



Quality Management System

I approve the following

LEPL Georgian Technical University

Rector / Chancellor _____

___ . ___ . 2022

Organizational Risks and Opportunities

According to the requirements of ISO 9001 Standard

MI-06

1st publication

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	<p>QMS</p> <p>Organizational Risks and Opportunities</p>	<p>MI-06 Amendment __/__/__</p>
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1. Goal

This Methodical Instruction describes the Actions to identify, assess and eliminate/reduce Organizational Risks to the Quality Management System at the LEPL Georgian Technical University, which are consistent with the goal, strategy of our Organization and determine the possibility of obtaining the established result.

2. Scope

The Instruction is mandatory for the employees of all structural units of the LELP Organization, 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:

MI - Methodical Instruction;

PD – Process description;

QMS Leader - Management Representative in matters of Quality Management;

Mand. - Mandatory;

Part. - Participator.

4. Planning, Actions towards the Risks and Opportunities.

When planning the Quality Management System in the University, the Risks and Opportunities are considered and determined, to address the guarantee that:

- The Quality Management System will give us the expected results;
- Perfects the desired efficiency;
- Will prevent or reduce adverse effects to the Organization;
- Will achieve improvement.

The Risk Management Plan for the Quality Management System (F-MI-06C) describes the process of managing risks posed by internal and external factors of the Organization. The requirements apply to Process Wwners - managers and those personnel who are responsible for planning and implementing risk mitigation measures in their own process.

The main stages of Risk Management are:

- Identification of threats - detection of negative factors of the process according to the occupied position (Mind manager and SWOT analysis can be applied);
- Report on incidents;
- Assessment of negative factors/threats;
- Determining the level of Risk;
- Selection of options/suggestions for Risk mitigation according to the position taken;
- Development of a Risk Mitigation Plan - according to the position held;
- Analysis of the Risk Mitigation Plan - by the Quality Management Coordinating Council;
- Implementation of Risk Mitigation Actions.

When planning Risks and Opportunities, the Organization considers the following:

- Actions aimed at Risks and Opportunities;
- Opportunities to integrate and introduce these actions into the processes of the Organization's Management System;
- To evaluate their effectiveness.

Process Owners determine the level of Risk according to the following classification:

Probability of occurrence (L)	X	Effect/severity (S)
Excluded	1	Insignificant for the Organization and QMS
Will not happen	2	Having slight influence
Possible	3	Reported
Will happen	4	With severe, prolonged influence
Definitely will happen	5	Destructive

The following formula is used for Risk Assessment:

$\text{Risk} = \text{Probability} \times \text{Influence}$
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Risk Management Model

Influence (S) Probability (L)	Insignificant	Having slight effect	Reported	With severe, prolonged influence	Destructive
Excluded	1	2	3	4	5
Will not happen	2	4	6	8	10
May happen	3	6	9	12	15
Will happen	4	8	12	16	20
Definitely will happen	5	10	15	20	25

Evaluated Risk Control and Monitoring

Risk level	Range of risk values	Description
Low	1-8	Actions for Risk Mitigation are not necessary, however, are desirable before the Risk occurs.
Moderate	9-15	Actions for Risk Mitigation are necessary before the Risk occurs The source of financing (if necessary) is defined and recorded in the document All decisions are made and Risk is controlled by process owners
High	16-25	Actions for Risk Mitigation are necessary before the Risk occurs The source of financing (if necessary) is defined and recorded in the document Decisions are made and Risks are controlled by top management

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At the Quality Management Working Group Meeting, a decision is made to reduce the Risk level and agree on Actions for the Risk Mitigation. Organization-Assessed (F-MI-06B) High Risk Mitigation Planning (F-MI-06C) is done in Risk Assessment and Planning Forms.

Threat Analysis and Risk Assessment for the Organizational and Quality Management System:

During the Risk Analysis, all threats in the Organization are identified (F-MI-06A), evaluated (F-MI-06B) and analyzed in detail. At the initial stage, general threats are identified in the value chain:

- Cost and financing structure;
- Potential for success;
- Typical threats;
- Special market threats;
- Threats from the legal/political sphere and others.

Threats modeling and Risk aggregation

Identified threats are systematized as follows:

- Underlying causes;
- Impact results;
- Systematic or non-systematic;
- According to the probability of occurrence.

In accordance with the requirements of the International Risk Management Standard, Risk Management is integrated with the existing Organizational Structure and Management System of the organization. The establishment of a Risk Management System includes the following elements:

- Development of Risk Policy by the Organization
- Identification of the threats
- Risk Assessment
- Limit Setting System
- Risk Reporting Rule
- Competencies and responsibilities in Risk Management
- Risk Management (reduction, prevention, mitigation, insurance) Planning
- Risk Monitoring Plan
- Risk Communication Planning
- Emergency Crisis Plan
- Required documentation.

