Name of Policy:	**Computer Validation Protocol**
Policy Number:	3364-108-110
Department:	Pathology/Laboratory – Blood Bank
Approving Officer:	Associate Professor Director, Clinical Pathology/Hematopathology
Responsible Agent:	Core Lab Coordinator (Michelle Bartkowiak, MT(ASCP)SBB) Manager, Lab (Cynthia O'Connell)
Scope:	Pathology/Laboratory – Blood Bank

THE UNIVERSITY OF TOLEDO 1872

Effective Date: 6/9/2008
Initial Effective Date: 3/1999

_____ New policy proposal	_____ Minor/technical revision of existing policy
_____ Major revision of existing policy	__X__ Reaffirmation of existing policy

(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 with consideration for applicable laboratory regulation, accreditation standards, and manufacturer's instructions. The validation protocol 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.
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 contains essential elements of computer validation protocol (see attachment B). Validation scripts may be provided by the software vendor and adapted to UMC 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 forms.
7. The BTS supervisor finalizes the written procedure and policies for the computer system.
8. The BTS Medical Director 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.

Approved by:	**Review/Revision Date:**
6-6-08	6/96 6/9/2008
Robert L. Booth, Jr., M.D. Date	2/97
Associate Professor	1/98
Director, Clinical Pathology/Hematopathology	3/99
	4/00
Review/Revision Completed By:	1/05
Michelle Bartkowiak, MT(ASCP)SBB	1/2008
	Next Review Date: 6/1/2011
Policies Superseded by This Policy:	

It is the responsibility of the reader to verify with the responsible agent that this is the most current version of the policy.

References:

Food and Drug Administration, Center for Biologics Evaluation and Research. Guideline on general principles of process validation. Rockville, MD: Food and Drug Administration, 1987.

Food and Drug Administration, Center for Biologics Evaluation and Research. Draft guideline for the validation of blood establishment computer systems. Rockville, MD: Food and Drug Administration, October 28, 1993. (Docket No. 93N-0394).

Food and Drug Administration, Center for Biologics Evaluation and Research. Guideline for quality assurance in blood establishments. Rockville, MD: Food and Drug Administration, 1995. (Docket No. 91N-0450).

Responsibilities for implementing and using a blood bank computer system. Arlington, VA: American Association of Blood Banks, 1989; revised 1990.

Guidelines for preparing standard operating procedures for blood bank computer systems. Arlington, VA: American Association of Blood Banks, 1991.

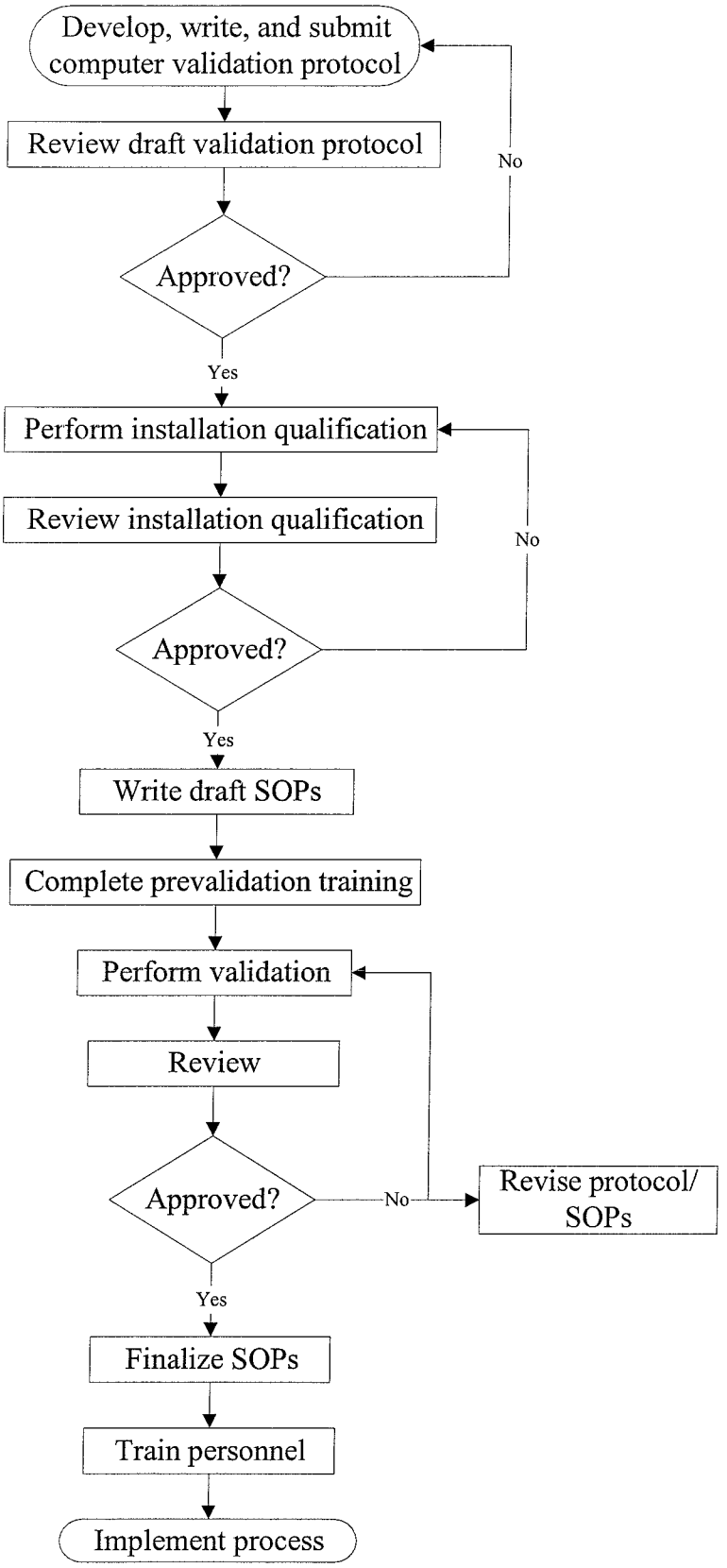
Blood bank/transfusion service computer systems software manufacturing process guidelines. Bethesda, MD: American Association of Blood Banks, 1993.

Blood bank/transfusion service computer system user validation guidelines. Bethesda, MD: American Association of Blood Banks, 1993.

Validation guidelines for microprocessor-controlled test instrument. Bethesda, MD: American Association of Blood Banks, 1993.

Attachment A

COMPUTER VALIDATION



Attachment B

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