
Quality management systems —

**Particular requirements for the application
of ISO 9001:2008 for automotive production
and relevant service part organizations**

Systèmes de management de la qualité —

*Exigences particulières pour l'application de l'ISO 9001:2008 pour la
production de série et de pièces de rechange dans l'industrie automobile*

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NOTE In this table of contents, ISO 9001:2008 headings are normal type face, IATF headings are in italics.

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In other circumstances, particularly when there is an urgent market requirement for such documents, a technical committee may decide to publish other types of normative document:

- an ISO Publicly Available Specification (ISO/PAS) represents an agreement between technical experts in an ISO working group and is accepted for publication if it is approved by more than 50 % of the members of the parent committee casting a vote;
- an ISO Technical Specification (ISO/TS) represents an agreement between the members of a technical committee and is accepted for publication if it is approved by 2/3 of the members of the committee casting a vote.

ISO/TS 16949 was prepared by the International Automotive Task Force (IATF), with support from ISO/TC 176, *Quality management and quality assurance*.

This third edition of ISO/TS 16949 cancels and replaces the second edition (ISO/TS 16949:2002), which has been technically amended according to ISO 9001:2008.

Boxed text is original ISO 9001:2008 text. The sector-specific supplemental requirements are outside the boxes.

In this Technical Specification, the word “shall” indicates a requirement. The word “should” indicates a recommendation. Paragraphs marked “NOTE” are for guidance in understanding or clarifying the associated requirement.

Where the term “such as” is used, any suggestions given are for guidance only.

Annex A forms a normative part of this Technical Specification.

Remarks for certification

The certification to this Technical Specification, including customer-specific requirements if any, is recognized by the customer members of IATF when achieved according to the IATF certification scheme (see the “Rules for achieving IATF recognition”).

Details can be obtained at the addresses of the local oversight offices of IATF cited below:

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IATF-France

Web site: www.iatf-france.com e-mail: iatf@iatf-france.com

Society of Motor Manufacturers and Traders Ltd. (SMMT Ltd.)

Web site: www.smmt.co.uk e-mail: quality@smmt.co.uk

Verband der Automobilindustrie Qualitätsmanagement Center (VDA-QMC)

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Introduction

0.1 General

ISO 9001:2008, Quality management systems — Requirements

Introduction

0.1 General

The adoption of a quality management system should be a strategic decision of an organization. The design and implementation of an organization's quality management system is influenced by

- a) its organizational environment, changes in that environment, and the risks associated with that environment,
- b) its varying needs,
- c) its particular objectives,
- d) the products it provides,
- e) the processes it employs,
- f) its size and organizational structure.

It is not the intent of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.

The quality management system requirements specified in this International Standard are complementary to requirements for products. Information marked "NOTE" is for guidance in understanding or clarifying the associated requirement.

This International Standard can be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer, statutory and regulatory requirements applicable to the product, and the organization's own requirements.

The quality management principles stated in ISO 9000 and ISO 9004 have been taken into consideration during the development of this International Standard.

0.2 Process approach

ISO 9001:2008, Quality management systems — Requirements

0.2 Process approach

This International Standard promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements.

For an organization to function effectively, it has to determine and manage numerous linked activities. An activity or set of activities using resources, and managed in order to enable the transformation of inputs into outputs, can be considered as a process. Often the output from one process directly forms the input to the next.

The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management to produce the desired outcome, can be referred to as the “process approach”.

An advantage of the process approach is the ongoing control that it provides over the linkage between the individual processes within the system of processes, as well as over their combination and interaction.

When used within a quality management system, such an approach emphasizes the importance of

- a) understanding and meeting requirements,
- b) the need to consider processes in terms of added value,
- c) obtaining results of process performance and effectiveness, and
- d) continual improvement of processes based on objective measurement.

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The model of a process-based quality management system shown in Figure 1 illustrates the process linkages presented in Clauses 4 to 8. This illustration shows that customers play a significant role in defining requirements as inputs. Monitoring of customer satisfaction requires the evaluation of information relating to customer perception as to whether the organization has met the customer requirements. The model shown in Figure 1 covers all the requirements of this International Standard, but does not show processes at a detailed level.

NOTE In addition, the methodology known as “Plan-Do-Check-Act” (PDCA) can be applied to all processes. PDCA can be briefly described as follows.

Plan: establish the objectives and processes necessary to deliver results in accordance with customer requirements and the organization's policies.

Do: implement the processes.

Check: monitor and measure processes and product against policies, objectives and requirements for the product and report the results.

Act: take actions to continually improve process performance.

