



Management Bulletin

North Carolina State Laboratory of Public Health | Laboratory Improvement Unit

Orientation and Training of New Testing Personnel

Orientation and Training

Consider the steps that must be taken in the process of learning to drive a car. First, orientation to the operation of a car along with the “rules of the road” is taught during classroom instruction. Then a permit is issued to the inexperienced driver to allow him to practice driving under the supervision of an experienced driver. There is a minimum amount of practice time required, but that time can be extended, if necessary. Finally, competency of driving skills is assessed during an observation by an official who will approve or prohibit unsupervised driving. If approved, a license for driving will be issued.

A similar process applies to testing in the clinical laboratory. New personnel in the laboratory must progress through several stages of training before approval to perform unsupervised patient testing can be issued. Orientation to the laboratory facilities is required for all new testers, even those with previous experience. Training should be provided by an experienced staffer and include all phases of laboratory testing, including reporting. The new tester should not report patient results until training has been completed and he has been determined to be competent.

Why Is Training Needed?

Training new laboratory personnel isn’t just a good idea; it is addressed in federal regulations. The federal regulations, known as CLIA ’88, address the need for orientation and training in several different standards. In section 42CFR 493.1423, the regulation states that testing personnel “have documentation of training appropriate for the testing performed prior

to analyzing patient specimens.” In 493.1235, the regulation states that “the laboratory must establish and follow written policies and procedures to assess employee competency.”

A structured orientation and training process ensures that all aspects of testing are addressed with the new laboratory employee. Orientation allows the new tester to become comfortable with the laboratory environment before learning specific procedures. An introduction to the specific analyzers and methodologies used in the laboratory should be included in the orientation, as well as the location of supplies, reagents, PPE, and safety equipment, such as the eye wash and fire extinguisher.

A good quality training process increases the odds of assuring the addition of a confident, competent employee to the staff. At the same time, it reduces the possibility of the new employee making mistakes and having to be retrained, which is costly and inefficient for the laboratory facility.

Who Should be Trained?

All persons assigned any laboratory duties must have training appropriate to those duties. Even technologists with many years of experience need to be oriented and trained in the processes, policies and procedures of a laboratory when starting employment at a new facility. Training should be provided by an experienced tester who, when applicable, has been successful with competency assessment challenges administered in the facility.

How Should Training Be Conducted?

Training should follow a well-defined process that is consistent for every new employee. Steps in the process may be shortened or lengthened according to the experience of the tester, but never omitted. The process should be described in a written policy included in the Laboratory Policy Manual.

The training process should include, at least, the following components:

- Review, by the new tester, of applicable manuals and procedures.
- Demonstration of the test procedure by the trainer.
- Observation of testing performed by the new tester.
- Comparison of duplicate testing results obtained by the trainer and the new tester.
- Explanation of instrument maintenance, troubleshooting, frequency of quality control, and acceptable quality control.

Training can also include attending applicable workshops, on-line programs, and self-study modules. Many manufacturers provide on-line training or CDs for their analyzers and these should be utilized when available.

Training Tools

Assuring thorough training can be accomplished by utilizing tools designed to track and document the steps in the process. The first requirement is having a written comprehensive **policy** for orientation and training of new testing personnel. The policy can be reinforced by creating a **checklist** that includes every aspect of the training process. The checklist provides a means to document when each part has been completed in a satisfactory manner. Another critical component for training is a manual that contains **current procedures** for all tests performed in the laboratory. Reading and understanding the test procedure is prerequisite

to performing any test. A **package insert** provided by the test manufacturer should also be available for review for additional information not contained in the procedure manual. **Quality Control (QC) log sheets** should be used to record controls for each test the trainee is authorized to perform. A **test requisition** should be used during training to assure the new tester is familiar with proper reporting methods for patient results.

Competency Assessment

After training is completed, the effectiveness of that training must be evaluated. As previously stated, CLIA regulations mandate that competency be determined for each tester. The Technical Consultant for the laboratory is responsible for evaluating the performance of every individual who performs moderate complexity testing at least semiannually during the first year and then annually after that. Competency can be assessed in several different manners ranging from direct observation to written quizzes. Training must be documented and competency reassessed if the methodology of the test changes. If a competency assessment is unsatisfactory, a corrective action plan must be developed and implemented. Corrective action may include additional on-site training, attending “wet” workshops and/or suspending testing by an individual. A written policy describing competency assessment frequency, methods, and corrective action must be in place for each facility.

Documentation

Orientation, training, and competency assessment of new testing personnel is not complete without documentation of each component. A copy of the education,

professional credentials and work experience of new testing personnel should be obtained and filed with either human resources or the laboratory manager. A checklist used during training can capture the dates and initials of the trainer(s). All training documents should be made available for review by the Laboratory Director. The Director must approve the new tester as the final step to performing patient testing.

Congratulations! The “license” has now been issued!

References:

http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Interpretive_Guidelines_for_Laboratories.html (Accessed 11/5/14)

Appendix C: Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services
<http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/apcpolicy.pdf>
(Accessed 11/5/14)

<http://www.shl.uiowa.edu/publications/cliacorner/2007q3.pdf> (Accessed 11/4/14)

APHL. 2013 CLIA Update: Tips for a Successful Survey.
<http://eo2.commpartners.com/users/APHL/downloads/588-909-13-3SlidesPerPage.pdf> (Accessed 11/4/14)

<http://www.cms2567.com/about.php> (Accessed 11/5/14)

Revised by Karen Wall, BSMT(ASCP)

Original release December 2010 by S. Felts



State of North Carolina • Roy Cooper, Governor
Department of Health and Human Services
Mandy Cohen, MD, MPH, Secretary, Division of
Public Health

www.ncdhhs.gov • www.publichealth.nc.gov

The Department of Health and Human Services does not discriminate on the basis of race, color, nation origin, sex, religion, age or disability in employment or the provision of services.