TRAINING UPDATE

Lab Location:	GEC, SGMC & WAH	**Date Distributed:**	7/5/2019
Department:	Mgmt & QA	**Due Date:**	7/31/2019
		Implementation:	**7/23/2019**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:
Training Verification   SGMC.QA3002 v1
Description of change(s):
This is a 'new' SOP that replaces our previous NQA corporate version. It is very similar to the old SOP but has been converted to our local SOP format and info that did not pertain to our labs was deleted This SOP will be implemented on July 23, 2019

Document your compliance with this training update by taking the quiz in the MTS system.

Non-Technical SOP

Title	**Training Verification**	
Prepared by	Leslie Barrett	Date: 6/4/2019
Owner	Cynthia Bowman-Gholston	Date: 6/4/2019

Local Approval		
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		
Local Issue Date:	Local Effective Date:	

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1. PURPOSE

This document describes the policy and process for documentation of required training for laboratory staff.

2. SCOPE

This policy and process applies to all Laboratory personnel.

3. RESPONSIBILITY

Responsible Party	Task
Laboratory Director	• Approves the initial document and any revisions.
Laboratory Director or Designee	• Recurring review of this document • Ensures personnel have satisfactorily completed initial training on all aspects related to their designated Test System
Technical Supervisor, Technical Consultant, or Pre-/Post-analytical Department Manager/Supervisor	• Implements this policy and process in the area(s) for which he/she is responsible • Identifies training needs and develops training materials • Ensures that each individual has successfully completed the appropriate training • Regularly evaluates the trainee's progress • Ensures that completed training is documented appropriately.
General Supervisor with training responsibilities	• Ensures compliance with this process in his/her department • Ensures that trainers are currently trained and competent on the applicable Test Systems / Modules • Develops training materials, as needed
Trainer	• Provides training and ensures that all learning objectives are understood and complete • Ensures that each trainee understands and is capable of performing the learning objectives covered in the training. • Makes suggestions for training materials, as applicable.
Quality Assurance Department	• Coordinates audits of the training process to ensure compliance with this procedure.

4. DEFINITIONS

Term	Definition
Authorization to Perform Testing	Documentation that a Laboratory Director has authorized an employee to perform responsibilities and job duties on which they have been trained.
Competency Assessment Profile	Specific activities used for documenting initial training and periodic competency assessment of a given test system, platform, module or procedure(s). The standard profile format includes 3 intervals, each with associated activities: • Training and the initial assessment • The first-year semi-annual (6-month) assessment • Annual assessment

Term	Definition
Electronic Document Control System (EDCS)	A computer system used to track and store electronic documents, such as SOPs.
EDCS or Medical Training Solutions (MTS) Assessment	Electronic documentation that an employee has knowledge of and understands changes or revisions to a procedure. The assessment is in the form of questions or attestation statement.
Initial Performance Assessment	Evaluation that demonstrates a trainee can perform all testing operations reliably in order to provide and report accurate results.
Learning Objectives	- Observable or measurable outcomes from a training exercise. - Learning objectives use action verbs and measure either cognitive or psychomotor skills. - They are key components of the procedures that describe the desired measurable outcomes when training is complete.
Previously Trained Employee	An employee without documentation of initial training or with documentation of previous training that does not meet current learning objectives.
Procedure	A description of a sequence of steps leading to a defined outcome or product. A procedure can be technical (analytical, pre-analytical, or post-analytical) or non-technical (administrative).
Media Lab (ML)	Laboratory's standard electronic document control software.
Test System	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 and can include reagents, components, equipment or instruments required to produce results. A test system may encompass multiple identical analyzers or devices. Different test systems may be used for the same analyte. Note: The above definition is derived from the CLIA regulations and/or CAP checklist requirements.
Training	A procedural based exercise of ensuring an employee can perform all objectives associated with a test system.
Training Module	Training modules are supervisory tools used to organize the contents of the department's training program and are not required to be maintained as part of each individual's training record. - For Testing Personnel - A Module is a documented list of procedures associated with a single Test System. Training on all applicable procedures must be completed prior to the performance of the Test System. - For Non-testing personnel – A Module is a documented list of procedures associated with a specific process, workstation or job assignment. Training on all applicable procedures must be completed prior to the performance of the job assignment.
Training Plan	A documented list of all Training Modules in a department. It serves as a "Table of Contents" for the department's Training Modules.
Training Update	A form (or equivalent record) used to document knowledge of changes or revisions to procedures.

