

Training and Competency

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CLIA '88

- Regulations pertaining to training and competency found at 42 CFR 493
- Oversight provided by Centers for Medicare and Medicaid Services of the Department of Health and Human Services
- Contracted to the respective State Agencies

Delegation of Duties

Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the pre-analytic, analytic, and post-analytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. – 42 CFR 493.1407 and 493.1445.

Delegation of Duties

- Director responsibility
- Specify duties/responsibilities
 - Consultant
 - Supervisor
 - Testing person
- Engaged in all phases of testing
 - Pre-analytical
 - Analytical
 - Post-analytical

Delegation of Duties

- Identifies authorized performance
 - Examinations
 - Procedures
- Supervision requirements
 - Specimen processing
 - Test performance
 - Result reporting
- Review requirement prior to reporting results
- Must be *current!*

Personnel

- Testing personnel
 - Waived, no credentials required
 - Non-Waived
 - High complexity
 - Moderate complexity

Personnel

ACADEMIC CREDENTIALS ONLY!

- GED
- HIGH SCHOOL
- ASSOCIATES OF SCIENCE OR ARTS
- BACHELORS OF SCIENCE OR ARTS
- MASTERS
- Ph.D.
- MD, DO, DPM

Academic Credentials

- Accredited institution – a nationally recognized accrediting agency or association.

Academic Credentials

- Recognized by the Secretary means a school or program that is approved by
 - Council of Medical Education of the AMA
 - One of the 8 regional accreditation programs listed at <http://www.ed.gov>
 - New York Board of Regents
 - National Institutional and Specialized Accrediting Bodies (www.adhes.gov)

Personnel

- Certification (ASCP, NCA, AMT, etc) not acceptable
- Foreign credentials must be evaluated
 - <http://www.naces.org>
 - <http://www.aice-eval.org>
- Licenses and registrations (nursing, respiratory therapy) not acceptable

Training

Training

- The laboratory director is responsible for ensuring that testing personnel have the appropriate education and experience, and receive the appropriate training for the type and complexity of testing performed.

Training

- What constitutes experience?
 - Clinical
 - Examination of and test performance on human specimens
 - Diagnosis, treatment and monitoring of patient

Training

- Seminars
- On / off site instrument training
- Technical training sessions, workshops, conferences given by professional organizations

Training

- Technical education including hands-on test performance
- In-services offered by appropriate staff
- Formal laboratory training program

Training

- Documentation of training applicable to the types and complexity of tests performed.
- Consisting of, but not limited to
 - Certificate / letter of training program completion
 - Attestation statements from lab director
 - Certificate of attendance for training session
 - Letters from employers

Training

- Must ensure that the individual has skills required for proper specimen collection
 - patient preparation
 - labeling
 - handling
 - preservation/fixation
 - processing/preparation
 - transportation
 - storage of specimen

Training

- How to achieve this goal?
 - Procedure review
 - Observation of task
 - Written quiz
 - Check lists
 - Scenarios, what-ifs

Training

- Set job goals early
- Organize training schedule
- Review expectations
- Create question/answer periods
- Assess strengths and weaknesses
- Initially, assign easy tasks and judge performance
- Monitor daily progress
- Communicate

Training

- Ensure job duties are clearly defined
- Assign more difficult tasks as training progresses
- Commend trainee for accomplishing goals
- Split workload with trainee
- Encourage trainee to find answers to questions
- Have trainee discuss decisions rather than tell them what to do in difficult situations.

Training

- Tips and warnings
 - Clarify expectations
 - Keep expectations high
 - Use failures as opportunities to learn
 - Discuss decisions
 - Provide mentors
 - Be patient!

Training

- Who can train?
 - Director
 - TS (high complexity)
 - TC
 - General Supervisor (high complexity)

Training

- Considerations for POC testing
 - Location of testing
 - Testing personnel
 - Terminology
 - Clear definition of testing process
 - Monitoring / Oversight
 - Evaluate program needs
 - Communication / Cooperation

Competency

- Competency**
- Evaluate / document the performance of individuals responsible for testing
 - At least semi-annually during the first year the individual tests patient specimens
 - Thereafter evaluations must be performed at least annually.

- Competency**
- Policies / procedures to monitor individuals
 - Assure competency
 - Process specimens
 - Perform test procedures
 - Report test results

Competency

- **Direct observation**
 - Test performance
 - Specimen handling, processing, testing
 - Instrument maintenance
 - Function checks
- **Monitor test results**
 - Recording
 - Reporting

Competency

- **Review**
 - Intermediate test results or worksheets
 - Quality control records
 - Proficiency testing results
 - Preventive maintenance records

Competency

- **Assessment**
 - Test performance
 - Previously analyzed samples
 - Internal blind samples
 - PT
 - Problem solving skills

Competency

- Responsibility of
 - Director
 - TS (high complexity)
 - TC
 - General Supervisor (high complexity)

Questions ?

Thank you !

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