[Organization logo]

[Organization name]

QUALITY MANUAL

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1. About the organization

1.1. Organizational structure

![Organizational chart]

Figure 1: Organizational chart

2. Purpose, scope and users

The Quality Manual documents the management system of [organization name] and demonstrates the capability of [organization name] to continuously provide products and services that address customer requirements.

2.1. Exclusions

[Organization name] excludes the following clauses of ISO 9001:2015:

- 

Exclusions do not affect the organization’s ability to address customer requirements and appropriate legal and regulatory requirements.

3. Terms and definitions


The latest revision of this document applies.

4. Context of the organization
4.1. Understanding the organization and its context

[Organization name] understands the context of the organization according to the Procedure for Determining the Context and Interested Parties.

4.2. Understanding the needs and expectations of interested parties

[Organization name] has determined the needs and expectations of interested parties and their needs and expectations according to the Procedure for Determining the Context and Interested Parties and listed them in the List of Interested Parties.

4.3. Determining the scope of the Quality Management System

[Organization name] has determined the boundaries and applicability of the Quality Management System in the Scope of Quality Management System.

4.4. Quality Management System and its processes

[Organization name] has established and implemented the QMS, which is maintained and continually improved according to the requirements of the ISO 9001:2015 standard including processes, their interconnections and interactions.

[organization name] determined the processes needed for the QMS and their application through the organization.

[Organization name] determined required inputs and desired outputs of the processes, criteria and methods needed for effective operation and control of these processes, as well as resources needed and responsibilities and authorities for processes in the Quality Management System and interactions between the processes are described in Figure 2: Process Map.

During management review, top management of [organization name] evaluates processes and makes changes needed in order to ensure that the processes achieve intended results and improve processes and the QMS.
5. Leadership

5.1. Leadership and commitment

5.1.1. General

The top management of [organization name] is taking accountability for the effectiveness of the QMS and providing resources to ensure that the Quality Policy and Quality Objectives are compatible with the strategic direction and the context of the organization.

The top management ensures that QMS requirements are integrated into [organization name]'s business processes, and that the QMS is achieving the intended results.

The top management communicates the importance of an effective QMS, promotes continual improvement, a process approach, and risk-based thinking, and supports relevant management roles to demonstrate leadership to their areas of responsibility.

5.1.2. Customer focus

The top management of [organization name] demonstrates leadership and commitment with respect to customer focus through ensuring:
that customer and statutory and regulatory requirements are defined, understood, and
consistently met
the risks and opportunities that can affect conformity of products and services and the ability
to enhance customer satisfaction are determined and addressed
the focus on enhancing customer satisfaction is maintained

5.2. Quality Policy
[Organization name] has defined the Quality Policy as a separate document and made it available to
employees and the public.

The Policy represents the framework for planning and improving the QMS, and setting general and
specific quality objectives.

5.3. Organizational roles and responsibilities
Responsibilities and authorities for relevant roles are assigned by the top management and
communicated within the organization. The top management assigns roles and responsibilities
for ensuring that the QM relates to the business processes and reporting on the performance of the QM,
including the QMS performance, to the top management.

6. Planning

6.1. Actions to address risks and opportunities
While planning the QMS, [organization name] considers the context of the organization, needs and
interests of relevant parties, and the scope of the QMS.

[organization name] determines risks and opportunities related to the ability to give assurance that
the QMS can achieve intended results, achieve declared results, prevent or reduce undesired
effects, be compatible with the context of the organization, and can achieve continual improvement.

Risks and opportunities related to the QMS are addressed according to the Procedure for Addressing
Risks and Opportunities.

6.2. Quality objectives and planning to achieve them
[job title] continuously defines measurable and timed quality objectives for the relevant functions
and levels within the organization. The objectives are monitored by [job title] in the context of
monitoring and measurement and management review.

Quality objectives are consistent with the Quality Policy and prescribed to all levels and functions in
[organization name], taking into account applicable requirements, relevance to conformity of
products and services, and enhancement of customer satisfaction.

The plans for achieving the objective are made for each defined quality objective.
realization of the objectives are defined and documented in the **Quality Objectives**. Realization of these plans is regularly measured by the job title in order to maintain qualification and include new or modified situations, or at least during regular management review.

### 6.3. Planning changes

When the organization determines a need for changes to the Quality Management System, [job title] takes responsibility to carry them out in a planned manner.

[job title] plans changes to the QMS considering the purpose of the changes and potential consequences, integrity of the QMS, and allocation or reallocation of responsibilities and authorities.

### 7. Resources

#### 7.1. Resources

[organization name] determines maintenance, and continual improvement of the Quality Management System.

#### 7.2. Competence

[Organization name] disposes the necessary staff with the needed knowledge and skills, and provides resources needed for establishment, implementation, maintenance, and improvement of the QMS.

