Name of Policy: **Process Control** **Policy Number**: 3364-107-303 **Approving Officer**: Medical Director, Clinical Pathology **Responsible Agent**: Director, Clinical Pathology Administrative Director, Lab **Scope**: Pathology Laboratory University of Toledo Medical Center	UTOLEDO HEALTH **Effective date:** 01/04/2025 **Original effective date**: 05/20/1995
Key words: Testing uniformity, policy & procedure contents, procedure review, record correction, leadership change	

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

(A) Policy statement

The Laboratory has defined the steps and activities necessary for documenting new and revised processes into written policies and procedures in compliance with The Joint Commission (TJC), NCCLS and CAP guidelines. All new tests performed must be validated to establish and verify performance specifications.

(B) Purpose of policy

To provide immediate reference for staff to policies and procedures that comply with current standards and practice. To promote uniformity and limit variation in the performance of test procedures and Laboratory operations. To ensure the accuracy, precision, sensitivity, and reportable ranges of new testing methods.

(C) Procedure

Process Control

1. Procedures Manuals are reviewed and signed every two years by one of the following: Laboratory Medical Director, department medical director, the division supervisor, laboratory manager, or lead technologist. Procedures are reviewed and validated by staff prior to effective date. New and revised procedures are approved by the Medical Director. All procedures are written in compliance with NCCLS guidelines (GP2-A2, vol.12, no. 10) and contain, to the extent possible, the following parts:
   - Title

- Principle - a paragraph concerning the type of reaction involved and clinical reasons for performing the test.
- Specimen Requirements
- Reagents - specific reagents, supplies and equipment used for the test.
- Procedure - detailed instructions written in a specific stepwise manner.
- Interpretation of Results
- 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 Policy Manual contains policies written, revised, or edited by supervisors, coordinators, managers, or lead technologists. Policies address the Quality System Essentials "A Quality System Model for Health Care; Approved Guideline", National Committee for Clinical Laboratory Standards, NCCLS, vol. 19, No. 20, October 1999, order no. GP26-A. New and revised policies are approved and signed by the Medical Director. 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 routine Laboratory operations 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.
4. All discontinued policies and procedures are kept on file for five years after removal from service.
5. All deviations from Lab policies and procedures must be documented appropriately in the variance log or report.
6. Lab staff assigned by manager will validate policies and procedures. New Test 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. New Test checklists will be filed with completed Change Control forms (see below).
7. 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.
8. Following a change in laboratory directorship, the new laboratory director approves the laboratory policies and procedures over a reasonable period of time.

Introduction of New Tests/Procedures/Processes

1. Establish the following for all new tests introduced:
   a. Accuracy and precision
   b. Analytic sensitivity and specificity (including interfering substances)
   c. Reportable range of patient test results (linearity)
   d. Reference intervals (normal values)

2. Each laboratory division shall have validation procedures specific to the test performed.

3. The laboratory division director will periodically evaluate the appropriateness of its reference ranges and take corrective action if necessary.

4. If changes in procedure are established, Hospital-wide communications are sent to the medical staff, house staff and nursing staff in advance of the initiation of the new procedures.

Change Control

Revisions in policy and procedure, or new policies and procedure to address needs identified through Process Improvement activities may be documented on a Change Control form. The completed form will accompany the new or revised policy or procedure for approval by Medical Director and for staff notification and training. Completed change control forms are kept on file until original version or current revision of policy/procedure is revised or removed from service.

Use of Abbreviations

Each department has a policy listing common abbreviations in use in the area. Some abbreviations common to all laboratories include:
R, Recd, RE (Received)
O, Op (Opened)
√ (Reviewed or Checked)
Exp (Expires)

Correction of records – Handwritten or otherwise.

Draw a single line through the error along with tech initials and date to correct recorded results. Record the correct information above or nearby. Overwritten information is not acceptable. The use of "White-out" or other means of obliteration is likewise unacceptable. Incorrect results entered into the computer must be handled according to policy 3364-107-106. The correct results are then reported.

References

"Clinical Laboratory Procedure Manuals", National Committee for Clinical Laboratory Standards, NCCLS, vol. 12, no.10, July 1992, order no. GP2-A2.
“A Quality System Model for Health Care; Approved Guideline”, National Committee for Clinical Laboratory Standards, NCCLS, vol. 19, No. 20, October 1999, order no. GP26-A.
AABB Quality Plan Manual/AABB Quality Program Self-Assessment Manual, 1994.

Approved by: /s/ _____ Name: Amira Gohara, M.D. Title: Medical Director, Clinical Pathology 1/10/2025 _____ Date *Review/Revision Completed by:* *Joshua Otiso, Administrative Director, Lab*	**Policies Superseded by This Policy:** • *Q-03* Initial effective date: 06/01/2001 Review/Revision Date: 01/04/2025 Next review date: 01/04/2027