OLIVE VIEW-UCLA MEDICAL CENTER
DEPARTMENT OF PATHOLOGY
POLICY & PROCEDURE

NUMBER: 1475
VERSION: 4

SUBJECT/TITLE: ADM 07.0: STAFF COMPETENCY VERIFICATION

POLICY: Competency of all new employees and/or employees who have been transferred to a new section or when a new test, methodology or instrumentation is introduced shall be evaluated semi-annually during the first year the individual tests patient specimens and at least annually thereafter. For new test methodology or instrumentation, the individual will be trained to perform the new procedure and his/her performance will be evaluated using the new test methodology or instrumentation.

PURPOSE: To establish procedures for evaluating and documenting the competency of all testing personnel to assure that staff maintain their competence to perform test procedures and report test results accurately, proficiently and promptly, in compliance with regulatory and accreditation standards.[1]

DEPARTMENT: PATHOLOGY

DEFINITIONS: **Competence** is defined as having the essential knowledge, skills and ability required to perform a process according to specifications.

Competency assessment is the procedure for periodically assessing the ability of each employee to perform and, for licensed personnel, report all assays that (s)he is authorized to perform, in an accurate, proficient, and timely manner, in compliance with the written procedure and all QA/QC policies.

Competency assessment requirements (as defined by CLIA '88): Regulatory and accrediting agencies require that competency assessment procedures shall include (but are not limited to):

1. Direct observations of routine test performance including, as applicable, patient/sample identification and preparation; and specimen collection, handling, processing and testing
2. Monitoring the recording and reporting of test results; including as applicable, reporting critical results

[1] CLIA '88, sections 493.1713,493.1451 (b) (8); California Business and Professions Code, Ch.3, Div. 2, Sect. 1209 (d)(e); CAP Checklist Commentary 01:5550; and JCAHO, HR.7.

3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records;
4. Direct observation of performance of instrument maintenance and function checks, as applicable
5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and,
6. Evaluation of problem-solving skills for tasks requiring judgment or interpretation.

Critical Steps: Procedural steps, which must be performed correctly to assure high quality laboratory results or that, could have serious impact if performed incorrectly (e.g. positive patient identification prior to blood collection, accurate reconstitution of controls, accurate labeling of aliquots). The staff member must pass all critical steps to pass a competency test section.

Section manager or "general supervisor qualified" individual: An individual, who meets CLIA requirements for general supervisor[2], and who, under the direction of the laboratory director and supervision of the administrative coordinator, provides day to day supervision of testing personnel and reporting of test results. In the absence of the laboratory director and administrative coordinator, (s)he is responsible for the proper performance of all laboratory procedures and reporting of test results.

New employee: A person will be considered "new" when their hire or transfer date falls within the previous 12 months.

Method training: The process of providing step-by-step instruction on how to perform a test. This includes related performance checks and documentation to verify the success or failure of that training. It is required for:

1. First time training on a new test.
2. When there is a significant change in methodology or instrumentation.
3. When an employee fails two attempts to complete Competency Assessment for a test procedure.
4. When an employee fails to complete Competency Assessment within the required time frame.

PROCEDURE: RESPONSIBILITIES:

The laboratory director is responsible for:

[2] General supervisor must possess a current state license in the state where the laboratory is located, have earned a bachelor's degree in a chemical, physical, biological, or clinical laboratory science, or medical technology from an accredited institution, and have at least 1 year of laboratory training or experience, or both, in high complexity testing. (CLIA '88 493.1461)

1. Ensuring that all personnel, prior to testing biological specimens, have the appropriate education and experience, receive appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform testing operations reliably to provide and report accurate results.
2. Ensuring that policies and procedures are established for monitoring individuals who conduct pre-analytical, analytical and post analytical phases of testing to assure that they are competent, maintain their competency, and, whenever necessary, identify needs for remedial training or continuing education to improve skills.
3. Ensuring that individuals responsible of competency assessments have the education and experience to evaluate the complexity of testing being assessed.
4. Ensuring the performance of section directors/technical supervisors, general supervisors, technical consultants, and clinical consultants is assessed and satisfactory.
   The assessment may take the form of a checklist or other record of performance of responsibilities, as defined by the individual's job description, see ADM 7.0 F2 Competency Assessment Performance Evaluation Forms Parts I (Attachment 2), & II (Attachment 3). Performance Evaluations for Clinical Laboratory Scientists and Laboratory Assistants are available in electronic format and can be accessed on intranet under Human Resources Department through Performance Link Net.
   Unsatisfactory performance must be addressed in a corrective action plan. Individuals in these roles who are also performing non-waived testing, competency assessment requirements for testing personnel also apply, including all six elements of competency at the required frequencies.

