TRAINING UPDATE

Lab Location:	GEC, SGMC & WAH	**Date Distributed:**	4/5/2018
Department:	Mgmt & QA	**Due Date:**	4/30/2018
		Implementation:	**4/11/2018**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Process and Equipment Validation Protocol SGAH.QA46 v2

This has been converted to a system SOP

Description of change(s):

The changes are minor. This update is intended to refresh your knowledge of this protocol.

Header: add other sites

Section 5, 6: update number for validation policy

This revised SOP will be implemented on April 11, 2018

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

Non-Technical SOP

Title	**Process and Equipment Validation Protocol**	
Prepared by	Leslie Barrett	Date: 7/27/2012
Owner	Cynthia Bowman-Gholston	Date: 7/27/2012

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

Review: .		
Print Name	**Signature**	**Date**

Form revised 3/31/00

TABLE OF CONTENTS

1. PURPOSE

This procedure describes the process of validation and revalidation of new and revised processes or procedures, and new or repaired equipment.

2. SCOPE

This procedure applies to all non-computer processes or procedures and equipment that require validation.

3. RESPONSIBILITY

- **Testing Personnel** will:
  - Follow the Validation Protocol as designed.
  - Document all steps of the validation protocol.
- The **Lab Services Director, Manager, or Supervisor** (or designee) will:
  - Ensure compliance with this procedure in his/her department.
  - Document all steps of the validation protocol.
  - Ensure that all staff is appropriately trained.
- The **Quality Assurance Department** will:
  - Manage validation documents on the electronic document control system
- The **Medical Director** will:
  - Approve the initial document and any subsequent revisions.
  - Approve all validations prior to implementation.
  - Approve validation protocols.

4. DEFINITIONS

Installation Qualification (IQ): ensures equipment is installed per requirements

- Equipment is installed per manufacturer's specifications
- Equipment operates within the limits required for the process and per manufacturer specifications

- Support utilities (water, electric, air, temperature) must meet manufacturer's specifications

Operational Qualification (OQ): ensures equipment can do what it is supposed to do. Examples: test alarms, check temperatures of empty refrigerator, test RPM/RCF and timers of centrifuge, QC results, etc.

Performance Qualification (PQ): ensures equipment does perform as expected. Test using normal samples under normal and extreme conditions. Must be performed by staff who will utilize the equipment.
Examples: fill the refrigerator and ensure it still maintains temperature in all areas of the refrigerator; ensure filling the refrigerator does not inhibit air flow; fill a centrifuge and make sure it runs appropriately with maximum and/or minimum load, etc.

Validation: "verification, where the specified requirements are adequate for intended use." (Reference: "International vocabulary of metrology, Basic and General concepts and associated terms (VIM) 2008").

Verification: "provision of objective evidence that a given item fulfills specified requirements."

5. PROCEDURE

1. The Supervisor or designee develops, writes, and submits validation protocol to include laboratory regulations, accreditation standards, and manufacturer's instructions. Refer to addenda B for guidelines.

   Notes:
   - An Equipment and Process Validation Protocol Form must be used to document the plan. Refer to Related Documents
   - For validation of test methods, refer to the procedure Policy for Laboratory Method Validation of Quantitative and Semi-Quantitative Methods, QDNQA743 ~~QDQC710~~.

2. The Laboratory Director reviews and approves draft protocol, or revises as needed.

3. Installation Qualification and Operational Qualification are performed and documented by the appropriate personnel. This may include Biomedical personnel, manufacturer's representative, in-house or other designated staff.

4. The Supervisor reviews and approves IQ and OQ documentation. Corrective action is documented as necessary.

5. The Supervisor or designee writes draft procedure(s) and training document. Pre-validation training is performed and documented for appropriate staff.

6. Assigned validation staff performs the Performance Qualification and validation. Data is collected and documented on appropriate forms (ie, QC, Maintenance logs)

7. The Checklist for New/Changed Procedure Implementation may be used to document completion of key tasks for technical processes (example: LIS changes, QC definitions, communication of changes to reference ranges or critical values, etc).
   - The form prompts for dates and initials for each task. Refer to Related Documents
   - The project champion is responsible for assuring each applicable item is completed, including appropriate documentation.
   - The form must be submitted with the final validation documentation when changes have the potential to impact analytical tests or test systems.

8. The Technical Supervisor and Medical Director review validation data and approve/disapprove validation via electronic document control system. The procedure(s) is finalized and approved via electronic document control system.