Term	Definition
Training / Initial Assessment	Documentation that training objectives have been met and that the training process for a specific Test System, module or procedure is complete.
Training Verification Form	Written documentation that training objectives have been met and that the training process for a specific Test System/Training Module is complete.

5. POLICY

5.1 Training must be performed on all employees involved in any phase of the testing process.

- Training must cover all applicable procedures for each individual.
- Training must be completed and documented <u>prior</u> to performing the Test System or any job-related task.
- Training must be performed when:
  - A new employee learns to perform a specific Test System. This includes individuals who are new to the company or have transferred from another department.
  - An existing employee requires remedial training due to unsuccessful competency assessment or has demonstrated inadequate test performance**.**
  - An existing employee learns to perform a procedure or Test System that he/she has not previously performed.
  - A new procedure or Test System is introduced in the department.
- Retraining <u>must</u> occur when problems are identified with personnel performance.
- 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 to demonstrate compliance with this requirement.
- Employees working in more than one laboratory (CLIA number), must have documentation of training with approval by each Laboratory Director or delegated Supervisor.
  - Comprehensive, duplicate training is not required as long as the Test System is identical at each location.
  - All differences must be addressed in CLIA laboratory specific training documents.

5.2 Trainers must have successfully completed training for the specific Test System and be currently competent to perform that Test System

- Laboratory Director delegation is not required for this responsibility <u>unless</u> the Trainer is specifically responsible for the Training Plan and signing/approving Training Verification.
- If a new Test System is created that involves a new laboratory method or process, the following individuals may assume responsibility for the initial training:
  - An individual trained by a manufacturer/vendor of a system or by an outside user of the system.
  - An individual who developed or validated the new method or process.
  - An individual delegated as responsible for SOP review and/or laboratory method validations in the department (i.e., Technical Supervisor, Technical Consultant, or Pre-/Post-analytical Department Manager)

5.3 Employees must be knowledgeable about the content of procedures and policies relevant to their scope of testing, including change to existing procedures.

- Prior to performing a <u>changed</u> procedure or Test System, the employee must acknowledge that they have read and understand the revisions. This acknowledgment must be documented and dated.

6. PROCESS

6.1 General Training Program Requirements

6.1.1 For Testing Personnel

- Define **Test Systems** in each testing department
- Group all pre-analytic, analytic, and post-analytic tasks and processes used to produce a test result or set of results.
  Note: The term Test System does not apply to non-technical tasks or processes
- Create a Training Plan for the department using the Training Plan template.
- Using the Training Module form (page 2 of the Training Plan document), list all procedures required to perform each Test System.
- Name each Test System/Training Module using terminology that clearly describes the Test System. **Optional:** The Test System/ Training Module may be numbered to facilitate tracking.
- Administrative procedures do not need to be included
- It is acceptable to create a limited number of sub-categories for a Test System if tasks are restricted due to experience level, shift, or other reasons. If Test Systems have sub-categories, the Training Module must clearly show which procedures are included for each sub-category.

6.1.2 For Non-Testing Personnel

- Group all procedures and tasks related to a specific process, workstation, bench, or assignment.
- Create a Training Plan for the department using the Training Plan template.
- Using the Training Module form (page 2 of the Training Plan document), list all procedures required to perform each process, workstation, bench, or assignment.
- Name each Training Module using terminology that clearly describes the process, workstation, bench, or assignment.

6.1.3 Create Training Verification Forms For Each Test System/Training Module

- Use the Training Verification template.
- Forms must specify if the trainee requires supervision for specimen processing, test performance or result reporting.

6.1.4 Initial Training Assessment

- An assessment of the trainee/employee's initial training must always be performed and documented
- Determine which of the following tools are most appropriate for ensuring that each learning objective is met for each test system or module:

- o   Direct observation of task performance
- o   Reporting of test results
- o   Review of associated records
- o   Assessment of analytical test performance (where applicable)
- o   Performance and documentation of instrument maintenance and function checks
- o   Problem solving skills (observed, written, or responses to verbal queries)

Note: It is <u>not necessary</u> to use all assessment tools for each individual learning objective.

