Personnel Training & Competency Assessment

COLA®

YOUR TRAINING PROGRAM SHOULD HAVE DEFINED OBJECTIVES, METHODS, AND TRAINING MATERIALS.

PERSONNEL TRAINING

Even with the simplest of tests, errors can occur if the test is not performed correctly, ultimately having an adverse effect on patient care. Accurate and reliable test results are achieved when a test is performed following all manufacturer instructions. Proper training and ongoing competency assessment will help to ensure the test is being performed correctly every time.

All new employees need orientation and training for YOUR lab. Every facility is different, and regardless of how much laboratory experience an individual has, new employees must be trained in the following areas:
- Their assigned duties and responsibilities
- Your laboratory policies, including your system for ensuring quality
- Your laboratory procedure manual(s)
- Procedures for all of the tests the individual will be authorized to perform
- Your laboratory quality assessment plan
- Your OSHA and safety practices
- Your computer system (LIS), or your paper test requisitions, records, and reports
- Your HIPAA protocols

Current employees need ongoing training:
- When new processes and test procedures are implemented
- When current processes and test procedures are changed
- Whenever the need for additional training is identified (e.g., a failed competency assessment, proficiency testing failure, identified problem)

The intent of training is to provide the individual with the knowledge and skills necessary to be competent in their assigned duties and responsibilities.

Additional training may be necessary to ensure ongoing competency. Your training program should have defined objectives, methods, and training materials. It should also specify a qualified individual as the trainer.

The trainer should be a qualified individual with technical laboratory experience who regularly performs the process or test procedure. The trainer may be an experienced lab co-worker, lab supervisor, or outside lab consultant. The following are important attributes of effective trainers:
- Good verbal skills
- Demonstrated attention to detail
- Demonstrated attention to Good Laboratory Practices
- Ability to objectively evaluate the individual and the effectiveness of the training
- Ability to provide constructive feedback

Develop a training checklist for each lab position that includes all the pre-analytical, analytical and post-analytical processes and procedures that are associated with that job, and document all training activities. After training, confirm competency before patient testing begins.

For quality test performance in your laboratory, training must ensure that all testing personnel are familiar with the following for each test procedure:
- The test name and purpose of the test
- The equipment necessary to perform the test
- Specimen collection and handling
- Preparation, labeling, use, and storage of reagents, standards, and controls
- Special requirements, safety procedures, etc.
- Instrument maintenance, function checks, and calibration, when applicable
- Step-by-step performance of the test procedure
- Quality control procedures including what constitutes acceptable results and when to report patients
- How to recognize and interpret inconsistent results and test system problems and perform troubleshooting
- Recommended corrective action when controls are unacceptable
- Necessary calculations and derivation of results, when applicable
- Reference ranges and critical values
- Result reporting
- Quality assessment procedures

It is important that personnel do not report test results on patient specimens until training is completed and competency is verified for each specific test procedure.

A basic protocol for test procedure training could include having the trainee:
- Read the entire package insert and/or test procedure to become familiar with the items listed above
- Observe the specimen collection, handling, and processing steps used to obtain the specimen and get it ready for testing
- Observe as the trainer performs and documents all applicable maintenance, start-up and function checks, calibration, and quality control procedures
- Observe as the trainer tests specimens
- Observe and discuss the evaluation of quality control result acceptability and interpretation of specimen results
- Perform all quality control procedures
- Perform the test using previously tested specimens and compare the results obtained

The trainer should evaluate the trainee's test performance and provide feedback, additional instruction, and follow-up evaluations to ensure effective training.

Personnel training must be documented and retained in the personnel files of all laboratory testing personnel.

PERSONNEL MUST NOT REPORT TEST RESULTS FOR PATIENT SPECIMENS UNTIL TRAINING IS COMPLETE AND COMPETENCY IS VERIFIED FOR EACH TEST PROCEDURE THEY PERFORM.

COMPETENCY ASSESSMENT

Competency Assessment is the means to confirm that training is effective and that personnel are capable of following established procedures to accurately perform laboratory testing that produces quality results.

The laboratory director must establish written policies and procedures to monitor the competency of individuals that perform testing.

The laboratory director or technical consultant/technical supervisor must follow those policies and procedures to periodically evaluate the competency of all staff involved in pre-analytic, analytic, and post-analytic phases of testing, as well as those responsible for supervision and consultation. This is not simply a traditional "employee performance review" of the individual's initiative, work ethic and interpersonal skills. The focus of competency assessment is to carefully evaluate the individual's continuing ability to:
• Perform assigned tasks according to the defined process and procedure
• Fulfill the duties and responsibilities of their position to assure accurate and reliable laboratory results.

The evaluation of each individual that performs testing must include assessment of actual test performance and interpretation of results. The competency evaluation of testing personnel must include, but is not limited to, the six methods required by the CLIA regulations and described in the table below.

Data from the various methods for evaluating competency can be gathered over time and placed in the personnel file for use at the time of scheduled competency assessments. This will aid in the observance of actual test performance and interpretation of results for all the different tests performed by the individual over the evaluation period. QA reviews that either confirm the proper performance of the reviewed activities (QC, maintenance, calibration, turn-around times, etc.) or identify problems can be used as data for assessing competency of the individuals involved in the activities. Another source of data is QA reviews performed by the individual being assessed, which contain elements related to identifying problems and problem solving skills that can be used for competency assessment.

