**Computer Validation Protocol**

**Policy Number:** 3364-108-110  
**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>New policy proposal</th>
<th>Major revision of existing policy</th>
<th>Minor/technical revision of existing policy</th>
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(A) **Policy Statement**

The Blood Transfusion Service has a plan to define, test and document computer process and procedures.

(B) **Purpose of Policy**

To describe the process of validation and revalidation of computer systems including the associated software.

(C) **Procedure**

The execution of the validation protocol provides documented evidence and a high degree of assurance that a specific process will consistently produce a specific result. Computer validations are performed on new hardware, new or upgraded software, and new and changed interfaces.

1. The BTS Supervisor devises an Implementation Plan including a validation protocol or outline with consideration for applicable laboratory regulation, risk assessment, accreditation standards, and manufacturer’s instructions and release notes. The validation protocol or outline is approved by the System Administrators and the BTS Medical Director.
2. The system is installed by manufacturer’s representative and Lab IS personnel and approved for proper function by the System Administrators.
3. Training for key personnel is provided by the manufacturer, if appropriate.
4. The key personnel develop and write procedures and flowchart processes. The System Administrator-level personnel develop and write computer training procedures, documentation form and competency test.
5. All procedures and processes are tested to see if expected results are actually obtained when the procedure or process is performed as written. The system is validated through execution of test cases. Each test case comprising the validation protocol or outline contains essential elements of computer validation protocol (see attachment B). Validation scripts may be provided by the software vendor and adapted as required to UTMC policy and procedure. Designated personnel perform the validation procedures and document the procedures accordingly.
6. The BTS Medical Director reviews the validation data and approves data by signing the validation protocol outline.
7. The BTS supervisor finalizes the written procedure and policies for the computer system.
8. The BTS Medical Director or designee reviews and approves the final procedure and policy manual.
9. The BTS Supervisor and designated personnel train all remaining personnel. The training is documented on computer training form. All personnel must achieve successful completion of competency test prior to “live” date.
10. An abbreviated version of this process will precede software upgrades with complete testing of applicable processes affected by changes. Release notes and scripts provided by vendor will be used for validation.
References:


COMPUTER VALIDATION

Develop, write, and submit computer validation protocol

Review draft validation protocol

Approved?

Yes

Perform installation qualification

Review installation qualification

Approved?

Yes

Write draft SOPs

Complete prevalidation training

Perform validation

Review

Approved?

Yes

Finalize SOPs

Train personnel

Implement process

No

Revise protocol/SOPs
ESSENTIAL ELEMENTS OF A COMPUTER VALIDATION PROTOCOL

System Description/ reason for validation

Title of test case
• **Function to be tested and type of case intended**

Purpose
• To ensure function to be tested yields expected results

Validation Activities/Procedure
• Instruction for performance of validation activity and documentation of actual results

Expected Test Results

Results Summary/ Acceptance

Review and Approval/Disapproval

Signatures and Dates