

[Organization logo]

[Organization name]

Commented [16A1]: All fields in this document marked by square brackets [] must be filled in.

QUALITY MANUAL

Commented [16A2]: If you want to find out more about the Quality Manual, see:

How to write the IATF 16949 Quality Manual
<https://advisera.com/16949academy/blog/2017/05/31/how-to-write-the-iatf-16949-quality-manual/>

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1. About the organization

1.1. Organizational structure

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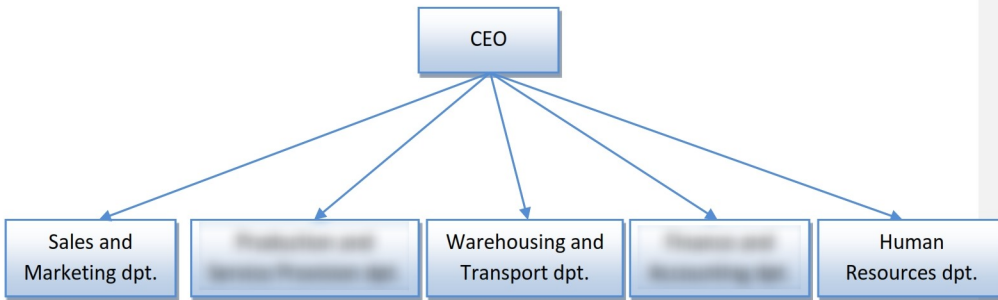


Figure 1: Organizational chart

2. Purpose, scope and users

The Quality Manual documents the management system of [organization name] and demonstrates

Commented [16A6]: 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 IATF 16949:2016:

- [List exclusions]

Commented [AT7]: Exclusions can be made from clause 8 of the IATF 16949:2016 standard related to product design only if the organization is not responsible for it (e.g., product design is performed by the customer). Name the clauses excluded from the QMS and provide justifications for exclusions.

3. Terms and definitions

For the purpose of this Quality Manual, [organization name] references the 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]

[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**.

[Job title] ensures that all supporting functions, whether onsite or remote, are included in the scope of the QMS. Customer specific requirements are considered to get this included in the scope of the QMS.

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 and customer specific requirements, including processes needed and their 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 Plan**. Sequences and interactions between the processes are described in Figure 2: Process Map.

[Organization name] has documented processes according to the management of product quality during product and process development, production, and purchasing in **Procedure for FMEA Risk Assessment**. During management review, top management of [organization name] evaluates the processes and checks the changes needed to make the system better. The processes include the standard quality, and improve the processes and the QMS. In addition, top management reviews interested parties, their requirements, and identifies necessary to address them.

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Commented [16A8]: For example, the document called Product Specification.

[organization name]

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 address 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 supports 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 across organizational levels. The top management assigns roles and responsibilities for ensuring that the QMS conforms to ISO 9001:2015 and reporting on the performance of the QMS, 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 expectations of interested parties, and the scope of the QMS.

[organization name] determines risks and opportunities related to the ability to give assurance that the QMS can address intended results, enhance desirable results, prevent or reduce undesired effects, is compatible with the context of the organization, and an efficient use of resources.

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

Contingency Plans are developed and documented 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 to give input to the context of planning and measurement and management review.

[organization name]

[Job title] is responsible for managing internal and external laboratories according to the **Laboratory Management Procedure**.

[Organization name] ensures the necessary knowledge resources for the operation of its processes and its control conformity objectives.

The knowledge is maintained and available to the employees as necessary.

7.2. Competence

[Organization name] disposes the necessary staff with the needed knowledge and skills, professional experience, and theoretical resources for establishing, implementing, maintaining and improvement of the QMS.

In cases where it is deemed necessary and justified, [organization name] will hire competent external resources and agreements that address QMS for resolution of activities for which the organization does not have adequate resources.

Managers are responsible for identifying the needs and conducting professional training of employees who carry out activities that may have a significant impact on the quality of product, service and customer satisfaction.

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

The method of ensuring the necessary competencies for roles, responsibilities, and activities for implementation and control activities within the QMS was 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 implications of nonconformance with the QMS requirements.

7.4. Communication

[Organization name] 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 will communicate.

7.5. Documented information

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

- Quality Policy, Quality Objectives

[organization name]

The maintenance process and related measurement system for maintenance effectiveness are defined in the **Procedure for Equipment Maintenance and Measuring Equipment**.

8.6. Release of products and services

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

Appearance items are subjected to inspection, measuring and testing, according to activities defined in **Production Part Approval Process Procedure**.

8.7. Control of nonconforming outputs

The organization ensures that outputs that do not conform to their requirements are identified and **controlled** 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] 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

The organization uses statistical methods and statistical approaches, data and information using their 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;
- conformity to legal requirements and standards;
- the effectiveness of actions taken to address risks and opportunities;

[organization name]

- the performance of external providers;
- the need for improvements to the Quality Management System.

Actions are prioritized based on progress to achieve objectives and trends.

9.2. Internal audit

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

These include:

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

10.2. Nonconformity and corrective action

[Organization name] handles nonconformities in order to control and correct them and deal with the 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 quality, delivery, and customer service nonconformities. Corrective actions are subject to a responsible individual and reported to senior and customer care according to the *Procedure for Management of Nonconformities and Corrective Action*.

The 8D problem-solving method and related tools are used systematically for solving customer claims and internal problems, and documented in the *Problem Solving 8D Template*.

10.3. Continual improvement

[Organization name] continually improves the capability, efficiency, and effectiveness of the Quality Management System.

[organization name]

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