Quality Management System

I approve the following

LEPL Georgian Technical University

Rector / Chancellor_____

__. __. 2022

Non-Compliance Management

According to the requirements of ISO 9001 Standard

MI-05

Revision: __

Copy No. __

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Table of Contents

1. Goal

The present Methodical Instruction (hereinafter - the Instruction) establishes the rules for Non-conformities Management identified during the current main Organizational and Customer Service implementation processes at LEPL Georgian Technical University (hereinafter - the Organization), which may become the reason for:

- Hindering the development of the Organization;
- Resulting harm to health;
- Significant financial/material loss;
- The reason for damaging the image.

2. Scope

The rules contained in the Instruction are mandatory for all employees in the Organization who perform their activities in the Quality Management System field.

3. Terms and abbreviations

The terms and definitions used in this Instruction correspond to the terms and definitions in ISO 9001 Standard.

The following specific abbreviations are applied within the Instruction:

QMS - Quality Management System;

QMS/M - Quality Management Manual

MI - Methodical Instruction;

QMS Manager/QMS Leader - Management Representative in matters of Quality Management;

Non-compliance - non-compliance with established requirements;

Mand. - Mandatory;

Part. - Participator.

4. General provisions

In case of non-compliance, our Organization:

a) Responds the Non-conformity and if applicable:

1) Implements actions for its control and correction;

2) Eliminates its causes in order to prevent recurrence;

b) Analyzes and evaluates the need to eliminate the cause of the Non-conformity and the necessary actions to prevent its recurrence or occurrence in another place:

1) By reviewing and analyzing Non-compliance;

2) By determining the cause of non-compliance;

3) By establishing the existence of similar inconsistencies, or the possibility of their occurrence;

c) Implements the necessary actions;

d) Analyzes the effectiveness of the implemented Corrective Actions;

e) If necessary, makes amendments to the Quality Management System;

Corrective Actions are appropriate to the consequences of the nonconformity.

The Organization keeps documented information as evidence:

a) The type of non-compliance, any subsequent actions and

b) On the results of any Corrective Actions.

Non-compliance is revealed when the characteristics of the current process or the final product are inconsistent with the specifications established by the employee of the Organization.

Non-compliant services / products (materials, equipment) procured and received on Site are immediately identified, banned and reported to the head of the department, who, together with the Organization's QMS Manager, decides on further Correction/Corrective Actions for such products. This decision is documented through the Protocol of Non-compliance (Appendix A), according to which the purchasing unit informs the Supplier of the fact and manages the Correcting Process for the Non-compliance.

5. Responsibilities for Non-compliance

The responsibilities are distributed as follows:

Task	Person responsible for procurement	Head of structural unit	QMS Manager
Detection of non-conformity on the procured product		Mand.	Part.
Identification and/or isolation of Nonconformity	Part.	Mand.	Part.

Non-compliance registration	Part.	Mand.	Part.
Supplier notification of non-conformity	Mand		
Decision on further measures		Part.	
Deviation Analysis		Part.	Mand.

In case of discovery of **Non-compliance of the Process**, any employee is obliged to inform the identified defect to the immediate supervisor, who, as necessary, will contact the QMS Manager using the Protocol of Non-compliance (Appendix A).

Non-conformance assessment and analysis

In order to make a decision in case of detection of Non-compliance, the deviation is subject to evaluations:

- Assessment of the level of deviation from established requirements, determination of criticality;
- Assessing the impact of Non-conformance on subsequent operations and final service Quality to determine the possibility of product improvement with or without process adjustments;
- Assessment of the economic feasibility of possible measures for inappropriate products/processes.

The mentioned evaluations are carried out by the relevant managers, through the intervention of specialists, if necessary. The decision on further action for the Non-compliance shall be documented as follows:

- Non-conformity in the case of the product/service provided by the Supplier - in the Protocol of Non-compliance;

- Non-conformity identified at the stages of daily work process implementation - in the Protocol of Non-compliance or Non-compliance Registration Log.

The verification results confirm that:

a) Implemented processes are completed and effective;

b) The input data of the threat analysis is periodically updated;

c) The Risk Management Plan is implemented and functions effectively;

d) The level of threat is within the allowed norms;

e) Other measures established by the Organization are implemented and function effectively.

Registration of Non-compliance - Non-compliance is reflected in the Non-conformance Report (F-MI-05A-01), indicating as follows:

- Date,
- A place where the non-conformity has been detected.
- Description of the deviation,
- The reason for the deviation,
- The decision
- Planned Action (Correction or Corrective Action),
- Registration of fulfillment of the Actions,
- Assessment of the effectiveness of the Action.

The completed Form, together with the relevant evidence (where the Non-conformance is recorded), is transferred to the QMS Manager, who registers the Non-conformance in the Non-conformance Database, discusses the results in the Coordination Council Meeting and applies the data analysis for the Continuous Improvement.

6. Supporting Documents

Item	Title
QMS/M	Quality Manual
MI-03	Internal Audit
MI-04	Correction and Corrective Actions

7. Agreement Sheet

Developed by:	Date	Signature
QMS Manager		

Annex A

F-MI-05A-01

Quality Management System

Protocol of Non-compliance No.

e: Time:	Structural unit:			
Non-compliance:	☐ Procurement ☐ Process ☐ Technical ☐ Personnel			
Description of Non-compliance: Classification of the Non-compliance: A B C				
Surname, name	Signature			
The Process to be blocked				
Decision	☐ Final	☐ To be improved	☐ Insignificant	☐
Applied in other terms				
Decision-maker	Position	Signature Date		

The following Actions implemented according to the decision	
Executor (surname, name) Position:	Signature: Date:

Annex B

F-MI-05B-01

Complaint form №

1. Details of person issuing the Complaint

Organization title _____

Focal point _____

Address, zip code _____

Phone _____

Fax _____

Email _____

2. Description

_____

_____

3. Problem detection

Date of Problem detection __

Description of the Problem

Do you require to correct the Problem? ☐ Yes ☐ No

_____

_____

Date _____ Signature of the Author of Complaint _____

Date _____ Signature of the receiver of Complaint _____

Annex C

F-MI-05D-01

#	Date	Complaint No.	Address, phone	Complaint	Reason for Complaint	Decision	Executors	Deadline for implementation	Date of implementation	Implementation marking

Annex D

F-MI-05D-01

Non-compliances registration Log No.

#	Time of Non-compliance detection	Characterization of Non-compliance	Number of Non-compliances	Protocol No.	Implemented Actions	Responsible person	Efficiency of the Action