- Define which of the above tools will be used to assess and demonstrate that the trainee can perform all tasks, testing operations, and/or procedural steps reliably.
  - o   For Testing Personnel, this demonstrates that he/she can provide and report accurate results.
- Document details of successfully completed test runs or tasks must be documented using batch numbers, dates, or other traceable information.
- If special documents are created as part of the Performance Assessment, such as a written quiz, these documents must be attached to the Training Verification record.

6.1.5   Previously Trained Employees
- Use a Training Verification Form when documentation of initial training is missing, previous training documentation does not meet the requirements of the current SOP, or initial training does not meet current learning objectives.
- Learning objectives must be the same as those used for newly trained employees

6.1.6   Remedial Training
- Use a Training Verification Form for employees who require additional training due to unsuccessful competency assessment or other reasons
- Learning objectives may be the same as those used for newly trained employees

6.2 Process for Initial Training

Step	Action
1	The Trainee must read all procedures listed in the Test System/Training Module.
2	The Trainee observes the performance of all procedural steps associated with the Test System/Training Module as performed by a qualified Trainer.
3	The Trainee practices performing procedural steps while observed and instructed by a qualified Trainer.
4	The Trainer uses assessment tools to evaluate the trainee's progress toward completing all required learning objectives.
5	On the Training Verification Form, the Trainee and Trainer initial and date, each Learning Objective as they are completed, indicating the trainee has had sufficient training and has demonstrated mastery of the knowledge, skills and abilities required to perform the procedures and/or the Test System.
6	The Trainee signs and dates the completed Training Verification Form, indicating they have had sufficient training and are confident to perform the procedures and/or the Test System.

Step	Action
7	The delegated Supervisor documents the outcome of the Initial Performance Assessment and ensures that all learning objectives are understood by the trainee, all learning objective have been completed successfully, and that training is complete.
8	The Laboratory Director or delegated Supervisor reviews the training documentation and Assessment of Initial Training and indicates if supervision is required for any phase of the testing process (i.e., specimen processing, test performance and/or result reporting).
9	The Laboratory Director or delegated Supervisor reviews the completed Training Verification Form. He/she signs the document indicating that the trainee is fully trained, demonstrates satisfactory performance, and is approved to perform the procedure and/or Test System. **Note:** The Laboratory Director is not required to sign the Training Verification Form directly IF training has been delegated to a qualified Supervisor.

6.3 Process for Previously Trained Employees

Step	Action
1	The Trainer or delegated Supervisor reviews applicable procedures and current learning objectives with the previously trained employee to ensure they meet all learning objectives as described on the current Training Verification Form.
2	The Trainer or delegated Supervisor must use the assessment tools to evaluate the previously trained employee's understanding of current learning objectives based on current performance of the Test System.
3	If gaps in previous training are identified supplemental training must be performed and documented.
4	The Trainer or delegated Supervisor Check ensures that Previously Trained Employee is recorded on the Training Verification Form.
5	The Trainee and Trainer or delegated Supervisor initial and date each Learning Objective on the Training Verification Form, as it is completed.
6	The delegated Supervisor documents the outcome of the Assessment of Training and ensures that all learning objectives have been successfully completed.
7	The Trainee signs and dates the completed Training Verification Form, indicating they have had sufficient training and are confident to perform the procedures and/or the Test System. • When applicable, the Trainer signs and dates the completed Training Verification indicating that supplemental training has been completed successfully and the trainee has demonstrated mastery of the knowledge, skills and abilities required to perform the procedure(s) and/or Test System.
8	The Laboratory Director or delegated Supervisor reviews the completed Training Verification Form. He/she signs the document, indicating that the trainee is fully trained, demonstrates satisfactory performance, and is approved to perform the procedures and/or Test System. **Note:** The Laboratory Director is not required to sign-off/approve IF training has been delegated to a qualified Supervisor.

