Name of Policy: Computer Validation Protocol Policy Number: 3364-108-110 Approving Officer: Senior Hospital Administrator Director, Blood Transfusion Service Responsible Agent: Blood Transfusion Service Supervisor Administrative Director, Lab Scope: University of Toledo Medical Center Pathology/Laboratory – Blood Bank	UTOLEDO HEALTH Effective date: 03/03/2025 Original effective date: 03/1999
Key words: Computer Validation, Lab Information System, Validation, Blood Bank Information System, Implementation Plan	

☐	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 (BTS) 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

(1) 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.

(a) 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.

(b) The system is installed by manufacturer's representative and Lab Information Systems (IS) personnel and approved for proper function by the System Administrators.

(c) Training for key personnel is provided by the manufacturer, if appropriate.

(d) 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.

(e) 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.

(f) The BTS Medical Director reviews the validation data and approves data by signing the validation protocol outline.

(g) The BTS supervisor finalizes the written procedure and policies for the computer system.

(h) The BTS Medical Director or designee reviews and approves the final procedure and policy manual.

(i) 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.

(j) 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.

(D) References

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

(2) 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).

(3) 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).

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

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

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

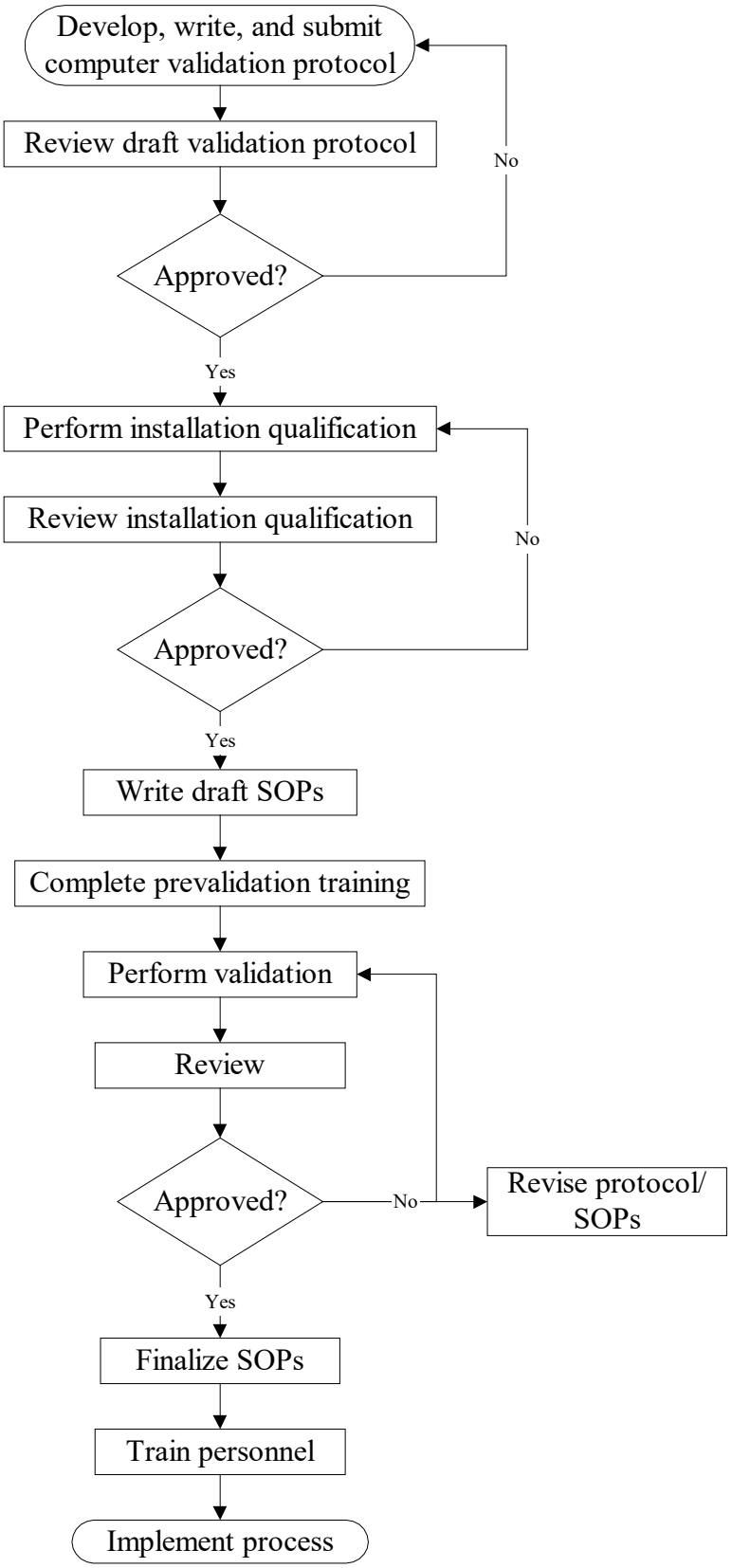
(7) Blood bank/transfusion service computer system user validation guidelines. Bethesda, MD: American Association of Blood Banks, 1993.

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

Approved by: /s/ _____ Lauren Stanoszek, M.D. Assistant Professor Director, Blood Transfusion Service 3/1/2025 _____ Date /s/ _____ Russell Smith Pharm D, MBA, BCPS, CPEL, FACHE Senior Hospital Administrator 3/3/2025 _____ Date *Review/Revision Completed by:* Danielle Weilnau MLS(ASCP)^{CM}	Policies Superseded by This Policy: • *None* Initial effective date: 03/1999 All Review/Revision Dates: 3/99 4/00 1/05 1/2008 6/9/2008 03/22/2011 3/01/2013 3/2/2015 3/1/2017 3/1/2019 3/1/2021 03/20/2023 03/03/2025 Next review date: 03/03/2027

Attachment A

COMPUTER VALIDATION



Attachment B

ESSENTIAL ELEMENTS OF A
COMPUTER VALIDATION PROTOCOL

(A) System Description/ reason for validation
    (1) Title of test case
    (2) Function to be tested and type of case intended
(B) Purpose
    (1) To ensure function to be tested yields expected results
(C) Validation Activities/Procedure
    (1) Instruction for performance of validation activity and documentation of actual results
(D) Expected Test Results
(E) Results Summary/ Acceptance
(F) Review and Approval/Disapproval
(G) Signatures and Dates