
**Quality systems — Automotive suppliers —
Particular requirements for the application
of ISO 9001:1994**

*Systèmes qualité — Fournisseurs de l'automobile — Exigences
particulières pour l'application de l'ISO 9001:1994*



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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 3.

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 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.

An ISO/PAS or ISO/TS is reviewed every three years with a view to deciding whether it can be transformed into an International Standard.

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

Boxed text in copyright notice, clause 4 and annex A is original ISO 9001:1994 text. The sector-specific supplemental requirements are outside the boxes.

In this Technical Specification, the word "shall" indicates requirements. Paragraphs marked "**NOTE**" are for guidance in understanding or clarifying the associated requirement. The word "should" appearing in a **NOTE** is for guidance only.

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

ISO/TS 16949 has been issued for provisional application in the automotive sector so that information and experience in its use may be gathered.

Remarks for certification

To obtain recognition of certification to this Technical Specification by the customer members of the IATF, a common global certification scheme has been developed and must be followed (see bibliography [7]). Customer-specific requirements supplemental to this Technical Specification, if any, shall be included in the audit in order to obtain customer recognition of such certification.

Details can be obtained from the organizations who support the International Automotive Task Force cited below.

NOTE All participating IATF OEMs and suppliers have customer-specific requirements in addition to this Technical Specification.

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Introduction

The goal of this Technical Specification is the development of fundamental quality systems that provide for continuous improvement, emphasizing defect prevention and the reduction of variation and waste in the supply chain. This Technical Specification defines the fundamental quality system requirements of the subscribing companies. It is recognized that there may be company-specific, division-specific, commodity-specific, and/or part-specific requirements in addition to those given in Figure 1.

This Technical Specification aligns existing automotive quality system requirements within the global automotive industry and avoids multiple certification audits.

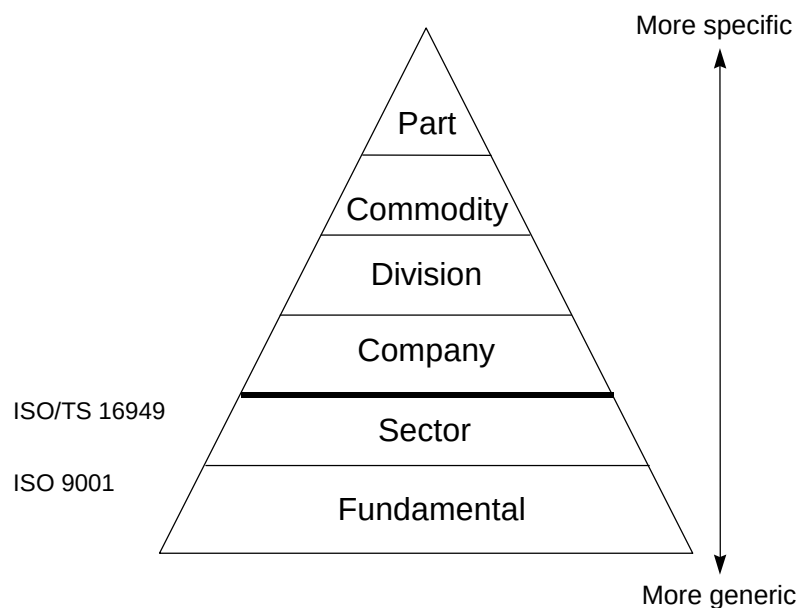
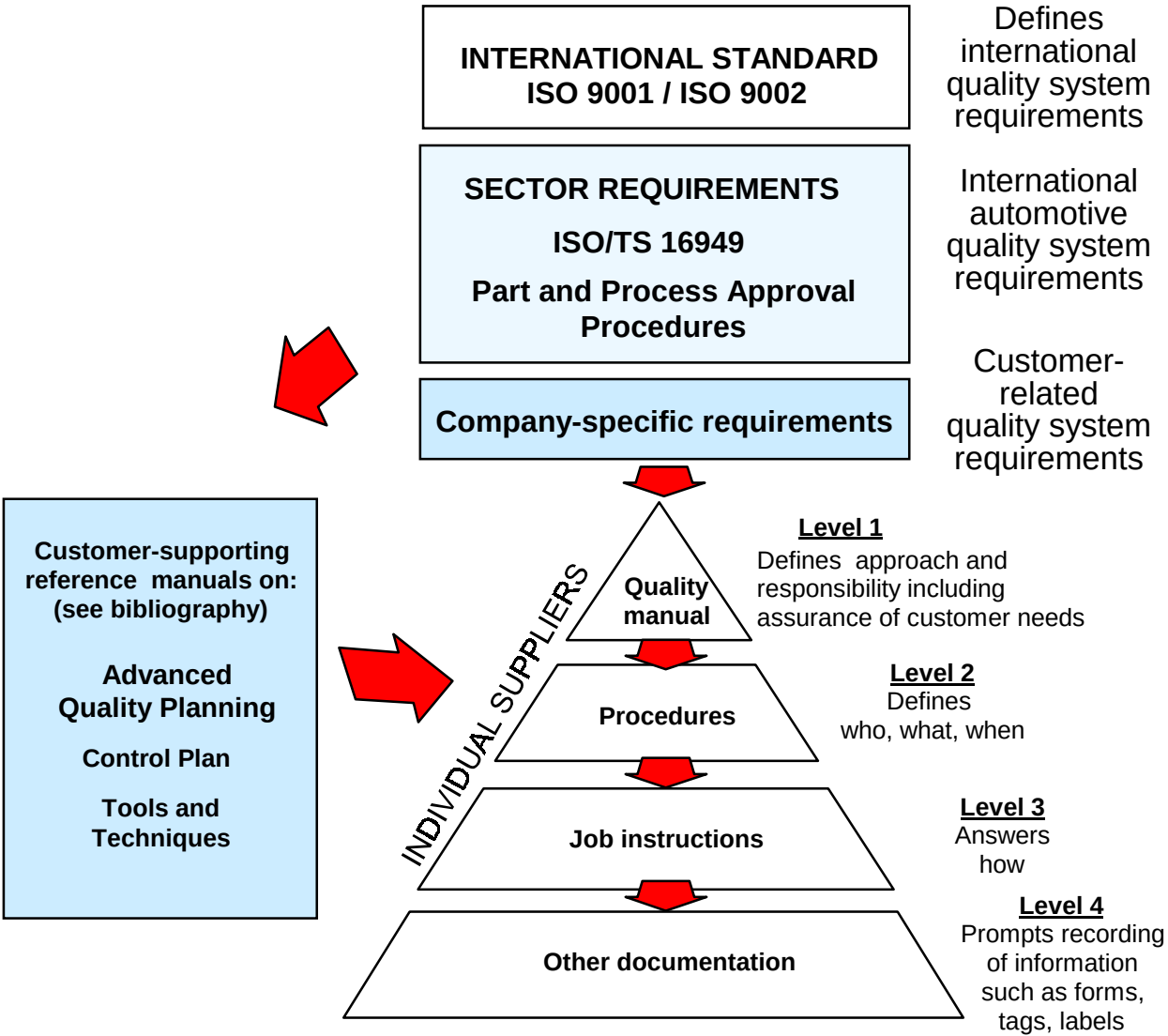


