Quality Management System

I approve the following

LEPL Georgian Technical University

Rector / Chancellor_____

__. __. 2022

Corrective Procedures

According to the requirements of ISO 9001 Standard

MI-04

Revision: __

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1. Goal

This methodological instruction (hereinafter - the Instruction) describes the process of Correction and implementation of Corrective Actions related to the detected non-conformity/complaint, the purpose of which is to ensure Continuous Improvement of the Quality Management System processes efficiency.

The Instruction aims to establish rules and make it possible to timely eliminate the cause of non-compliance, identify possible problems/risks to prevent their recurrence or occurrence, use targeted analysis of problems and processes.

2. Scope

The Instruction is mandatory for the employees of all structural units of the LELP Georgian Technical University, who carry out their activities in the Quality Management 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;

Mand. - Mandatory;

Part. - Participator.

A nonconformity/risk can be identified by any employee involved in the QMS. Non-conformity/risk detection is registered as follows:

- According to the QMS Processes - during process monitoring by the person responsible for the process;
- By the Internal Audits - in Audit Reports by the Internal Auditors, provided in MI-03 Internal Audit;
- According to changes in legislation and regulatory norms;
- During the performance of services by sub-tenant organizations.

Actions implemented in case of non-compliance - the Organization defined the Corrective Actions and Correction Actions to be carried out in case of exceeding the critical limits and non-compliance with the action criteria in the Risk Management Plan.

The Organization must be sure that:

a) The reason for non-compliance is identified;

b) Repetition of the incident is avoided.

The Verification Results confirm as follows:

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

b) The level of danger is within the allowed norms;

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

Corrective Actions - in case of non-compliance, the Organization:

a) Reacts to the non-conformity and if possible:

1) Takes measures 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 non-compliances, or the possibility of their occurrence;

c) Implements the necessary actions;

d) Analyzes the effectiveness of the implemented Corrective Actions;

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

Corrective Actions must be commensurate with the consequences of the non-conformity. The Organization keeps the following documented information as evidence:

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

b) The results of any Corrective Actions.

Competent authorized persons evaluate the results obtained during the monitoring process and choose the necessary Correction and Corrective Actions.

Corrective Action taken in case of unsatisfactory results include:

a) Trend analysis of monitoring results that may reveal loss of control;

b) Determining the cause of non-compliance;

c) Developing measures to avoid non-compliance;

d) Documented results of Corrective Actions;

e) Review of the implemented Corrective Actions and evaluation of their effectiveness.

Corrective Actions are carried out in order to continuously maintain the compliance of all QMS indicators with the established requirements, as well as to improve the QMS based on the results of the Audit Results, the analysis of the reported data and the results of the QMS analysis by the Management. The basis for taking Corrective Actions is identified/potential non-compliance, i.e. non-fulfillment of established requirements.

Potential non-compliances can be identified as follows:

- During functioning of the Operating Process
- As a result of Internal/External Audits
- During QMS analysis.

4. Responsibilities

Responsibilities within the Correction/Corrective Action Management process are divided as follows:

Task	QMS coordination group	QMS Manager	Head of the structural unit	Relevant responsible employee
Non-conformity/risk detection		Mand	Mand	Mand
Non-compliance/risk analysis	Mand		Mand	
Determining the causes of non-compliance/risk	Part		Mand	
Determining the need for Correction/Corrective Action	Mand	Mand	Mand	
Implementing Correction/Corrective Actions		Mand	Mand	Mand
Analysis of the effectiveness of the measures taken	Mand	Mand		
Control of relevant records		Mand		

5. Implementation of Correction and Corrective Actions

Determination and analysis of the cause of non-compliance/risk is carried out by the head of the relevant structural unit together with the employees. The cause of the non-conformity/risk occurrence is discussed according to the monthly reporting procedure at the meetings of the QMS Coordination Group.

According to the analysis, the head of the relevant structural unit determines the Correction and Corrective Actions (Appendix A). Corrections/Corrective Actions are reported to all structural units involved in their implementation, officials and QMS Managers.

The need for Correction/Corrective measures may be identified, namely:

- Due to errors made during the process;
- In case of unforeseen risk;
- In case of errors made during the execution of documentation;
- In case of inappropriate management of processes;
- In case of non-compliance/risk arising due to insufficient training of personnel;
- As a result of weak control of the delegated processes;
- In case of risk of deviation from regulatory documents (insufficient information).

The Correction/Corrective Action Plan is sent to all structural units, officials and QMS Managers involved in its implementation.

6. Supporting documents

Item	Title
QMS/M	Quality Manual
ISO 9001	Quality Management System, requirements
MI-03	Internal Audit
MI-05	Non-compliances management

7. Agreement Sheet

Developed by:	Date	Signature
QMS Manager		
Agrees:		

Annex A

FF-MI-04-A-1

Corrective Actions

Date	Category of Corrective/ Preventive Actions	Description of non-compliance/deviation; Description of the Risk/Improvement potential	Reason/Action	Responsible person	Implementation deadline	Implementation efficiency level