6.4 Process for Remedial Training

Step	Action
1	The Trainer or delegated Supervisor ensures that the employee meets all of the current learning objectives described on the Training Verification Form by reviewing the procedure(s) and current learning objectives with the employee.
2	The Trainer or delegated Supervisor **documents the specific area(s) that address the deficiencies identified during competency assessment or other reasons for the remedial training.**
3	The Trainer or delegated Supervisor evaluates the employee's understanding of current learning objectives based on current performance of the Test System using applicable assessment tools.
4	The delegated Supervisor documents the reason for remedial training on the Training Verification form.
5	The Trainee and Trainer initial and date each Learning Objective as it is completed.
6	The delegated Supervisor documents the outcome of the Assessment of Remedial Training and ensures that all learning objectives have been successfully completed.
7	The Employee signs and dates the completed Training Verification Form to indicate they have had sufficient remedial training and are confident to perform the procedures and/or the Test System.
8	When applicable, the Trainer signs and dates the completed Training Verification Form to indicate that remedial training has been completed successfully and the trainee has demonstrated mastery of the knowledge, skills and abilities required to perform the procedures and/or Test System.
9	The delegated Supervisor reviews the training documentation and Assessment of Remedial Training and signs and dates the completed Training Verification Form signifying that the trainee is fully re-trained and meets current learning objectives for the Test System.

6.5 Organization of Manual or Paper Training Records

Step	Action
1	File the department Training Plan and Training Modules separately from individual employee training records.
2	File completed Training Verification documents in the employee's training file / folder to ensure that records can be readily retrieved. **Note**: It is not necessary to keep copies of routine records used to evaluate the initial performance assessment as long as the details of successfully completed runs or tasks are traceable to the original source document (i.e., documented using batch numbers, dates, or other traceable information).
3	File completed Training Verification documents separately from competency assessment documentation.
4	File Training Updates chronologically.
5	Current Training records must be readily available in the laboratory

Step	Action
6	File inactive/outdated Training records separately from the current/active records and retain according to the retention policy.

6.6 Process for Revised or Updated Procedures

Step	Action
1	The Trainer or delegated Supervisor reviews procedural changes or revisions with all trained employees. • For most changes this may be accomplished during department meetings, a quick in-service or brief explanation with trained employees. • Documentation can be accomplished using an EDCS/MTS Assessment or Training Update Form. **Note**: When extensive changes to a procedure or Test System necessitate re-training, new Training Verifications must be completed for **all** previously trained employees. **Do not use** the Assessment or Training Update Form.
2	Trained employees must read the procedural revisions.
3	Trained employees sign and date the Training Update Form, acknowledging they have read and understand the changes in the specified procedures. This process may be documented electronically.
4	A single Training Update may be used for processes that affect multiple SOPs on an on-going basis (e.g., all department SOPs are renumbered or reformatted but content is not changed). It is not necessary to issue a Training Update for each individual SOP.
5	Other documentation, such as an email communication, is an acceptable format provided a copy is retained with other department training records.
6	Create an MTS Update/Assessment for revisions or changes to procedures (e.g., added, deleted, reformatted or moved information).
7	Develop questions to test the employee's knowledge of the revisions.
8	Trained employees are notified that an Update has been assigned.
9	Employees complete the assigned MTS procedure review and quiz, and results are evaluated by MTS.
10	If a passing grade is not obtained, the Supervisor must evaluate the employee's understanding of the changes and then re-assign the Assessment. Refer to MTS procedure for details.

7. RELATED DOCUMENTS

- Authorization of Personnel and Delegation of Responsibilities, QA procedure
- Competency Assessment, QA procedure
- Medical Training Solutions (MTS), General Laboratory procedure
- Training Plan template (AG.F450)
- Training Verification template (AG.F449)
- Training Update template (AG.F448)

8. REFERENCES

1. Clinical Laboratory Standards Institute (CLSI). Training and Competence Assessment Approved Guideline, GP21-A3. Wayne, PA.
2. Code of Federal Regulations CLIA Public Health 42 CFR Part 493
3. College of American Pathologists Laboratory Accreditation Checklists
4. Quest Diagnostics *Policy for Training Verification* QDNQA736

9. DOCUMENT HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes SGAHQDNQA736v2.1		

10. APPENDICES

None