9. The Supervisor or assigned validation staff train remaining staff and document.

10. The process or equipment is implemented.

6. RELATED DOCUMENTS

- Policy for Laboratory Method Validation of Quantitative and Semi-Quantitative Methods, QDNQA743
- Process/Equipment Validation Protocol, Transfusion Service, QDHBB303
- SmartSolve® (Pilgrim) EDCS: Managing New, Revised, Expire and Recurring Review of Documents, QA procedure
- Equipment and Process Validation Protocol Form (AG.F204)
- Checklist for New/Changed Procedure Implementation (AG.F279)

7. REFERENCES

Process/Equipment Validation Protocol, Transfusion Service, QDHBB303

8. REVISION HISTORY

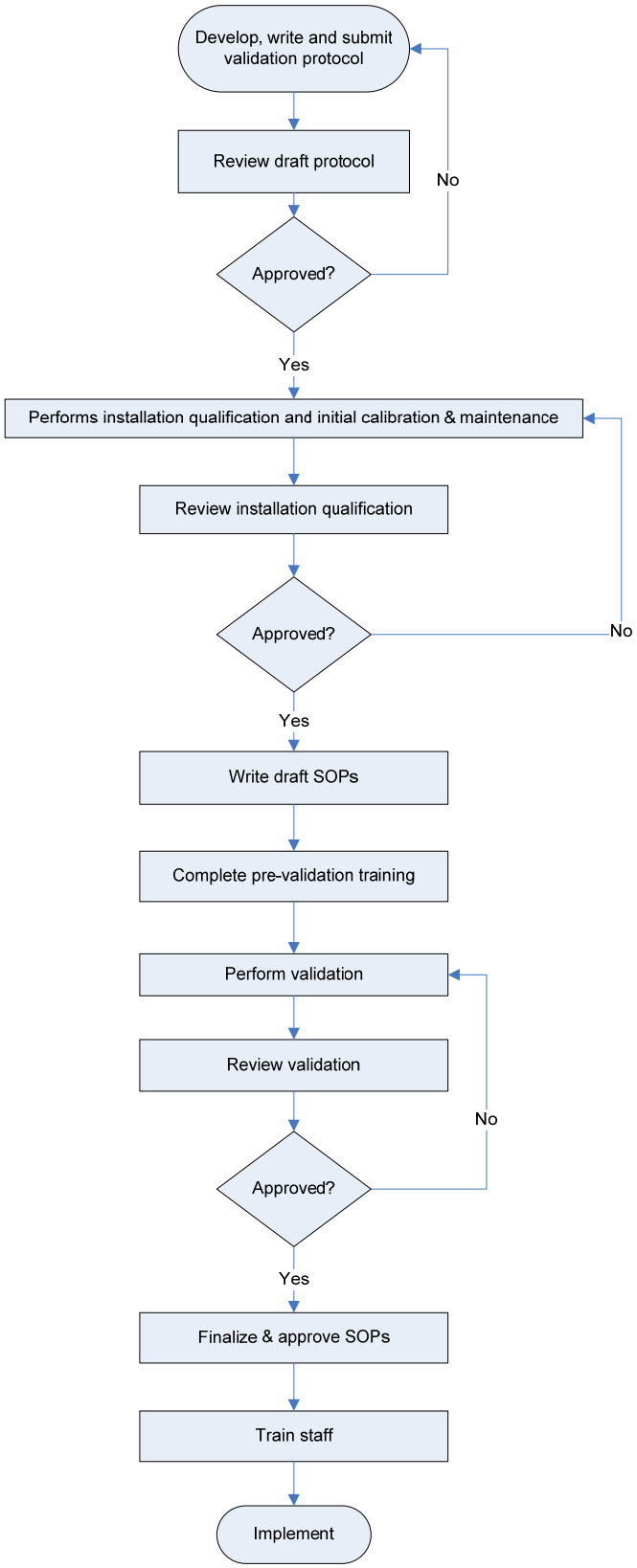
Version	Date	Reason for Revision	Revised By	Approved By
000	3/25/14	Section 5: add process for using Checklist for New/Changed Procedure Section 6: update EDCS title, add Checklist form Section 9: form moved to section 6 Footer: version # leading zero's dropped due to new EDCS in use as of 10/7/13.	L Barrett	C Bowman
1	3/23/18	Header: add other sites Section 5, 6: update number for validation policy	L Barrett	C Bowman

9. ADDENDA AND APPENDICES

A. Process Validation Flow Chart
B. Validation Protocol Format

ADDENDUM A

PROCESS VALIDATION FLOW CHART



Form revised 3/31/00

ADDENDUM B
VALIDATION PROTOCOL FORMAT

The following items are provided as guidelines for a validation protocol.

A. Title and protocol approvals

This section contains the protocol title and a space for a signature approving the protocol.

B. Purpose

1. Identify what equipment or process is being addressed in the validation.
2. Identify the reason the validation or revalidation is required

C. Requirements and Specifications

1. Identify the performance requirements for the equipment or process with the following:
   a. Equipment capabilities and parameters
   b. Regulatory requirements and industry standards associated with the equipment or process
2. References (operator's manual, package insert, etc.)

D. Test Plan

1. Installation Qualifications
   a. Identify all steps required to verify that the equipment was properly installed in environmental conditions that meet the manufacturer's specification.
   b. Provision for sign-off that the installation qualification has been met.

2. Operational Qualifications
   a. Identify all steps required to verify that the equipment or process operates within established limits and specifications supplied by the manufacturer.

3. Performance Qualifications
   a. Identify all steps required to verify that the equipment performs as expected for its intended use in the processes established by the facility and that the output meets the facility's specification.

4. General requirements
   - Each test should compare the expected results from the requirements against the actual results.
   - All steps should provide a space for the person performing the validation to initial and date.
   - The validation plan should specify the number of process runs, when applicable, to provide an accurate measure of variability among successive runs.