QMS

Organizational Risks and Opportunities

MI-06 | Revision __/__

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1. Purpose

This methodological instruction describes the measures for identifying and assessing organizational risks relating to the quality management system of the LEPL "Georgian Technical University", and for eliminating/reducing them, which correspond to our organization's mission and strategy and determine the ability to achieve the established result.

2. Scope

This methodological instruction is mandatory for all structural units of the organization that fall within the scope of the QMS.

3. Terms and Abbreviations Used

The terms and definitions used in this methodological instruction correspond to the terms and definitions given in the ISO 9001 standard, as well as:

The following specific abbreviations are used in this methodological instruction:

MI – Methodological Instruction;

PD – Process Description;

QMS Leader – representative in the field of quality management;

Mand. (სავ) – Mandatory;

Part. (მონაწ) – Participant.

4. Planning; Actions Addressing Risks and Opportunities

When planning the quality management system, the University takes into account and determines the risks and opportunities aimed at providing assurance that:

- the quality management system will deliver the expected results;
- it enhances the desired effectiveness;
- it will prevent, or reduce, undesired effects on the organization;
- it will achieve improvement.

The risk management plan for the quality management system (F-MI-06C) describes the risk management process carried out in response to the organization's internal and external factors. The requirements apply to process owners – managers – and to the personnel who are responsible for planning and implementing risk elimination measures in their own processes.

The main stages of risk management are:

- Hazard identification – detection of negative factors of the process according to the position held (a mind map and SWOT analysis may be used);
- Report on incidents that have occurred;
- Assessment of negative factors/hazards;
- Determination of the risk level;
- Selection of options/proposals for eliminating risks according to the position held;
- Development of a risk elimination plan – according to the position held;
- Analysis of the risk elimination plan – by the Quality Management Coordination Council;
- Implementation of risk elimination measures.

When planning risks and opportunities, the organization takes into account:

- measures addressing risks and opportunities;
- the possibilities for integrating and implementing these actions in the processes of the organization's management system;
- evaluation of their effectiveness.

Process owners determine the risk level according to the following classification.

Probability of occurrence (L)	X	Impact/Severity (S)
Excluded	1	Insignificant for the organization and the QMS
Will not happen	2	Having minor impact
Possible	3	Reported
Will happen	4	Serious, long-term impact

Probability of occurrence (L)	X	Impact/Severity (S)
Inevitably	5	Devastating

The following formula is used for risk assessment:

RISK = PROBABILITY × IMPACT

Risk Management Model

Probability (L) \ Impact (S)	Insignificant	Minor impact	Reported	Serious, long-term impact	Devastating
Excluded	1	2	3	4	5
Will not happen	2	4	6	8	10
Possible to happen	3	6	9	12	15
Will happen	4	8	12	16	20
Will inevitably happen	5	10	15	20	25

Control and Monitoring of the Assessed Risk

Risk level	Range of risk values	Description
Low	1–8	• Risk elimination measures are not mandatory, but are desirable before the risk occurs.
Medium	9–15	• Risk elimination measures are mandatory before the risk occurs • The funding source (if needed) is determined and recorded in a document • All decisions are made, and the risk is controlled, by process owners
High	16–25	• Risk elimination measures are mandatory before the risk occurs • The funding source (if needed) is determined and recorded in a document • The decision is made, and risks are controlled, by top management

At the meeting of the quality management working group, a decision is made on reducing the risk level and the risk elimination measures are agreed. Planning (F-MI-06C) of the measures for reducing the high risks assessed by the organization (F-MI-06B) is carried out in the risk assessment and planning forms.

Hazard Analysis and Risk Assessment with Respect to the Organization and the Quality Management System:

When carrying out risk analysis, all hazards existing in the organization are identified (F-MI-06A), assessed (F-MI-06B) and analyzed in detail. At the initial stage, general hazards are identified within the value chain:

- cost and financing structure;
- potential for success;
- typical hazards;
- specific market hazards;
- hazards from the legal/political sphere, and others.

Hazard Modeling and Risk Aggregation

The identified hazards are systematized according to:

- causes;
- consequences of impact;
- systematic or non-systematic nature;
- probability of occurrence.

In accordance with the requirements of the international risk management standard, risk management is integrated with the organizational structure and management system already existing in the organization. The establishment of a risk management system implies the following elements:

- development of a risk policy by the organization
- identification of hazards
- assessment of risks
- a limit-setting system
- rules for risk reporting
- competencies and responsibilities in risk management
- planning of risk overcoming (reduction, prevention, elimination, insurance)
- a risk monitoring plan
- planning of risk communication
- a plan for emergency crisis situations
- necessary documentation.

