Name of Policy:	**Process Control/Change Control**	THE UNIVERSITY OF TOLEDO MEDICAL CENTER
Policy Number:	3364-108-104	
Department:	Pathology/Laboratory – Blood Bank	
Approving Officer:	Chief Operating Officer - UTMC Director, Blood Transfusion Service	
Responsible Agent:	Blood Transfusion Service Supervisor Administrative Director, Lab	
Scope:	Pathology/Laboratory – Blood Bank	**Effective Date: 3/20/2023** Initial Effective Date: 6/1996

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

(A) Policy Statement

The Blood Transfusion Service has defined the steps and activities necessary for documenting new and revised processes into written policies and procedures in compliance with AABB and CAP guidelines.

(B) Purpose of Policy

To provide immediate reference for Blood Transfusion Service staff to policies and procedures that comply with current AABB standards and practice and CAP guidelines.

To promote uniformity and limit variation in the performance of test procedures and routine Blood Bank operations.

(C) Procedure

Process Control

1. Procedures Manual is written, revised and reviewed biennially by the Blood Transfusion Service Supervisor, Medical Director or designee. Procedures are reviewed and validated by BTS staff prior to effective date. New and revised procedures are approved by the Medical Director of the Blood Transfusion Service. All procedures are written in compliance with CLSI guidelines (Quality Management System: Development and Management of Laboratory Documents; Approved Guideline - Sixth Edition. CLSI document QMS02-A6) and contain, to the extent possible, the following parts:
   - Title
   - Principle and Clinical Significance - a paragraph concerning the type of reaction involved and clinical reasons for performing the test.
   - Patient Preparation
   - Specimen Requirements
   - Reagents - specific reagents, supplies and equipment used for the test including preparation of any solutions necessary.
   - Procedure - detailed instructions written in a specific stepwise manner.
   - Interpretation of Results – includes entry of test results and computer downtime procedure
   - Calibration and calibration verification procedures
   - Quality control procedures
   - Limitations
   - Procedure Notes - includes special precautions, limitations of procedure, helpful hints, interfering substances or clinical conditions.
   - References - textbooks, manufacturers product inserts, publications, etc. used in preparing the procedure. List author, title, edition number, pages, publisher, place of publication, volume number, year of publication or revision.

2. The Quality System Manual contains policies written, revised or edited by the Blood Transfusion Service Supervisor or designee. Policies are reviewed and validated by BTS staff prior to effective date. New and

revised policies are approved by the Medical Director of the Blood Transfusion Service and reviewed biennially. Each policy contains the following parts:

- A statement of policy
- Purpose of policy
- Standard Operating Procedure - a detailed explanation of the policy statement as applied to Blood Transfusion Service routine and addressing applicable key elements of each critical control point.

3. Each policy and procedure contains a record listing original version date, current version revision and review dates and the identification of the person performing review. Hand-written revisions, if not extensive, are acceptable and must be dated and initialed. Current and retired versions of procedures, policies and forms are tracked in the Pathology (Z drive) Document Control folder.

4. All discontinued policies and procedures hard copies are kept on file for five years after removal from service. Discontinued documents should be sequestered in an archive or "old" file on the Z drive.

5. All deviations from BTS policies and procedures must be documented appropriately in a lab occurrence report (See Policy #3364-108-106).

6. BTS staff will validate policies and procedures. Validation assures the policy or procedure clearly and accurately states the practice intended and agreement of the policy or procedure with the stated reference material. Staff is notified of revised or new procedures with the Staff Notification form. Staff will acknowledge notification and understanding of new/revised procedures and policies by signing Staff notification form.

Change Control

Significant revisions in policy and procedure, or new policies and procedures to address significant need for change identified through Process improvement activities may be documented on a Change Control form, if appropriate. The form will accompany the new or revised policy or procedure for approval by Medical Director of Blood Transfusion Service and for staff notification and training to serve as an explanation of the revision of new procedure, if needed. Completed Change control forms are kept on file until original version or current revision of policy/procedure is revised or removed from service.

Approved by:		**Review/Revision Date:**
/s/ Lauren Stanoszek, M.D. Assistant Professor Director, Blood Transfusion Service	03/21/2023 Date	6/96 03/20/2023 8/98 3/99 7/00 1/05 6/9/2008 3/22/2011 3/01/2013
/s/ Christine Stesney-Ridenour Chief Operating Officer - UTMC	03/21/2023 Date	3/2/2015 03/01/2017 03/01/2019 03/01/2021
Review/Revision Completed By: Danielle Weilnau, MLS(ASCP)CM		**Next Review Date:** 3/1/2025
Policies Superseded by This Policy:		

Reference:
AABB Standards for Blood Banks and Transfusion Services, current edition.
AABB Quality Plan Manual/AABB Quality Program Self Assessment Manual, 1994, A6.1-A6.5

Quality Management System: Development and Management of Laboratory Documents; Approved Guideline - Sixth Edition. CLSI document QMS02-A6, 2013.