Correction Procedures

MI-04

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1. Purpose

This methodological instruction (hereinafter – the "Instruction") describes the process of implementing correction and corrective measures in response to an identified nonconformity/complaint, the purpose of which is to ensure the continual improvement of the effectiveness of the processes of the quality management system.

The Instruction aims to establish rules and make it possible to eliminate the cause of a nonconformity in a timely manner, to identify potential problems/risks in order to prevent their recurrence or occurrence, and to apply a purposeful analysis of the problem and of the processes.

2. Scope

This Instruction is mandatory for the employees of all structural units of the LEPL (Legal Entity of Public Law) Georgian Technical University who carry out their activities within the scope of quality management.

3. Terms and Abbreviations Used

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

The following specific abbreviations are used in the Instruction:

- QMS – Quality Management System;
- QMS/M – Quality Management Manual;

- MI – Methodological Instruction;
- QMS Manager – Management representative for quality management matters / QMS leader;
- Mand. (სავ) – Mandatory;
- Part. (მონაწ) – Participates.

A nonconformity/risk may be identified by any employee involved in the QMS. The identification of a nonconformity/risk is recorded:

- According to QMS processes – by the person responsible for the process during process monitoring;
- According to internal audits – by internal auditors in audit reports, as set out in MI-03 "Internal Audit";
- According to changes in legislation and regulatory norms;
- By subcontracting organizations during the performance of services.

Actions applied in case of non-fulfilment – in the risk management plan, the organization has defined the corrective actions and correction measures to be carried out in cases where critical limits are exceeded and where the criteria for actions are not met.

The organization must be certain that:

- a) the cause of the nonconformity has been identified;
- b) recurrence of the incident has been prevented.

The verification results confirm that:

- a) the risk management plan has been implemented and is functioning effectively;
- b) the hazard level is within the permitted norms;
- c) other measures established by the organization have been implemented and are functioning effectively.

Corrective actions – in the event of a nonconformity, the organization:

- a) reacts to the nonconformity and, if applicable:
  - 1) takes action to control and correct it;
  - 2) eliminates the causes that gave rise to it in order to prevent its recurrence;
- b) analyzes and evaluates the need to eliminate the root cause of the nonconformity and the actions required so that it does not recur or occur elsewhere:
  - 1) by reviewing and analyzing the nonconformity;
  - 2) by determining the root cause of the nonconformity;
  - 3) by establishing whether similar nonconformities exist, or could potentially occur;
- c) implements the necessary actions;
- d) analyzes the effectiveness of the corrective action carried out;
- e) if necessary, makes changes to the quality management system.

Corrective actions must be commensurate with the effects of the nonconformity.

The organization retains documented information as evidence of:

- a) the nature of the nonconformity and any subsequent actions taken; and
- b) the results of any corrective actions.

The evaluation of results obtained in the monitoring process is carried out by competent authorized persons, who select the necessary correction and corrective actions.

In the event that unsatisfactory results are identified, the corrective action carried out includes:

- a) analysis of the trend of monitoring results, which may reveal a loss of control;
- b) determination of the cause of the nonconformity;
- c) development of measures to prevent the nonconformity;
- d) documented results of the corrective measures;
- e) review of the corrective actions applied and evaluation of their effectiveness.

Corrective actions are carried out in order to continually maintain conformity of all QMS indicators with the established requirements, as well as to improve the QMS on the basis of audit results, analysis of reported data, and the results of management's review of the QMS. The basis for implementing corrective actions is an identified/potential nonconformity, i.e., a failure to meet established requirements.

A potential nonconformity may be identified:

- during the functioning of an operational process;
- as a result of internal/external audits;
- during the review of the QMS.

4. Responsibilities

Within the process of managing correction/corrective actions, responsibilities are distributed as follows:

Task	QMS Coordination Group	QMS Manager	Head of Structural Unit	Relevant Responsible Employee
Identification of nonconformity/risk		Mand.	Mand.	Mand.
Analysis of nonconformity/risk	Mand.	Mand.		
Determination of causes of nonconformity/risk		Part.	Mand.	
Determination of the necessity of correction/corrective actions	Mand.	Mand.	Mand.	

Task	QMS Coordination Group	QMS Manager	Head of Structural Unit	Relevant Responsible Employee
Carrying out correction/corrective actions		Mand.	Mand.	Mand.
Analysis of the effectiveness of measures taken	Mand.	Mand.		
Control of relevant records		Mand.		

Note: In the source PDF the column positions of the "Mand./Part." entries were extracted without cell boundaries, so the assignment of entries to columns above is a best reconstruction. Please verify against the original table.

5. Implementation of Correction and Corrective Actions

The determination and analysis of the cause of a nonconformity/risk is carried out by the head of the relevant structural unit together with the employees.

The cause of the occurrence of a nonconformity/risk is discussed at meetings of the QMS Coordination Group in accordance with the monthly reporting procedure.

Based on the analysis, the head of the relevant structural unit determines the correction and corrective actions (Annex A). The correction/corrective actions are communicated to all structural units involved in their implementation, to the official concerned, and to the QMS Manager.

The necessity of correction/corrective measures may be established, in particular:

- due to errors made during the course of a process;
- in the case of an unforeseen risk;
- in the case of errors made in the preparation of documentation;
- in the case of improper management of processes;
- where a nonconformity/risk arises due to insufficient training of personnel;
- as a result of weak control over outsourced (transferred) processes;
- where a risk arises of deviation from regulatory documents (insufficient information/awareness).

The plan of correction/corrective measures is sent to all structural units involved in its implementation, to the official concerned, and to the QMS Manager.

6. Accompanying Documentation

Designation	Title
QMS/M	Quality Manual
ISO 9001	Quality Management System – Requirements

Designation	Title
MI-03	“Internal Audit”
MI-05	“Management of Nonconformity”

7. Approval Sheet

Developer:		Date	Signature
QMS Manager			
Approver:			

Annex “A” – Correction Measures

Form FF-MI-04-A-1

Date: _____

Corrective / Preventive	Measure Category	Description of Nonconformity/Deviation; Description of Risk/Improvement Potential	Cause / Measure	Responsible Person	Completion Deadline	Effectiveness Level