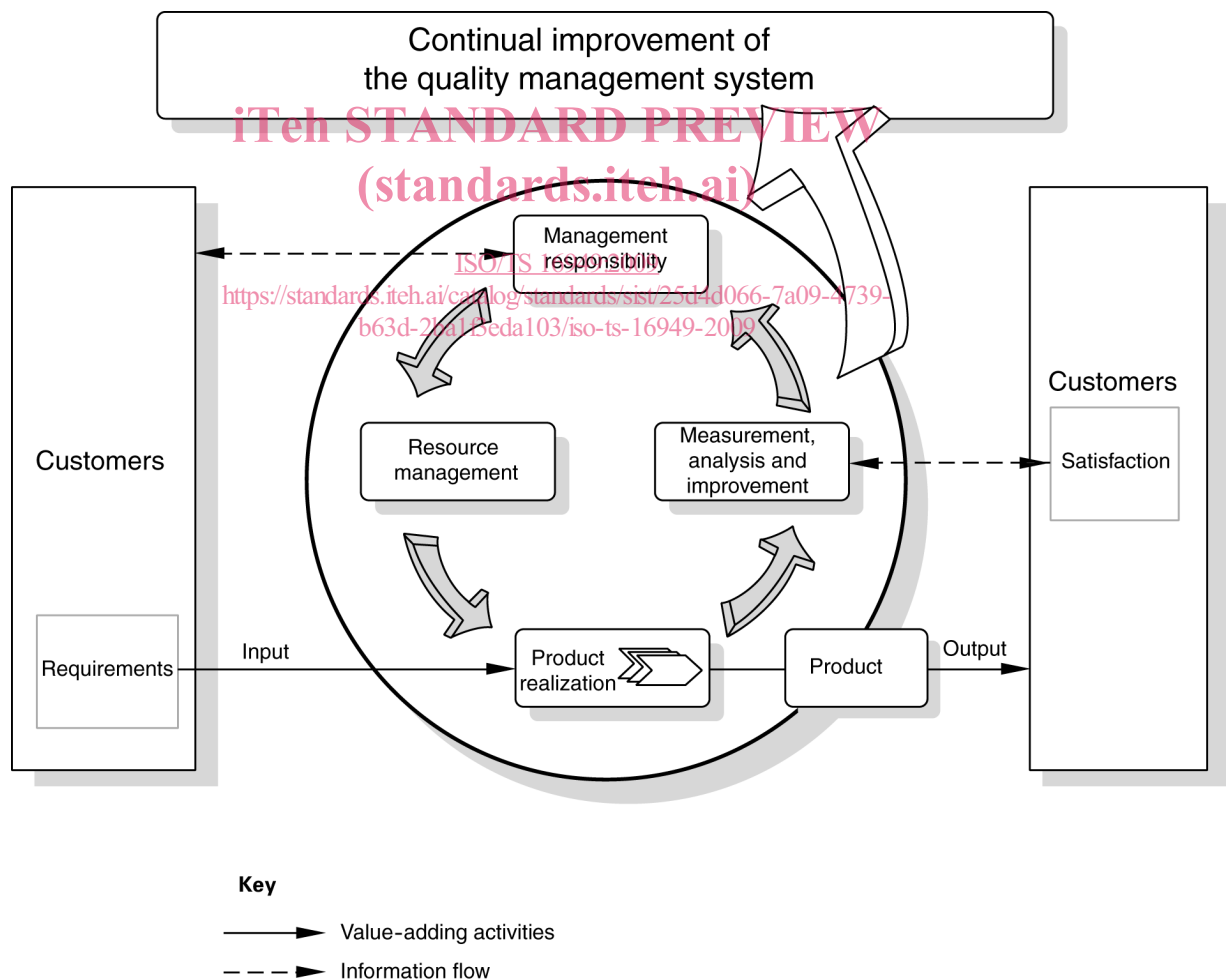


Figure 1 — Model of a process-based quality management system

0.3 Relationship with ISO 9004

ISO 9001:2008, Quality management systems — Requirements

0.3 Relationship with ISO 9004

ISO 9001 and ISO 9004 are quality management system standards which have been designed to complement each other, but can also be used independently.

ISO 9001 specifies requirements for a quality management system that can be used for internal application by organizations, or for certification, or for contractual purposes. It focuses on the effectiveness of the quality management system in meeting customer requirements.

At the time of publication of this International Standard, ISO 9004 is under revision. The revised edition of ISO 9004 will provide guidance to management for achieving sustained success for any organization in a complex, demanding, and ever changing, environment. ISO 9004 provides a wider focus on quality management than ISO 9001; it addresses the needs and expectations of all interested parties and their satisfaction, by the systematic and continual improvement of the organization's performance. However, it is not intended for certification, regulatory or contractual use.

NOTE The knowledge and use of the eight quality management principles referred to in ISO 9000:2005 and ISO 9004:— should be demonstrated and cascaded through the organization by top management.