The supervisor is responsible for:

1. Specifying in writing the responsibilities and duties of each individual under his/her supervision engaged in the performance of pre-analytic, analytic, or post-analytic phases of clinical laboratory testing, including which tests or examinations the individual is authorized to perform, whether supervision is required for the individual to perform specimen processing, test performance, or results reporting, and whether supervisor or director review is required prior to the individual reporting patient test results.
2. Evaluating on an on-going basis, the competency of all personnel under his/her supervision, and assuring that staff maintain competency in pre-analytic, analytic, and post-analytic testing procedures.
3. Identifying training needs and ensuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed.
4. Annually evaluating and documenting the performance of all testing

personnel/semiannually during the first year an individual tests patient specimens.

5. Providing orientation to all testing personnel upon hire and whenever new methodologies and/or instruments are introduced.

SCOPE: Competency Assessment is an integral part of the laboratory's Quality Improvement program. This policy applies to all Olive View-UCLA Medical Center Clinical Laboratory personnel who are involved in the pre-analytical, analytical or post-analytical phase(s) of clinical laboratory testing. Each employee shall be evaluated for competency in performing each test or group of tests that (s)he is authorized to perform and/or report. All employees will be assessed on key procedures annually. Key procedures will be determined by the section supervisor and are defined as major, regular recurring procedures that could have serious impact if performed incorrectly. Non-key procedures will be assessed on a rotational basis.

1. Stand Alone Tests: Tests, which utilize technologies and/or techniques, which are not utilized, by other tests performed in the laboratory. All competency assessment requirements must be completed for any stand-alone test, including but not limited to: manual cell counts, cell identification, timed procedures, procedures requiring dilution, etc.
2. Grouped Assays /non-automated equivalent test systems: Certain tests may be so similar in technology and required knowledge and skills that the demonstration of competence in one is judged adequate to demonstrate competence in other technologically similar assays.
   When tests are "grouped" with one or more others for purposes of demonstrating competence, only one of the grouped tests requires "direct observation", but all remaining competency assessment requirements must be completed.
3. Grouped Assays /non-automated non-equivalent test systems: In cases where one assay within a group requires additional skills or techniques that are not required by others, yet methods are technologically equivalent, the assays may still be grouped with certain assays designated as "more complex".
   a. Successful completion of the direct observation phases for the "more complex" assay may be applied to completion of all assays in the group, but all remaining competency assessment requirements must be completed.
   b. Successful completion of the direct observation phases for any "less complex" assay may not be applied to completion of any "more complex" assays in the group.
4. Grouped Assays /automated test system: For each automated test group, all system assays must either be declared equivalent test systems or more complex assays must be identified by the general supervisor.
   a. Successful completion of the Direct Observation phases for the "more complex" assay/s may be applied to completion of all assays in the group.

b. Successful completion of the Direct Observation phases for any "less complex" assay may not be applied to completion of any "more complex" assays in the group.

FREQUENCY:

Competency of all new employees and/or employees who have been transferred to a new section or when a new test, methodology or instrumentation is introduced shall be evaluated semiannually during the first year the individual tests patient specimens (e.g. for all tests initially trained during the first 6 months of employment, competency will be reassessed during the second 6 months interval of employment; for tests initially trained during the second 6 months, competency will be reassessed during the third 6 month interval).

Thereafter, evaluations will be performed annually unless test methodology or instrumentation changes, in which case, prior to the reporting of patient test results, the individual will be trained to perform the new procedure and his/her performance will be evaluated using the new test methodology or instrumentation.

Retraining and reassessment of employee competency shall also occur when problems with an employee's performance are identified. An employee who does not meet a standard will be immediately suspended from performance of that task until remedial action has been completed and the individual has been reevaluated and is deemed to be competent in performing the task.

Failure to successfully demonstrate competency will result in immediate revocation of that employee's authorization to run that test for purposes of reporting patient results until remediation has been completed and competency has been achieved and documented.

Remediation Process for performance that fails to meet the established standard for competent performance:
Procedures to be followed when the competency of any individual falls below the established standard for competent performance shall include but not be limited to the following:

- Immediate suspension and removal from performing the task until remediation is complete and competency has been achieved and documented.
- Documented retraining as necessary.
- Oral or written counseling of the employee as appropriate.
- Reassignment to another shift or lab section, when appropriate.
- Discharge from County service when employee performance remains below the standard for competence despite efforts at remediation.

PROCEDURE:

A. Training and documentation - section supervisor responsibilities.

The laboratory section managers (or designee) of nonwaived testing (moderate/ high complexity) is responsible for:

1. Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing, and testing.
2. Monitoring the recording and reporting of results.
3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.
4. Direct observation of performance of instrument maintenance and function checks.
5. Assessment of test performance through testing of previously analyzed specimens, internal blind testing samples, or external proficiency samples.
6. Assessment of problem-solving skills.
7. Evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens, and annually thereafter.
8. Training and evaluating the individual's performance prior to instituting a new method or instrument.
   Staff members will receive appropriate training and in-services on new equipment and procedures at the time of implementation.
9. Developing training/competency assessment programs and documenting and maintaining records of all competency assessment activities applicable to his/her section staff and scope of testing.

