### Name of Policy: Process and Equipment Validation Protocol

**Policy Number:** 3364-108-111  
**Department:** Pathology/Laboratory – Blood Bank  
**Approving Officer:** Chief Executive Officer - UTMC  
Associate Professor, Director, Clinical Pathology/Hematopathology  
**Responsible Agent:** Core Lab Manager (Michelle Bartkowiak, MT(ASCP)SBB)  
Administrative Director, Lab (Cynthia O’Connell)  
**Scope:** Pathology/Laboratory – Blood Bank  

<table>
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<th>Effective Date:</th>
<th>03/01/2017</th>
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(A) **Policy Statement**

The Blood Transfusion Service has a plan to define, test and document new processes, procedures and equipment.

(B) **Purpose of Policy**

To describe the process of validation for new processes, procedures and equipment.

(C) **Procedure**

**Process Control**

1. The execution of the validation protocol provides documented evidence and a high degree of assurance that a specific process, procedure or equipment will consistently produce a specific, intended result. Validation is performed on new processes, new procedures or new equipment.

   1. The BTS Supervisor writes a validation protocol with consideration for applicable laboratory regulation, risk assessment, accreditation standards, and manufacturer’s instructions. The validation protocol is approved by the BTS Medical Director.
   2. New equipment is installed by manufacturer’s representative or Biomedical personnel. Initial calibration and maintenance is demonstrated, performed and documented.
   3. Training for BTS Supervisor and designated personnel is provided by the manufacturer, if applicable.
   4. The BTS Supervisor or designated personnel develop and write procedures.
   5. A validation protocol is developed, containing essential elements (Attachment A). The specific validation protocol is outlined and documented on the validation protocol template (see attachment B). The validation protocol recommended by the vendor may be used as a guide.
   6. The process is validated through execution of a documented plan. The BTS Supervisor and designated personnel perform the validation procedures and document the procedures accordingly.
   7. The BTS Medical Director reviews the validation data and approves data by signing the validation protocol forms.
   8. The BTS Supervisor finalizes the written procedure.
   9. The BTS Medical Director reviews and approves the final procedure.
   10. The BTS Supervisor and designated personnel train all remaining personnel. The training is documented on the annual competency checklist.
   11. Records of validation are maintained in BTS Supervisor office.
Approved by:

Robert L. Booth, Jr., M.D.  
Associate Professor  
Director, Clinical Pathology/Hematopathology

Date

Daniel Barbee, RN, BSN, MBA  
Chief Executive Officer - UTM C

Date

Review/Revision Completed By:  
Michelle Bartkowiak, MT(ASCP)SBB

Policies Superseded by This Policy:

References:


ATTACHMENTS:

Attachment A: Essential elements of Process Validation  
Attachment B: Process Validation Protocol
Attachment A

**ESSENTIAL ELEMENTS OF A PROCESS VALIDATION PROTOCOL**

Title

Purpose

System description

Validation activities
- Installation qualification – verification of correct installation of systems and support; capability of consistent operation as required by design and process.
- Operational qualification – system produces effective and reproducible results
- Process/product qualification – process produces effective and reproducible results

Acceptance criteria – as determined by BTS Medical Director and Supervisor

Test results

Results summary

Review and approval/disapproval

Signature and dates
Attachment B

PROCESS VALIDATION PROTOCOL

Process Title: ________________________________

I. Purpose of Validation

II. System Description

III. Responsibilities

Installation Qualification to be performed by: ________________________________

Installation Qualification to be reviewed by: ________________________________

Maintenance / Calibration to be performed by: ________________________________

Support Services required and provided by: ________________________________

Validation to be performed by: ________________________________

Validation to be reviewed by: ________________________________
IV. Validation Protocol

A. SOPs/Personnel/Equipment/Materials Required

B. Test Samples Required

C. Testing Conditions

D. Data Collected

E. Acceptance Criteria

Protocol prepared by: ___________________________  Protocol approved: Yes  No
Protocol reviewed by: ___________________________  Protocol approved by: _________
V. Conclusion

A. Validation Results

B. Comments/Actions:

C. Signatures

Performed by: ___________________________ Date: _______________

Approved by: ___________________________ Date: _______________

Medical Director Review: ___________________ Date: _______________

D. Result Acceptable?

Yes   No

Comments: