results are not reported until all corrective actions have been taken and the test system is properly functioning.
 6. Provide assistance to all being provided.
 7. Verifying that staff are trained and competent prior to performing testing on patient specimens independently.
 8. Verifying that testing personnel are evaluated continuously during the first year of hire, and thereafter annually, as being competent for assigned tasks and that method activities is performed when staff do not perform as expected. **NOTE:** Direct observation must be performed by supervisor assuming General Supervisor/NYS Laboratory Supervisor qualifications.
 - Signatures:**
 - Technical Supervisor/Laboratory Section Director: [Signature]
 - General Supervisor: [Signature]
- Letter 3: Delegation of Duties General Supervisor/NYS Laboratory Supervisor to Employee**
 - As General Supervisor/NYS Laboratory Supervisor of [Name], I delegate the following duties to [Name]:**

(Please check the box(es) that apply.)

 - Day-to-day supervision of test performance for testing personnel.
 - Monitoring the laboratory processes to ensure that acceptable levels of analytic performance are maintained, to include review of quality control, instrument and equipment maintenance, and other quality assurance activities.
 - In the event of non-compliance, ensuring that results of test examinations are not reported until all corrective actions have been taken and the test system is properly functioning.
 - Resolution of method problems in accordance with policies and procedures established by the CLIA Laboratory Director or Technical Supervisor Section Director.
 - Monitoring of test performance.
 - Ensuring that method activities are taken when test system deviate from the laboratory's established performance specifications.
 - Provide assistance to all being provided.
 - Verifying that staff are trained and competent prior to performing testing on patient specimens independently. **NOTE:** Duties are not used to meet the qualifications of a General Supervisor/NYS Laboratory Supervisor.
 - Verifying that testing personnel are evaluated continuously during the first year of hire, and thereafter annually, as being competent for assigned tasks and that method activities is performed when staff do not perform as expected. **NOTE:** Direct observation must be performed by supervisor assuming General Supervisor/NYS Laboratory Supervisor qualifications.
 - Signatures:**
 - General Supervisor: [Signature]
 - Employee: [Signature]
- Letter 4: Delegation of Duties CLIA Laboratory Director to Clinical Consultant**
 - As CLIA Laboratory Director, I delegate the following duties to a Clinical Consultant in [Name]:**
 1. Be available to provide consultation to the laboratory's clients.
 2. Assess the laboratory's clinical testing and reporting tools are ordered to meet clinical requirements.
 3. Ensure that reports of test results include pertinent information required for specific clinical interpretation, as applicable and commensurate to the laboratory's claims on matters related to the quality of the test results reported and their interpretation (including specific patient population).
 4. **NOTE:** CLIA or other regulatory responsibilities are outlined at the following: [Department Laboratory Section Director Responsibilities](#).
 - Signatures:**
 - CLIA Lab Director: [Signature]
 - NYS Lab Director (if different from CLIA Lab Director): [Signature]
 - Clinical Consultant: [Signature]



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

Competency Assessment

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

Next Upcoming Webinar

Coaching Staff & Leadership Behaviors

Heidi Miksanek

June 12, 2019