For waived testing, it is not necessary to assess all six elements at each assessment event. The POCT program may select which element to assess but must follow the more stringent state or local regulations if in place.

B. Training and documentation — staff member responsibilities

1. New staff members will be trained by:
   a. The individual departments in the OVMC laboratory as it pertains to their job function and instrumentation used, and/or by their supervisor or designee.
2. Orientation and training checklists will be:
   a. Followed, checked off, and signed by the trainers and the supervisor.
   b. Completed prior to the six month evaluation.
   c. Filed in the employee's personnel file in the laboratory.

3. Twice during the first year of employment, and yearly thereafter staff will be required to:
   a. Read established procedure manuals.
   b. Read established policies.
   c. Review operators' manuals.
   d. Document reading and review of above items.
   e. Be directly observed by the supervisor or designee in routine test performance, including, as applicable, patient/sample identification and preparation, and specimen collection, handling, processing and testing
   f. Be monitored on recording and reporting of test results; including as applicable, reporting critical results
   g. Review intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records
   h. Be directly observed by the supervisor or designee in performing instrument maintenance and function checks, as applicable
   i. May be required to perform testing on previously analyzed specimens, internal blind testing samples or external proficiency testing samples.
   j. Demonstrate problem-solving skills.
4. The staff member being evaluated must pass the technical competency test according to the directions on the test. If a staff member fails any particular part of the test, (s)he must immediately be retrained and tested in that particular area before (s)he is allowed to report out-patient results in that area. The additional training will be documented in the employee's personnel file.
5. The results of the technical competency evaluation will be incorporated into each staff member's annual performance review and filed in the staff member's personnel file in the laboratory.

C. Technical competency testing forms

1. Testing forms with items specific to the individual worksite of the staff member will be designed, revised, or deleted by the laboratory section supervisor.
2 Technical competency forms will be reviewed yearly by the section supervisor or designees from the appropriate OVMC laboratory department.

BACKGROUND:

The Clinical Laboratory Improvement Act of 1988 requires the laboratory director ensures that all personnel, prior to testing biological specimens, have the appropriate education and experience, receive appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. All testing personnel complete a Professional Qualifications Declaration Form ADM 7.0 F1 (Attachment 1) which is kept in their personnel file.

Prior to employment, competency is assessed by the following means:
1) Review of records:

- Verification that class specifications for the position (e.g. education, training, experience) are met.
- Verification of licensure or certification, if applicable.

2) Job interview:

- Assessment of the individual's basic knowledge of the job.
- Assessment of the individual's ability to communicate at a level necessary to meet the requirements of the position.

All new employees are provided with orientation and training in the following areas:
1) Network-wide New Employee Orientation

- Los Angeles County/ Olive View- UCLA Medical Center Personnel and Payroll policies.
- Patient / Guest Relations training.
- Earthquake Preparedness training.
- Fire/ Life Safety training.
- Evaluation for color blindness, if applicable. (performed by Employee Health Services)

2) Pathology Department Orientation (to be completed within 48-hours of start of employment)

- Laboratory organization chart and staff.
- Laboratory layout.
- Olive View Personnel Policies and Guidelines.
- Pathology Department Personnel Policies.
- Role of the employee in Patient/Guest/Employee Relations.
- Safety (Universal precautions, fire safety, evacuation routes, hazardous substances, Right-to Know, SDS, spill kits, spill clean-up, disaster procedures).
- Role of the employee in QA/QI.

- Overview of Pathology Department Manuals*
  - Policies and Procedures
  - Safety
  - Chemical Hygiene
  - Quality Assurance / Improvement
  - Specimen Collection
  - Quality Control
- Health programs for employees.
- Parking / Traffic Control.
- Cafeteria.

3) Laboratory Section-specific training

- Section training materials
  - Policy and procedure manuals
  - QC
  - SDS book for chemicals used in the section
- Outline and schedule for training
- Class specification / duty statement
- Tasks and standards for job based performance evaluations
- Section QI program and QI indicators
- HIS training

Relationship of Performance Appraisal to Training and Verification		
Activity	**When it is done**	**Purpose**
Initial Training	After hire	To introduce employee to the job.
Training Verification	At completion of training	To assure readiness for job tasks.
Retraining/ Re-verification	1. As needed for new methods or procedures per any changes. 2. Twice during first year of employment and at least once annually thereafter.	Required by CLIA '88
Appraisal	Annually/ Semiannually during the first year of service.	To verify continued competency to perform job tasks.

DATE	REVISION MADE	BY:	REV:
4/5/2010	Changed Policy Number (ADM 7.0) and put in PPM format.	Julie Foley	ADM 7.0
10/31/2019	Added under Responsibilities: Lab Director's Individuals responsible for competency assessments have the education and experience to evaluate the complexity of testing being assessed. Performance assessment of supervisors/consultants is assessed and satisfactory.	Rachel Dauz	ADM 7.0v3
10/31/2019	Revised ADM 7.0 Form 1 format	Rachel Dauz	ADM 7.0v3F1

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