In cases where it is deemed necessary and justified, [organization name] will hire competent external personnel and organizations for realization of activities for which the organization does not have adequate resources.

Managers are responsible for identifying the needs and conducting professional training of their staff to carry out the duties that have a significant impact on the quality of products, service and customer satisfaction.

Each organizational part manager /process owner is responsible for the suitable competency of his workteam, on the basis of education, training, and/or work experience, in accordance with the requirements of their work.

The method of ensuring the necessary competencies for roles, responsibilities, and authorities for competence is set from the situation that is established in accordance with the

**Competence, Training and Awareness Procedure**. Records of completed training and training effectiveness are kept by the management representative.

#### 7.3. Awareness

[organization name] ensures that persons doing work under its control are aware of the Quality Policy, relevant quality objectives, their contribution to the effectiveness of the QMS, and importance of non-conformance with its QMS.
7.4. Communication

[job title] is responsible for determining internal and external communications relevant to the QMS, including subject, timing, method of communication, as well as who and with whom to communicate.

7.5. Documented information

Documented information of the Quality Management System is carried out through the following documents:

- Quality Policy, Quality Objectives
- Quality Manual
- Procedure for Document and Record Control
- Documents, including records, required by ISO 9001, are given in the List of Internal Documents
- Documents, including records, which organization cannot be determined to be necessary, are given in the List of Internal Documents

8. Operation

8.1. Organizational planning and control

[job title] is responsible for planning and developing processes needed for product realization according to the Procedure for Production and Service Provision.

8.2. Requirements for products and services

Communication with customers, the process of determining and reviewing the requirements related to product and services, and changes to requirements for product and services are defined in the Sales Procedure.

8.3. Design and development of products and services

[job title] represents persons responsible for planning, realization, and management of product design and development and project management according to the Procedure for Design and Development.

8.4. Control of externally provided processes, products and services

By documenting an adequate method for evaluation and selection of suppliers, [organization name] ensures that delivered product is compliant with specified purchasing requests according to the Procedure for Purchasing and Evaluation of Suppliers.

8.5. Production and service provision

[Organization name] defines activities of planning and executing the product realization process under controlled conditions, in order to ensure full capability of the process and to meet...
nonconformity assurance. At the same time, all necessary resources for execution of these
processes are provided according to the Procedure for Production and Service Provision and
Warehousing Procedure.

8.6. Release of products and services

The organization has implemented adequate arrangements at appropriate stages to verify that the
product and service requirements are met, according to the Procedure for Production and Service
Provision.

8.7. Control of nonconforming outputs

The organization ensures that outputs that do not conform to their requirements are identified and
controlled to prevent their unintended use or delivery, according to the Procedure for Management
of Nonconformities and Corrective Actions.

9. Performance evaluation

9.1. Monitoring, measurement, analysis and evaluation

9.1.1. General

[Top-level management] and process owners in [organization name] define what will be monitored
and measured, as well as the methods and timing for monitoring and measuring. Results of the
monitoring and measuring will be evaluated at appropriate levels and functions in the organization
and the top-level management will evaluate the performance of the QMS during the management
review.

9.1.2. Customer satisfaction

[Organization name] analyzes and evaluates appropriate data and information arising from
monitoring and measurement.

The results of the analysis are used to evaluate:

- conformity of products and services;
- the degree of customer satisfaction;
- the performance and effectiveness of the Quality Management System;
- if planning has been implemented effectively;
- the effectiveness of actions taken to address risks and opportunities;
- the performance of service providers;
- the need for improvements to the Quality Management System.
9.2. **Internal audit**

The organization conducts internal audits at planned intervals to demonstrate the conformity and effectiveness of the Quality Management System according to the *Procedure for Internal Audit*.

9.3. **Management review**

[Top-level management] of [organization name] conducts regular reviews of the QMS at least once a year, according to the *Procedure for Management Review*.

10. **Improvement**

10.1. **General**

[organization name] determines and selects opportunities for improvement and implements any

These include:

- improving products and services to meet requirements, as well as to address future needs
- preventing, detecting, or reducing customer dissatisfaction
- improving the performance and effectiveness of the Quality Management System.

10.2. **Nonconformity and corrective action**

The organization identifies, investigates, and documents nonconformities in order to control and correct them and deal with their consequences, according to the *Procedure for Management of Nonconformities and Corrective Action*.

[Organization name] has established a corrective action system to investigate and document the root cause and actions to correct supplier, internal, and customer reported nonconformities. Corrective actions are assigned to a single individual and tracked by number and completion date, according to the *Procedure for Management of Nonconformities and Corrective Action*.

10.3. **Continual improvement**

[Organization name] continually improves the suitability, adequacy, and effectiveness of the Quality Management System.

The organization considers the results of analysis and evaluation, and the outputs from management reviews, to determine if there are needs or opportunities to be addressed as part of continual improvement.