Name of Policy: Non-conforming Events in Laboratory **Policy Number**: 3364- 107-127 **Department:** Pathology – Laboratory **Approving Officer**: Chief OperatingOfficer - UTMC **Responsible Agent**: Director, Clinical Pathology Administrative Director, Lab **Scope**: Pathology, Laboratory	THE UNIVERSITY OF TOLEDO MEDICAL CENTER **Effective date: 1/04/2023** **Original effective date**: 1/04/2021
Key words:	

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

(A) Policy statement

A 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

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.

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

Assess Effectiveness

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

Save all documentation and review in Quality Management Meetings.

Approved by:		**Review/Revision Date:** 1/04/2023
/s/ Amira Gohara, M.D. Professor Director, Clinical Pathology	01/05/2023 Date	
/s/ Christine Stesney-Ridenour Chief Operating Officer-UTMC *Review/Revision Completed by:* *Heather Byrd – Administrative Director - Lab*	01/10/2023 Date	**Next Review Date:** 1/4/2025