



LabGuide 3



This LabGuide pertains to QSE Personnel and the General Phase of the Path of Workflow.

Laboratory Director Responsibilities

Clinical laboratories must have a qualified laboratory director who is responsible for the overall operation and administration of the laboratory. Meeting these responsibilities requires time and effort, but the laboratory director's role is essential to the success of the laboratory. Some responsibilities can be delegated to qualified individuals, but the laboratory director remains ultimately responsible.

A laboratory director may direct no more than five non-waived labs, and is required by the Clinical Laboratory Improvement Amendments of 1988 (CLIA) to meet the following responsibilities.

Responsibilities can be grouped in the following categories:

(p1) General

(p1) Procedural

(p2) Personnel

(p2) Proficiency Testing

(p3) Quality Control

(p3) Quality Assessment

General Responsibilities

The laboratory director must:

- Be accessible to the laboratory to provide onsite, telephone, or electronic consultation as needed
- Ensure that the physical plant and environmental conditions are appropriate for the testing performed
- Provide a safe environment that protects employees from physical, chemical, and biological hazards
- Ensure compliance with applicable regulations (federal, state, accrediting agency)
- Verify that responsibilities that can be delegated are properly performed if they are delegated

Procedural Responsibilities

The laboratory director must:

- Ensure testing systems provide quality laboratory services for pre-analytic, analytic, and post-analytic phases of testing
- Ensure test methods selected have the capability of providing quality results
- Ensure verification procedures used are adequate to determine accuracy, precision, and other pertinent performance characteristics of the method
- Ensure that reports of test results include pertinent information required for interpretation
- 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
- Ensure that an approved procedure manual is available to all personnel.
- Ensure that laboratory personnel are performing the test methods as required for accurate and reliable results



Did you know that CLIA defines specific personnel positions for Moderate Complexity and High Complexity laboratories? Laboratory Director, Clinical Consultant, Technical Consultant and Testing Personnel are defined for Moderate Complexity. Laboratory Director, Clinical Consultant, Technical Supervisor, General Supervisor and Testing Personnel are defined for High Complexity.

Personnel Responsibilities

The laboratory director must:

- Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, supervision, and accurate performance of tests and reporting of test results
- Ensure that only qualified personnel perform testing, and that prior to testing patient specimens, all personnel receive the appropriate training for the type and complexity of services offered, and demonstrate that they can perform all testing operations reliably to produce and report accurate results
- Specify in writing the list of responsibilities and duties for each individual performing pre-analytic, analytic, and post-analytic phases of testing that states the level of activity each is authorized to perform, whether supervision is required, and whether consultant or director review is required prior to reporting patient test results
- Ensure that policies and procedures are established for monitoring individuals who conduct pre-analytical, analytical, and post-analytical phases of testing to verify that they maintain competency to:
 - Process specimens
 - Perform test procedures
 - Report test results promptly and proficiently
- Identify needs for remedial training or continuing education to improve skills whenever necessary
- Ensure that a general supervisor provides on-site supervision of high complexity test performance by testing personnel who have qualified by certain means

Proficiency Testing Responsibilities

The laboratory director must:

- Ensure that the laboratory is enrolled in an approved proficiency testing (PT) program
- Ensure that PT samples are tested in the same manner as patient samples
- Ensure that PT samples are tested in compliance with regulations prohibiting referral of specimens and communication or sharing of results
- Ensure that PT results are returned on time to the PT program
- Ensure that PT results are reviewed by the appropriate staff and a corrective action plan is followed when PT results are unsatisfactory

Proficiency Testing is an independent means of measuring the quality of your laboratory testing.

Quality Control Responsibilities

The laboratory director must:

- Ensure that a quality control program is established and maintained to identify failures in quality as they occur
- Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system
- Ensure that remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified, and patient test results are reported only when the system is functioning properly

Quality Control is one component of your overall Quality Assessment program.

Quality Assessment Responsibilities

The laboratory director must:

- Ensure that a quality assessment program is established and maintained to monitor general, pre-analytic, analytic, and post-analytic laboratory activities in order to identify errors or potential problems that could lead to errors
- Ensure that corrective actions are taken for identified errors, and that corrective actions are evaluated for their effectiveness and ability to prevent a recurrence

Conclusion

In summary, the laboratory director is responsible for ensuring that the laboratory provides accurate, reliable, and timely testing services. It is also important and necessary for the laboratory director to work with other physicians who order tests and with nursing and administrative personnel to be the "face" of the laboratory. Being an active liaison with other healthcare professionals can have great benefit for the laboratory and will support these ongoing work relationships.

When the laboratory undergoes an onsite regulatory inspection, the inspector will look for evidence of active involvement by the laboratory director in the daily operations of the laboratory. Effective direction and oversight of the laboratory has a positive impact on day-to-day operations, test results, and consequently, patient care.

Additional Resources:

CLIA Brochure # 7: Laboratory Director Responsibilities,

available at www.cms.hhs.gov/CLIA/downloads/brochure7.pdf

COLA's LabUniversity® on-line course *Laboratory Director Responsibilities*

available at www.cola.org

Relevant COLA Accreditation Criteria: PER 4

References:

COLA Accreditation Manual. June, 2007.

CLIA Requirements, 42 CFR, Part 493, Subpart M, 493.1407 and 493.1445