0.4 Compatibility with other management systems

ISO 9001:2008, Quality management systems — Requirements

0.4 Compatibility with other management systems

During the development of this International Standard, due consideration was given to the provisions of ISO 14001:2004 to enhance the compatibility of the two standards for the benefit of the user community. Annex A shows the correspondence between ISO 9001:2008 and ISO 14001:2004.

This International Standard does not include requirements specific to other management systems, such as those particular to environmental management, occupational health and safety management, financial management or risk management. However, this International Standard enables an organization to align or integrate its own quality management system with related management system requirements. It is possible for an organization to adapt its existing management system(s) in order to establish a quality management system that complies with the requirements of this International Standard.

0.5 Goal of this Technical Specification

The goal of this Technical Specification is the development of a quality management system that provides for continual improvement, emphasizing defect prevention and the reduction of variation and waste in the supply chain.

This Technical Specification, coupled with applicable customer-specific requirements, defines the fundamental quality management system requirements for those subscribing to this Technical Specification.

This Technical Specification is intended to avoid multiple certification audits and provide a common approach to a quality management system for automotive production, and relevant service part organizations.

Quality management systems — Particular requirements for the application of ISO 9001:2008 for automotive production and relevant service part organizations

1 Scope

1.1 General

ISO 9001:2008, Quality management systems — Requirements

1 Scope

1.1 General

This International Standard specifies requirements for a quality management system where an organization

- a) needs to demonstrate its ability to consistently provide product that meets customer and applicable statutory and regulatory requirements, and
- b) aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

NOTE 1 In this International Standard, the term "product" only applies to

- a) product intended for, or required by, a customer,
- b) any intended output resulting from the product realization processes.

NOTE 2 Statutory and regulatory requirements can be expressed as legal requirements.

This Technical Specification, in conjunction with ISO 9001:2008, defines the quality management system requirements for the design and development, production and, when relevant, installation and service of automotive-related products.

This Technical Specification is applicable to sites of the organization where customer-specified parts, for production and/or service, are manufactured.

Supporting functions, whether on-site or remote (such as design centres, corporate headquarters and distribution centres), form part of the site audit as they support the site, but cannot obtain stand-alone certification to this Technical Specification.

This Technical Specification can be applied throughout the automotive supply chain.

1.2 Application

ISO 9001:2008, Quality management systems — Requirements

1.2 Application

All requirements of this International Standard are generic and are intended to be applicable to all organizations, regardless of type, size and product provided.

Where any requirement(s) of this International Standard cannot be applied due to the nature of an organization and its product, this can be considered for exclusion.

Where exclusions are made, claims of conformity to this International Standard are not acceptable unless these exclusions are limited to requirements within Clause 7, and such exclusions do not affect the organization's ability, or responsibility, to provide product that meets customer and applicable statutory and regulatory requirements.

The only permitted exclusions for this Technical Specification relate to 7.3 where the organization is not responsible for product design and development.

Permitted exclusions do not include manufacturing process design.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 9000:2005, *Quality management systems — Fundamentals and vocabulary*

3 Terms and definitions

ISO 9001:2008, *Quality management systems — Requirements*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000 apply.

Throughout the text of this International Standard, wherever the term “product” occurs, it can also mean “service”.

3.1 Terms and definitions for the automotive industry

For the purposes of this document, the terms and definitions given in ISO 9000:2005 and the following apply.

3.1.1

control plan

documented description of the systems and processes required for controlling product

NOTE See Annex A.

3.1.2

design responsible organization

organization with authority to establish a new, or change an existing, product specification

NOTE This responsibility includes testing and verification of design performance within the customer's specified application.

3.1.3

error proofing

product and manufacturing process design and development to prevent manufacture of nonconforming products

3.1.4

laboratory

facility for inspection, test or calibration that may include, but is not limited to, chemical, metallurgical, dimensional, physical, electrical or reliability testing

3.1.5**laboratory scope**

controlled document containing

- specific tests, evaluations and calibrations that a laboratory is qualified to perform,
- a list of the equipment which it uses to perform the above, and
- a list of methods and standards to which it performs the above

3.1.6**manufacturing**

process of making or fabricating

- production materials,
- production or service parts,
- assemblies, or
- heat treating, welding, painting, plating or other finishing services

3.1.7**predictive maintenance**

activities based on process data aimed at the avoidance of maintenance problems by prediction of likely failure modes

3.1.8**preventive maintenance**

planned action to eliminate causes of equipment failure and unscheduled interruptions to production, as an output of the manufacturing process design

3.1.9**premium freight**

extra costs or charges incurred additional to contracted delivery

NOTE This can be caused by method, quantity, unscheduled or late deliveries, etc.

3.1.10**remote location**

location that supports sites and at which non-production processes occur

3.1.11**site**

location at which value-added manufacturing processes occur

3.1.12**special characteristic**

product characteristic or manufacturing process parameter which can affect safety or compliance with regulations, fit, function, performance or subsequent processing of product