**TRAINING AND COMPETENCY**   **Administrative Procedure 755.A**

PURPOSE:

To establish and maintain Department of Pathology and Laboratory Medicine staff training and competency criteria. To document and maintain records of staff performance of assigned tasks, and ensure compliance with department's written policies and procedures and other departmental guidelines.

POLICY:

A department training and competency evaluation program must comply with the following regulatory and accrediting organizations: College of American Pathologists (CAP), The Joint Commission (JC), AABB Standards, and CLIA. The Section Medical Director is responsible for performing and documenting competency assessment for high complexity testing. These duties may be delegated in writing.

DEFINITIONS:

Training: The development of skills, knowledge and experience for a particular test, method, or instrument prior to reporting patient test results.

Competency: The application, knowledge, and experience after initial training to assess if personnel are performing testing correctly.

PROCEDURE:

A. Training:

> **Per CAP Checklist GEN.55450,** records that all laboratory personnel have satisfactorily completed training on all tasks performed, as well as instruments/methods applicable to their designated job must be maintained. The records may be maintained either in paper form or electronic form.

1. Activities requiring judgment or interpretive skills must be included in the training checklist.
2. Training must include demonstration of skills required for proper test performance of pre-analytic, analytic, and post-analytic phases of testing, as applicable.
3. Training documentation and records must make it possible for the inspector to determine what methods/instruments were trained.
4. The signature or initials of the Assessor on the training documents attests the Trainee's ability to perform each task under the expected level of oversight during routine patient testing.
5. Re-training must occur when problems are identified with employee performance, in direct observation of duties, in employee errors, or in competency assessment.
    a. After re-training, employees are assessed on the portions of the assessment that fell below expected competency.
    b. If after re-training the employee is unable to pass the competency assessment, further action will be taken. This may include supervisory review of work, reassignment of duties, or other actions deemed appropriate by the Laboratory Director.

        c.   Employees demonstrating competency after re-training may resume their assigned duties.

6.   Documentation of training and re-training is the responsibility of the Section Supervisor. Training documents must include date(s) of training, name of trainee, name of trainer, date training completed and signature of supervisor.

B. Competency Participation:

1.   All personnel will participate in a formal and regular competency program.

2.   Competency evaluations are required for licensed, certified, and non-licensed staff members. Competency must be assessed for each method for which the staff member performs testing. Per CAP Checklist GEN.55505 laboratory staff must complete competency assessment as stated below. Competency evaluations must be performed under the following situations:

        a.   At least semiannually, the first assessment within seven months from initiation of testing and second assessment no later than twelve months from the start of testing during the first year an individual tests patient specimens (new employees).

        b.   Annually for all staff who have performed assigned duties for more than one year.

        c.   Within 12 months of patient testing for tests that are put back into production after intermittent testing.

        d.   When an employee fails to demonstrate satisfactory performance of job duties, retraining and re-assessment of competency is required.

C. Competency Assessment:

1.   Elements of competency Assessment for Nonwaived Testing must include, but are not limited to, the following elements as outlined in the **CAP Checklist: GEN.55500 Competency Assessment**:

        a.   _Direct observations of routine patient test performance, including, as applicable, patient identification and preparation; and specimen collection, handling, processing and testing_

        b.   _Monitoring the recording and reporting of test results, including, as applicable, reporting critical results_

        c.   _Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records_

        d.   _Direct observation of performance of instrument maintenance and function checks_

        e.   _Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and_

        f.   _Evaluation of problem-solving skills_

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Refer to Addendum A as an example of competency checklist.

2. For waived testing, not all six elements need to be assessed. Per **CAP Checklist GEN.55499,** the POCT program may select which elements to assess for waived testing

   a. Documentation of competency is the responsibility of the Section Supervisor. Each section shall maintain documentation in paper form or electronic form (such as CAP Competency Assessment Program). All documentation must include date(s) of evaluation, name of employee being evaluated, name of supervisor/trainer/assessor.

3. Additional competency requirements are stated in the following excerpt from **CAP Checklist: GEN.55500 Competency Assessment**

   NOTE: Competency assessment records must include all six elements described below for each individual on each test system during each assessment period, unless an element is not applicable to the test system. The laboratory must identify the test systems that testing personnel use to generate test results, including both primary and back-up methods used for patient testing. If a single test or analyte is performed using different test systems, a separate assessment is required.
   A TEST SYSTEM is the process that includes pre-analytic, analytic, and post-analytic steps used to produce a test result or set of results.
   - _A test system may be manual, automated, multi-channel or single use._
   - _It includes instructions, reagents, supplies, equipment and/or instruments required to produce test results._
   - _It may encompass multiple identical analyzers or devices._
   - _It may include multiple tests performed on the same testing platform (eg, analyzer), unless tests have unique aspects, problems, or procedures (eg, pretreatment of specimens prior to analysis. In those situations, competency must be assessed as a separate test system to ensure personnel perform those aspects correctly._
   The competency procedure must outline the practices and procedures used to evaluate competency. Assessment of the elements of competency may be coordinated with routine practices and procedures if they are assessed by an individual qualified to assess competency (GEN.55510). Laboratories often use a checklist to record and track elements assessed. Records supporting the assessment must be retained (copies of worksheets, maintenance logs, etc. or information traceable to the original record).

