

[Organization logo]

[Organization name]

QUALITY MANUAL

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Commented [9A2]: If you want to find out more about the role of the Quality Manual in the new version of the standard, see

- article: The future of the Quality Manual in ISO 9001:2015 <http://advisera.com/9001academy/knowledgebase/the-future-of-the-quality-manual-in-iso-90012015/>
- free online course: ISO 9001 Foundations Course <http://training.advisera.com/course/iso-90012015-foundations-course/>

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1. About the organization

1.1. Organizational structure

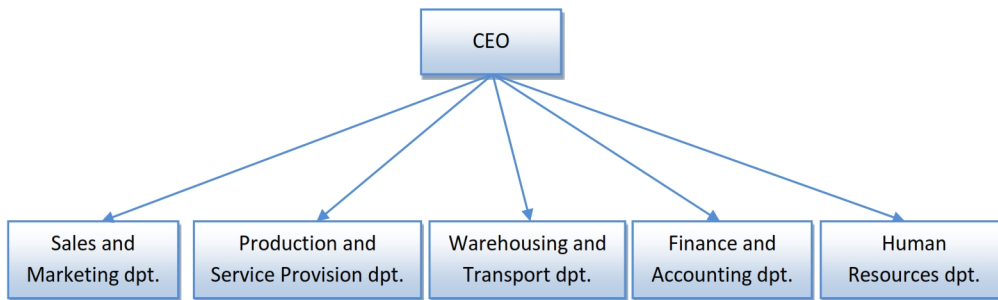


Figure 1: Organizational chart

Commented [9A5]: Adapt to organization's needs.

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.

Commented [9A6]: If Quality Management System is applied only to part of organization, name that part of organization.

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.

Commented [9A7]: Exclusions can be made only from clause 8 of the ISO 9001:2015 standard. Name the clauses excluded from QMS and provide justifications for exclusions.

3. Terms and definitions

For the purpose of this Quality Manual, [organization name] references the terms and definitions listed in the ISO 9000:2015 "Quality Management Systems Fundamentals and Vocabulary" document.

The latest revision of this document applies.

4. Context of the organization

4.1. Understanding the organization and its context

[organization name]

[Organization name] considers 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 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 needed and their interactions.

[organization name] determined the

[Organization name] determined required as well as resources needed and responsibilities and authorities for processes in the **Quality Plan**. Sequences and interactions between the processes are described in Figure 2: Process Map.

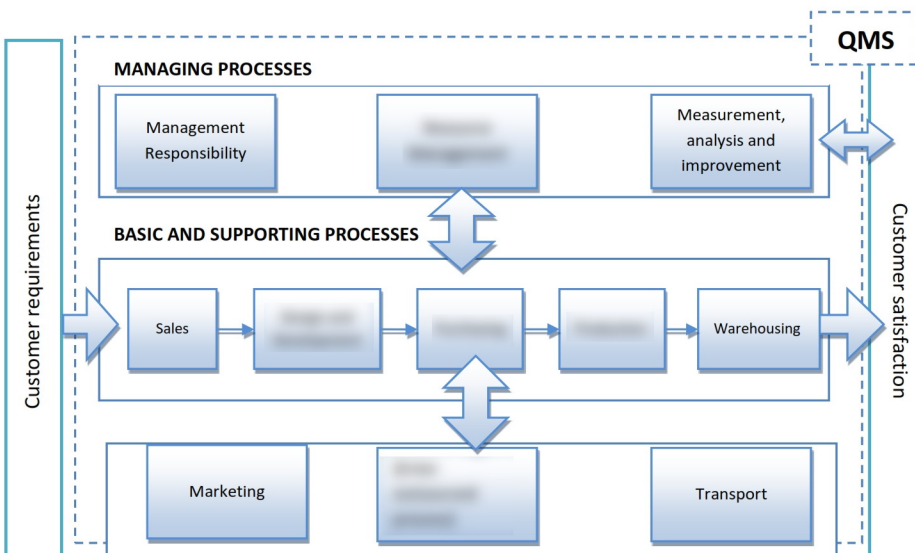


Figure 2: Process Map

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

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

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
- [redacted]
- [redacted]

5.2. Quality Policy

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

This Policy represents [redacted]

5.3. Organizational roles and responsibilities

Responsibilities and authorities for relevant roles are assigned by the top management and communicated within [organization name]. The top management assigns roles and

[redacted]

6. Planning

6.1. Actions to address risks and opportunities

While planning the QMS, [organization name] considers the context of the organization, needs and expectations of interested parties, and the scope of the QMS.

[organization name] determines risks and opportunities related to the QMS to plan actions to address them. The QMS is planned to address risks and opportunities, taking into account the context of the organization, and the needs and expectations of interested parties.

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 defined with the Quality Policy and are measurable, aligned with the strategic direction, and consistent with the context of the organization, and the needs and expectations of interested parties.

The plans for achieving the objective are made for each defined quality objective.

Activities in the plans include quality objectives, responsibilities, resources, and measures to be taken to ensure the achievement of the objectives in the Quality Management System. The plans include measures to monitor and measure the performance of the Quality Management System, and to ensure the achievement of the objectives in the Quality Management System.

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 context of the organization, and the needs and expectations of interested parties, and the scope of the QMS, and the risks and opportunities of the organization.

7. Resources

7.1. Resources

[organization name] determines and provides resources needed for establishment, implementation, maintenance, and continual improvement of the Quality Management System.

7.2. Competence

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

Sales Procedure.

8.3. Design and development of products and services

Development.

Procedure for Design and

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

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

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

[organization name]

[top-level management] and process owners in [organization name] define what will be monitored, measured, and reported to management and customers. The monitoring and measuring will be conducted in accordance with the responsibilities and the top management will ensure the effectiveness of the QMS using the management system.

9.1.2. Customer satisfaction

[Organization name] monitors customers' perceptions of the degree to which their needs and expectations have been fulfilled according to the **Procedure for Measuring Customer Satisfaction**.

9.1.3. Analysis and evaluation

[Organization name] analyzes customer satisfaction data and information using the monitoring and measuring.

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;
- the effectiveness of customer satisfaction data and information;
- the effectiveness of customer satisfaction data and information;
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9.2. Internal audit

[Organization name] conducts internal audits at planned intervals to demonstrate conformance 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 necessary actions to meet customer requirements and enhance customer satisfaction.

These include:

- [organization name] determines and selects opportunities for improvement, in order to enhance customer satisfaction and effectiveness.
- [organization name] determines and selects opportunities for improvement, in order to enhance customer satisfaction and effectiveness.

[organization name]

- improving the performance and effectiveness of the Quality Management System.

10.2. Nonconformity and corrective action

[Organization name] [redacted] according to the **Procedure for Management of Nonconformities and Corrective Action**.

[Organization name] [redacted] Corrective actions are assigned to a responsible 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 [redacted] the Quality Management System.

The organization considers the results of [redacted] [redacted] [redacted]