Name of Policy: Process and Equipment Validation Protocol Policy Number: 3364-108-111 Approving Officer: Senior Hospital Administrator Director, Blood Transfusion Service Responsible Agent: Blood Transfusion Service Supervisor Administrative Director, Lab Scope: Pathology/Laboratory – Blood Bank	UTOLEDO HEALTH Effective date: ~~03/01/2025~~ Original effective date: 09/2000
Key words: Process, Equipment, Validation, Protocol, Install	

☐	New policy proposal	☒	Minor/technical revision of existing policy
☐	Major revision of existing policy	☐	Reaffirmation of existing policy

(A) ~~(A)~~ Policy Statement

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

(B) ~~(B)~~ Purpose of Policy

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

(C) ~~(C)~~ Procedure

(1) Process Control

(a) ~~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.~~(i) 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.~~(ii) New equipment is installed by manufacturer's representative or Biomedical personnel. Initial calibration and maintenance is demonstrated, performed and documented.

~~3.~~(iii) Training for BTS Supervisor and designated personnel is provided by the manufacturer, if applicable.

~~4.~~(iv) The BTS Supervisor or designated personnel develop and write procedures.

~~5.~~(v) 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.~~(vi) 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.~~(vii) The BTS Medical Director reviews the validation data and approves data by signing the validation protocol forms.

~~8.~~(viii) The BTS Supervisor finalizes the written procedure.

~~9.~~(ix) The BTS Medical Director reviews and approves the final procedure.

~~10.~~(x) The BTS Supervisor and designated personnel train all remaining personnel. The training is documented on the annual competency checklist.

(xi) Records of validation are maintained in the BTS Supervisor ~~Core Lab Manager~~ office.

(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. Guideline for Quality Assurance in Blood Establishments. Rockville, MD: Food and Drug Administration, 1995. (Docket No. 91N-0450).

(3) A Model Quality System for the Transfusion Service, AABB, 1997.

Approved by:	Policies Superseded by This Policy:
_____ Lauren Stanoszek, M.D. Assistant Professor Director, Blood Transfusion Service	• *None* Initial effective date: 09/2000
_____ Date	All Review/Revision Dates: 9/00 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 ~~03/01/2025~~
_____ Russell Smith Pharm D, MBA, BCPS, CPEL, FACHE Senior Hospital Administrator	
_____ Date	Next review date: ~~03/01/2027~~
Review/Revision Completed by: Danielle Weilnau MLS(ASCP)^{CM}	

~~11.~~

Approved by: Lauren Stanoszek, M.D. Date Assistant Professor Director, Blood Transfusion Service Christine Stesney-Ridenour Date Chief Operating Officer - UTMC Review/Revision Completed By: Danielle Weilnau, MLS(ASCP)CM	Review/Revision Date: 9/00 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 Next Review Date: 3/1/2025
Policies Superseded by This 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.

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A Model Quality System for the Transfusion Service, AABB, 1997.

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: