



CLIA Policy: Personnel Competency

Date: 3/17/2014

Supercedes: 3/4/2013

Ohio Department of Health, Bureau of Public Health Laboratory

Personnel Competency Policy

Purpose: This policy has been developed to meet the **Clinical Laboratory Improvement Amendments (CLIA) Standard 493.1235 (Standard Requirements for Personnel Competency Assessment Policy)**.

Principle: Training and competency assessments are necessary to ensure that laboratory staff report tests promptly, accurately and proficiently; ensure that laboratory staff is competent to perform test procedures; and ensure that satisfactory performance of test procedures remain consistent. In summary CLIA Standard 493.1235 states that the laboratory must establish and follow written policies and procedures to assess employee competency.

1. General Information on Competency Assessments

- 1.1. Competency assessments shall be performed before results are reported based on unassisted performance of a procedure (i.e. initial competency) and then again approximately six months later. Thereafter, competency assessment must be performed at least annually.
 - 2.1.1. Failure to complete a six-month or annual competency assessment as indicated above shall result in the exclusion of the staff member from performing the assay.
 - 2.1.2. The Supervisor over the assay must meet with the Laboratory Director to discuss the necessary actions to take before reinstatement of the staff's ability to perform the assay independently.
- 1.2. The assessments may be conducted by laboratory staff that is competent (completed the six-month competency assessment on the procedure) and that meets the following qualifications.
 - 1.2.1. Earned doctoral, master's, or bachelor's degree in chemical, physical, biological or clinical laboratory science from an accredited institution; and have at least 1 year of laboratory training or experience, or both, in high complexity testing; or
 - 1.2.2. Earned associate degree in a laboratory science and have at least 2 years of laboratory training or experience, or both, in high complex testing.
- 1.3. The Supervisor over the procedure must review and approve all assessments.



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2. Components of a Competency Assessment

- 2.1. The initial competency shall be assessed by a combination of the following items, as applicable.
 - 2.1.1. Trainee's reading of the standard operating procedure;
 - 2.1.2. Trainee's education on preanalytic methods (i.e., specimen collection, handling, storage and accessioning);
 - 2.1.3. Trainee's education on analytical methods (i.e., laboratory testing procedure, maintenance, troubleshooting, quality control and calibration);
 - 2.1.4. Trainee's education on postanalytical methods (i.e., result interpretation, method limitations, and result reporting); and
 - 2.1.5. Trainee's satisfactory completion of a laboratory practicum or proficiency. This can be accomplished by several means including the use of archived samples or a side-by-side analysis of current samples.

- 2.2. Six-month and annual competency shall be assessed by a combination of the following items, as applicable.
 - 2.2.1. Staff member's review of the standard operating procedure (annual competency only);
 - 2.2.2. Evaluator's direct observation of procedure performance by staff member (preanalytic, analytic and postanalytic);
 - 2.2.3. Evaluator's review of staff member's completed quality control records;
 - 2.2.4. Evaluator's review of staff member's proficiency test results;
 - 2.2.5. Evaluator's review of staff member's completed equipment maintenance records; and
 - 2.3.6. Assessment of staff member's problem solving skills. This can be accomplished by several means including the use of a quiz or the staff member's participation in a remedial/corrective action.

- 2.3. Should the test methodology or instrumentation change due to the addition of a new test system, a new initial competency assessment must be performed.

- 2.4. Should a deficiency be identified during the six month or annual assessment, the staff member will be excluded from performing the test until action can be taken to correct the problem. The Supervisor must consult with the Laboratory Director on the appropriate corrective action. Corrective action can include but is not limited to:
 - 2.4.1. Review of the protocol;
 - 2.4.2. Observation of another trained and competent staff member;
 - 2.4.3. Practice of the procedure with known samples; or
 - 2.4.4. Reinstitution of formal training.



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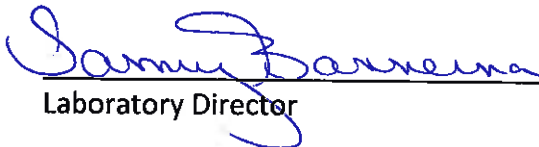
3. Documentation

- 3.1. The "Ohio Department of Health Laboratory Initial Training Form" will be completed to satisfy the requirements of initial training. Completed forms will be provided to the Laboratory Director for review and approval. Upon approval by the Laboratory Director, the staff member will be considered trained and able to perform the assay independently.
- 3.2. The "Ohio Department of Health Laboratory Six Month and Annual Assessment Form" will be completed to satisfy the requirements of six month and annual assessments. Completed forms will be provided to the Laboratory Director for review and approval.
- 3.3. Original copies of training or assessment documents will be maintained by the Quality Assurance (QA) office. Documents are maintained for the duration the staff member is employed by the Ohio Department of Health Laboratory plus two years post departure date.

Signature Approvals



QA Officer / 3/24/2014
Date



Laboratory Director / 3/17/2014
Date