


<b>Name of Policy:</b>	<b>Process and Equipment Validation Protocol</b>	 <b>Effective Date:</b> 6/9/2008 Initial Effective Date: 9/2000
<b>Policy Number:</b>	3364-108-111	
<b>Department:</b>	Pathology/Laboratory – Blood Bank	
<b>Approving Officer:</b>	Associate Professor Director, Clinical Pathology/Hematopathology	
<b>Responsible Agent:</b>	Core Lab Coordinator (Michelle Bartkowiak, MT(ASCP)SBB) Manager, Lab (Cynthia O’Connell)	
<b>Scope:</b>	Pathology/Laboratory – Blood Bank	
<input type="checkbox"/> New policy proposal <input type="checkbox"/> Major revision of existing policy		<input type="checkbox"/> Minor/technical revision of existing policy <input checked="" type="checkbox"/> Reaffirmation of existing policy

**(A) Policy Statement**

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

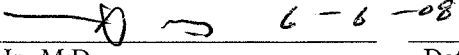
**(B) Purpose of Policy**

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 , 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.
4. The BTS Supervisor or designated personnel develop and write procedures.
5. The validation protocol is developed (Attachment A). The validation protocol contains essential elements of validation protocol (see attachment B).
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.

<b>Approved by:</b>   _____ Robert L. Booth, Jr., M.D. Associate Professor Director, Clinical Pathology/Hematopathology  Review/Revision Completed By: Michelle Bartkowiak, MT(ASCP)SBB	<b>Review/Revision Date:</b> 9/00 1/05 1/2008 6/9/2008  <b>Next Review Date:</b> 6/1/2011
<b>Policies Superseded by This Policy:</b>	

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

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### I. Purpose of Validation

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### II. System Description

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### 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: \_\_\_\_\_

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**IV. Validation Protocol**

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**A. SOPs/Personnel/Equipment/Materials Required**

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**B. Test Samples Required**

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**C. Testing Conditions**

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**D. Data Collected**

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**E. Acceptance Criteria**

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Protocol prepared by: \_\_\_\_\_

Protocol approved: Yes No

Protocol reviewed by: \_\_\_\_\_

Protocol approved by: \_\_\_\_\_

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**V. Conclusion**

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**A. Validation Results**

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**B. Comments/Actions:**

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**C. Signatures**

**Performed by:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Approved by:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Medical Director Review:** \_\_\_\_\_ **Date:** \_\_\_\_\_

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**D. Result Acceptable?**

**Yes**      **No**

**Comments:**