Examples of the organization's general risks:

<u>Personnel –</u>

- Outflow of qualified personnel
- Employment contracts – risks related to legislation
- Leakage of confidential information (know-how)

- Shortage of specific competence on the labor market
- Embezzlement, fraud
- Sabotage, blackmail
- Negligence, indifference
- Indifference, demotivation, fatigue
- Corporate culture
- Company pension provision
- Occupational health and safety

Monitoring

- Absence of a monitoring system
- Absence of a notification and internal/external communication system
- Insufficient physical security measures
- Weak control of the company, its entrances and its territory.

Technical provision of equipment and systems

- Technically faulty equipment and supply systems
- Absence of a preventive maintenance program
- Absence of control of electricity and of the earthing circuit of electrical equipment
- Malfunction of gas, water, and heating-air-conditioning systems
- Failure of supply systems – absence of alternative systems
- Absence of maintenance instructions for technical systems.

Building risks

- Location, construction
- Impossibility of receiving assistance in case of need
- Technical defects in the protection of the building

Risks of responsibilities, relationships

- Absence of clearly defined responsibilities
- Absence of an internal/external communication system
- Absence of rules for relations with contractors

Organization's risks –

- Strategic risks
- Investment risks
- Risks of incorrect or weak resource management
- Operational risks

- Natural hazards – hurricane, flood, hail, earthquake, landslide
- Risks related to project management (missed deadlines, cost overruns, incomplete contracts, ineffective change management, insufficient communication)
- Organizational risks – absence of crisis management, ineffectiveness of software
- Ineffective management of ecological problems.

Market risks –

At the organization level

- Company image
- Organizational ethics
- Patents and trademarks, copyright, the right to equal competition
- Risks arising from taxes – surcharges, incorrect assessments
- Economic decline.

Legal risks –

- Changes in laws
- Contracts (rent, lease, construction, etc.)
- Employment contracts
- Normative acts on the right to participate in activities
- Contracts with suppliers and clients
- Liability in case of property damage
- Liability for product/system/project
- Insurance contracts
- Anti-corruption policy
- Tax and economic laws
- Requirements of environmental protection and the labor inspectorate.

Management risks –

- Strategic direction is not optimal
- Management errors – incorrect delegation
- Centralist management style
- Coordination deficit
- Absence of planning and control (unconsolidated balance, deficient planning, shortcomings in investment implementation)
- Inability to make decisions
- Inadequate hierarchical structure
- High staff turnover rate

5. Quality Management Objectives and Planning of Measures to Achieve Them

For significant functions, levels and processes, our organization has established quality management objectives in documented form, which include risk-reduction measures, on the principle of "evidence-based decision-making".

The objectives:

- are consistent with our quality management policy
- are measurable and take into account the established requirements
- are aimed at conformity with product/project and service requirements and at improving customer satisfaction
- can be monitored and updated as necessary
- are communicated to personnel.

When planning the quality management objectives (F-MI-07A), we take into account:

- what is to be done
- what resources will be needed for this
- who will be the responsible person
- when it will be completed
- how the results will be evaluated.

The planning of quality management objectives is carried out annually (form) – see F-MI-07A. Risk-reduction measures often end up in the quality objectives planning program document, especially in the case of a high-level risk that requires investment.

6. Accompanying Documented Information

Designation	Title
ISO 9001	Quality Management System
MI-07	Organizational Context, Internal and External Factors
MI-02	Control of Documented Evidence
MI-03	Internal Audit
MI-04	Correction and Corrective Actions
MI-05	Management of Nonconformity
QMS/P	Quality Management Policy
QMS/O	Quality Objectives – Strategic Plan
F-MI-01A-01	List of External Documented Information
F-MI-01B-01	List of Internal Documented Information

Designation	Title
F-MI-02A-01	List of Documented Evidence
MR	Management Review

7. Approval Sheet

Developer	Date	Signature
QMS Leader		
Agreed		

Annex “A” – Form F-MI-06B-01

Risks and Opportunities – Organization Risk Assessment Form

No.	Description of Hazard	Risk Owner	Risk Assessment: Probability (1-2-3-4-5)	Impact (1-2-3-4-5)	Risk Level (1-25)	Acceptable / Unacceptable Risk	Risk Opportunity	Required Resources

In the source form, “Risk Assessment” is a merged header spanning the Probability, Impact and Risk Level columns.

Prepared by:

Process owner _____

Date: ___/___/_____

Approved by:

Rector _____

Date: ___/___/_____

Annex “B” – Form F-MI-06C-01

Plan of Emergency Crisis Measures for Risk Mitigation/Elimination

No.	Risk and Its Level	Planned Activity / Measure	Responsible: Implementation	Responsible: Control	Elimination Deadline	Criteria for Verifying the Measure	Required Resource	Risk SMART Indicator / Note on Implementation

In the source form, “Responsible” is a merged header over “Implementation” and “Control”; the last two headers are “Risk SMART indicator” and “Note on implementation”, shown here as one column.

Prepared by:

Process owner _____

Date: ___/___/_____