Name of Policy: **Non-conforming Events in Laboratory** **Policy Number**: 3364-107-127 **Approving Officer**: Medical Director, Clinical Pathology **Responsible Agent**: Director, Clinical Pathology Administrative Director, Lab **Scope**: Pathology Laboratory University of Toledo Medical Center	**Effective date:** 01/04/2025 **Original effective date**: 01/04/2021
Key words: Non-conformity, policies & procedures, root cause analysis, solution effectiveness, quality management	

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

(A) Policy statement

Non-conformity is any occurrence that is not in accordance with policies, procedures or expectations. A non-conformance means that something has gone wrong and must be corrected. Non-conformances are addressed by identifying the root cause of the problem and developing a plan of correction to remediate.

(B) Purpose of policy

To develop a corrective action plan, a root cause analysis when a non-conformance occurs within the laboratory.

(C) Procedure

1. Use root cause check sheet when starting procedure.

- Determine:
  - What happened.
  - Why it happened.
  - What to do to prevent it from happening again.
- Must be impartial, methodical information driven.
- Include all personnel involved in the error for the analysis.
- Clearly state the purpose is not to assign blame.
- Write down the specific problem – Map the process – See examples.
- Ask why the problem happened.

- If the answer does not identify the root cause, ask why again until there is agreement until the root cause has been identified.
- Ask what proof there is that the cause exists and is there proof is contributed to the problem.

2. Develop and Implement a Solution

- Identify changes for each root cause.
- Consider solution types.
- Interview key players and stakeholders about feasibility of various options.
- Identify sources of resistance.
- Develop a change management approach.
- Plan the solution.
- Walk through the solution.
- Do a FMEA (Failure Mode and Effects Analysis).
- Obtain approval of change.

3. Assess Effectiveness

- Choose an assessment approach.
- Make necessary changes.
- Monitor the change over time.
- Look for similar problems with similar root causes.

4. Save all documentation and review in Quality Management Meetings.

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:** • Initial effective date: 01/04/2021 Review/Revision Date: 01/04/2025 Next review date: 01/04/2027