Examples of General Risks to an Organization include the following:

Staff -

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- Outflow of qualified personnel
- Employment contracts - Risks related to legislation
- Flow of confidential information (know-how).
- Lack of specific competence in the labor market
- Embezzlement, fraud
- Sabotage, blackmail
- Carelessness, indifference
- Indifference, lack of motivation, fatigue
- Corporate culture
- Company pension provision
- Occupational health and safety

Monitoring

- Absence of Monitoring System
- Lack of notification and internal/external Communication System
- Insufficient physical security measures
- Weak control of the company, its entrance, territory.

Maintenance of equipment and systems

- Malfunctioning equipment and delivery systems
- Absence of Preventive Maintenance Program
- Electricity, lack of control of the grounding circuit of electrical equipment
- Failure of gas, water, heating and air conditioning systems
- Failure of supply systems - absence of alternative systems
- Absence of service instructions for technical systems.

Building-related risks

- Location, construction
- Inability to get help when needed
- Technical defects in building protection

Risks of responsibilities, relationships

- Absence of clearly established responsibilities
- Absence of internal/external communication system
- Absence of rules of relations with contractors

Risks of the organization

- Strategic risks

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- Investment Risks
- Risks of mismanagement or poor management of resources
- Operational Risks
- Natural threats - tornado, flood, hail, earthquake, landslide
- Risks related to project management (overdue, cost overruns, incomplete contracts, ineffective change management, insufficient communication)
- Organizational Risks - lack of Crisis Management, software inefficiency
- Inefficient management of environmental problems.

Market Risks -

At the Organization level

- Company image
- Organizational ethics
- Patents and trademarks, copyright, right to equal competition
- Tax risks - additions, incorrect assessments
- Economic downturn.

Legal risks -

- Changes in laws
- Agreements (rent, lease, construction, etc.)
- Labor contracts
- Normative acts of the right to participate in activities
- Agreements with suppliers and customers
- Liability in case of property damage
- Product/system/project responsibility
- Insurance contracts
- Anti-corruption policy
- Tax and economic laws
- Environmental protection, labor inspection requirements.

Management risks -

- The strategic direction is not optimal
- Leadership mistakes - wrong delegation
- Centralist style in leadership
- Lack of coordination
- Absence of planning and control (non-consolidated balance sheet, incomplete planning, deficiencies in investment implementation)
- Inability to make decisions

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- Inadequate hierarchical structure
- High employee turnover rate

5. Quality Management goals and planning Actions for their implementation

For important functions, levels and processes, our Organization has established Quality Management Objectives in the form of a document, which includes Risk Reduction Actions based on the principle: “evidence-based decisions”.

Goals:

- It is permanent for our Quality Management Policy
- It is measurable and considers the established requirements
- Aimed at improving compliance with product/project and service requirements and customer satisfaction
- It can be monitored and updated as needed
- Quality Objectives are communicated by staff.

When planning Quality Management Objectives (F-MI-07A), we consider the following:

- What should be done
- What resources will be needed for this?
- Who will be the responsible person?
- When will it end?
- How will the results be evaluated?

Quality Management Goals are planned annually (form), please refer to F-MI-07A.

Risk Reduction Actions are often included in the Quality Objectives Planning Program document, especially in the case of high-level risk that requires investment.

6. Supporting documents

Item	Title
ISO 9001	Quality Management System
MI-07	Organization context, internal and external factors
MI-02	Documented evidence management
MI-03	Internal Audit

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MI-04	Correction and Corrective Actions
MI-05	Non-compliances management
QMS/P	Quality Management Policy
QMS/O	Quality Goals – Strategic Plan
F-MI-01A-01	External documented information list
F-MI-01B-01	Internal documented information list
F-MI-02A-01	Documented evidence list
MR	Management Review

7. Agreement Sheet

Developed by:	Date	Signature
QMS Leader		
Agreed:		



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Annex A

F-MI-06B-01

Risks and Opportunities – Organization Risks Assessment Form

N	Description of threat	Risk Owner	Risk Assessment			Acceptable /Unacceptable Risk	Risk probability	Resources needed
			Probability (1-2-3-4-5)	Influence (1-2-3-4-5)	Risk level (1-25)			

Developed by:

Approved by:

Process Owner _____

Rector _____

Date: __/__/____

Date: __/__/____



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Annex B

F-MI-06C-01

Risk reduction/mitigation Emergency Crisis Plan

N	Risk and its level	Planned Activity/Action	Responsible		Mitigation deadline	Criteria to check the Actions	Resources needed	Smart indicator of the Risk	Remark upon implementation
			Implementation	Control					

Developed by

Process Owner _____

Date: __/__/____