4. Individuals responsible for competency assessments are to have the education and experience to evaluate the complexity of the testing being assessed. The duties

of performing competency assessment may be delegated by the Laboratory Director to qualified personnel. Per (**CAP Checklist Gen.55510 Qualifications of individuals assessing competency** vary by the complexity of the testing.
The following include the minimum qualifications for assessors:

- _High complexity testing: Section director (technical supervisor) or individual meeting general supervisor qualifications_
- _Moderate complexity testing: Technical consultant or individual meeting those qualifications_
- _Waived testing: May be determined by the laboratory director_

D. Development of Internal Competency Assessment:
Following current CAP guidelines referred to in this procedure, section supervisors or specialists will develop internal assessments and will:
1. Ensure all employees complete competency evaluations.
2. Create checklists or use the CAP Competency Assessment program specific to each section (see sample templates in Addendum A). Checklists should include every test system, process, and/or skill required of the employee for a given evaluation.
3. Review competency criteria periodically and revise as necessary.
4. If a test, exam or quiz is used, define the acceptable scores on the various assessment instruments; a score of $\geq 80\%$ is the threshold for satisfactory performance (based on CLIA's use of 80% as the lower limit for satisfactory performance on proficiency tests).
5. Develop and implement a corrective action plan in the case of unacceptable performance. The goal is to provide employees every chance to improve and become competent. The focus of corrective action should be on education, and punitive action should be avoided whenever possible.
   a. Determine the cause of unacceptable performance: if there is a lack of knowledge, then re-educate; if there is a performance error, then provide training and practice; if there is a system problem, then re-evaluate and make appropriate system changes.
   b. If, after retraining, the employee is unable to satisfactorily pass the assessment, then further action should be taken. This may include supervisory review of work, reassignment of duties, or other actions deemed appropriate by laboratory management.
   c. Corrective action and/or retraining must be fully documented. Employee must successfully complete retraining and competency assessment before resuming his/her duties.
6. Document and maintain competency and training records in the section. Competency assessment and training records must be maintained for a minimum of two years (five years for transfusion medicine). After the initial two-year (or five-year) period, records of successful ongoing competency assessment may be used in lieu of training records.

7.   Assessment of problem solving skills include observation of employee and/or documentation from employee that demonstrates:

     a.   Response to technical or procedural problems.

     b.   Troubleshoot (equipment, assay, test, instrument, etc.).

     c.   Analyze and correct proficiency testing errors.

     d.   Evaluate, resolve and report specimen problems.

     e.   Analyze and recommend work flow changes.

     f.   Appropriate response to personnel issues (for supervisors).

     g.   Ongoing documentation of problem solving may be kept by employee and brought to supervisor's attention for periodic review. Employee should: identify problem; perform and document steps taken to resolve problem; review applicable policies and procedures; propose alternate course of action if no resolution can be reached.

E.   Performance assessment of supervisors/Consultants is assessed at least biennially using a checklist for delegated functions. If the individuals in these roles are also performing non-waived testing, competency assessment requirements for testing personnel, including all six elements of competency at the required frequency.

     a.   Unsatisfactory performance will be addressed in a corrective action plan.

REFERENCES:

- Clinical Laboratory Improvement Amendments (CLIA 88): 42 CFR Part 493.1413(b) (8), 49.1415 (b) (8), Final Rule, February 28, 1992.
- College of American Pathologists (CAP) Laboratory General Checklist, 2021 edition.
- AABB Standards for Blood Banks and Transfusion Services, 32nd edition, 2020.
- Clinical and Laboratory Standards Institute (CLSI); *Training and Competence Assessment*; Approved Guideline –4th Edition. CLSI Document QMS03-A3 (ISBN 1-56238-803-7).

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Addendum A: Example of competency checklist

Competency Checklist
July 1, 2014 - June 30, 2015

Employee Name
Special Chemistry

Test System	Comp. Complete	Direct observation of test performance	Monitoring the recording/reporting of test results	Review of intermediate test results, QC, PM, and proficiency testing	Direct observation of maintenance and function checks	Analysis of previously analyzed samples, competency samples, or proficiency samples	Evaluation of problem-solving skills
Special Chemistry							
Centaur							
Immulite							
Sweat Chloride							
Mono Testing							
Ultra 2							
HBe/aHBe ELISA							
Quantiferon TB Gold							
DS2							
Abbott i1000							

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PROCEDURE HISTORY

Date	Written Revised By	Revision	Approved Date	Approved By
10/98	Delores G. Brown	New	10/98	R. Green
08/00	D. Brown	Annual Review	8/00	R. Green
11/02	J. Huang and B. Harris	Annual Review	11/02	R. Green
9/03	B. Harris	Annual Review	9/03	R. Green
11/04	J. Huang and B. Harris	Revised	11/04	R. Green
11/05	J. Huang and B. Harris	Annual Review	11/05	R. Green
10/06	B. Harris	Revised	10/06	R. Green
02/07	B. Harris	Revised	03/07	R. Green
5/08	D. Wright	Revised	6/08	R. Green
6/09	D. Wright	Revised	6/09	L. Howell
07/10	D. Wright	Revised	7/10	L. Howell
09/12	T. Cox	Revised: added intermittent testing; references	10/12	L. Howell
12/12	T. Cox	Revised: added CAP Test System	12/12	L. Howell
09/14	T. Cox	Revised: added competency delegation	09/14	L. Howell
9/16	S. Okimura	Revised: added current CAP information	09/16	L. Howell
12/17	N. Kaur	Revised: added current CAP information and merged Attachment 1 as Addendum A	12/17	L.Howell Via OnBase
08/20	E. Karanja/ N.Kaur	Revised: Added use of CAP Competency Assessment program, updated references	08/20	L. Howell Via OnBase

10/21	B. Brownlow	Revised: Added reference to new CAP checklist item GEN.55505 regarding competency frequency. Added new language regarding successful training. Updated reference to new CAP and AABB checklists		