Maintain detailed documentation of competency assessments, including clearly indicating the outcome. Was the individual found to be competent?

Competency assessments should occur every six months for the first year and annually thereafter for all testing personnel, supervisors, and technical consultants. Physicians and other providers that perform testing, especially microscopy, should be included. Create and follow policies and procedures to identify when an individual needs remedial training or continuing education to improve skills.

EVALUATION METHOD	EXAMPLE
Direct observation of patient test performance, including patient preparation; specimen handling, processing, and testing; and result interpretation	Watch employee performroutine work processes and procedures, and use a checklist to determine if all steps were properly completed.
Review of testing worksheets, quality control records, proficiency testing performance, and preventive maintenance records	Review worksheets, documentation forms, quality control records, and PT records for completeness, following proper policies and procedures, and follow-up of problems.
Direct observation of instrument maintenance and function checks	Watch employee perform instrument maintenance and function checks, and review documentation for completeness, correctness, and follow-up of problems.
Monitoring the recording and reporting of test results	Review worksheets, daily computer printouts,or test logs for incomplete results or incorrect entries.Compare test logs to final reports, evaluate turn-around-times, and adherence to policies and procedures.
Assessment of test performance by testing previously analyzed samples, internal blind or split samples, or proficiency testing samples	Assign a set of samples to test to determine if the correct results are obtained. Rotate performance of proficiency testing among all testing personnel.
Assessment of problem solving skills	Review problem logs and incident reports to determine if the root cause was determined, and if proper corrective actions were taken to resolve the problem. Interview personnel about or provide quizzes on how problem situations, including QC failures, would be handled.

CONTINUING EDUCATION

Continuing Education (CE) is important for all laboratory employees to ensure knowledge of the latest industry trends, which in turn, allows for continual interest in day-to-day responsibilities. It is a good way for employees to become aware of the latest developments in medical laboratory practices, and can help your lab provide better patient care more efficiently.

Neither CLIA nor COLA specify a minimum amount of continuing education; however, there are some state specific continuing education requirements that must be met either annually or biannually (depending on the state). COLA requires some form of relevant CE that is lab-related and documented.

There are many sources for laboratory continuing education, including:
• Conferences, seminars, workshops, and meetings
• Presentation and review of case studies
• Training on instruments or kits by the manufacturer
• Annual required training (safety, bloodborne pathogens)
• Online courses
• Articles in laboratory publications

Document all continuing education activities with the date, topic, source, and CE credits or time duration spent in the activity. Retain this documentation in the personnel file. A CE log form is useful for this purpose.

SEEK OUT OPPORTUNITIES FOR PROFESSIONAL GROWTH AND DEVELOPMENT THROUGH CONFERENCES, EDUCATION AND PROFESSIONAL ORGANIZATIONS.

PROFESSIONAL DEVELOPMENT

Laboratory professionals should look for opportunities for ongoing professional growth and development including:

• Active membership in a professional organization
- Read their journal articles
- Write an article for publication in the journal
- Participate in membership surveys
- Explore any continuing education opportunities that the organization offers
- Become an officer and serve at the local, state, regional, or national level
- Participate on a committee or task force
- Write a letter expressing interest in participating, or have an associate recommend you as a member
- Volunteer for projects and complete assignments on time

• Attend a regional or national meeting or conference
- Share what you have learned with your co-workers

• Obtain an advanced degree or certification
- Master's degree in healthcare administration or another laboratory medicine field
- Certification in a clinical laboratory specialty (e.g., specialist in chemistry, hematology, blood bank, etc.)
- Certification as a Quality Auditor or Quality Manager
- Certification as a Diplomate in Laboratory Management (DLM)

SUMMARY

Thorough initial training is essential for all new employees, followed by ongoing training when processes and procedures change. Competency Assessment confirms that training was effective and that personnel are capable of following established procedures to accurately perform laboratory testing that produces quality results. Competency can be enhanced through continuing education and opportunities for professional development. Proper training followed by ongoing competency assessment will help ensure that testing is performed correctly every time to give confidence that reliable results are produced by your laboratory.

WHAT ARE THE CLIA REQUIREMENTS?

The relevant CLIA requirements can be found at
http://www.ecfr.gov/cgi-bin/text-idx?SID=1248e3189da5e5f936e55315402bc38b&node=pt42.5.493&rgn=div5#se42.5.493_11407 (paragraphs 11, 12)
http://www.ecfr.gov/cgi-bin/text-idx?SID=1248e3189da5e5f936e55315402bc38b&node=pt42.5.493&rgn=div5#se42.5.493_11413 (paragraphs 7, 8, 9)

WHAT ARE THE COLA REQUIREMENTS?

COLA accreditation criteria **PER 1-6 and WAV 6** address the personnel training and competency requirements for COLA laboratories.

HELPFUL RESOURCES:

• LabUniversity® Online Courses at www.labuniversity.org
- *Laboratory Personnel Requirements*
- *Competency Assessment*
- *QSE Personnel*
- *MLE CEexpress 7: Training and Competency Assessment*

COLA is a physician-directed organization whose purpose is to promote excellence in laboratory medicine and patient care through a program of voluntary education, consultation, and accreditation

Comments? Feedback? Questions?
Email us at info@cola.org or call us at 800-981-9883

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