Figure 1 — Quality related requirements

Figure 2 demonstrates the progression of quality system documentation.



NOTE Once recorded, level 4 items may become a quality record (see 4.16).

Figure 2 — Quality System Documentation Progression

In this Technical Specification, quality planning activities of all pre-launch phases have been integrated under the new heading: "Product realization".

For suppliers with product design responsibility, product realization also includes product design (see 4.4).

Product realization in the context of quality planning is discussed in 4.2.4. The structure is outlined below:

- 4.2.3 Quality planning
 - 4.2.3.1 Quality planning – ISO 9001:1994
 - 4.2.3.2 Quality plan requirements
- 4.2.4 Product realization
 - 4.2.4.1 General
 - 4.2.4.2 Measurements
 - 4.2.4.3 Review cycle
 - 4.2.4.4 Multidisciplinary approach
 - 4.2.4.5 Tools and techniques
 - 4.2.4.6 Computer-aided design
 - 4.2.4.7 Special characteristics
 - 4.2.4.8 Feasibility review
 - 4.2.4.9 Management of process design
 - 4.2.4.9.1 General
 - 4.2.4.9.2 Process design input
 - 4.2.4.9.3 Process design output
 - 4.2.4.9.4 Process verification
 - 4.2.4.10 Control plan
 - 4.2.4.11 Product approval process

Quality systems — Automotive suppliers — Particular requirements for the application of ISO 9001:1994

1 Scope

This Technical Specification specifies, in conjunction with ISO 9001:1994, the quality system requirements for the design/development, production and, when relevant, installation and servicing of automotive-related products.

This Technical Specification is applicable to production and service part supplier and subcontractor "sites" providing:

- a) parts or materials, or
- b) heat treating, painting, plating, or other finishing services, or
- c) other customer-specified products.

NOTE "Remote locations" such as design centres and corporate headquarters form part of the site audit, however they cannot obtain stand-alone certification to this Technical Specification.

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

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this Technical Specification. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this Technical Specification are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 8402:1994, *Quality management and quality assurance — Vocabulary*.

ISO 9001:1994, *Quality systems — Model for quality assurance in design, development, production, installation and servicing*.

ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*¹.

3 Terms and definitions

For the purposes of this Technical Specification the terms and definitions given in ISO 8402:1994 and in annex A apply. However where there are terms for which the wording of the definition differs in ISO 8402:1994, the definitions in annex A apply.

¹ Revision of ISO/IEC Guide 25:1990.

4 Quality system requirements

4.1 Management responsibility

4.1.1 Quality policy

4.1.1.1 Quality policy – ISO 9001:1994

The supplier's management with executive responsibility shall define and document its policy for quality, including objectives for quality and its commitment to quality. The quality policy shall be relevant to the supplier's organizational goals and the expectations and needs of its customers. The supplier shall ensure that this policy is understood, implemented and maintained at all levels of the organization.

4.1.1.2 Objectives

The supplier shall define goals, objectives and measurements to deploy the quality policy. Objectives for achieving quality shall be included in the business plan.

NOTE The goals and objectives should address customer expectations and be achievable within a defined time period.

4.1.1.3 Customer satisfaction

The supplier shall have a documented process for determining customer satisfaction, including frequency of determination, and how objectivity and validity are assured. Indicators to monitor trends of customer satisfaction and dissatisfaction shall be documented and supported by objective information.

NOTE Consideration should be given to both internal and external customers.

4.1.1.4 Continuous improvement

Continuous improvement in quality, service, cost, and technology shall be provided for in the Quality Policy.

The supplier shall identify opportunities for quality and productivity improvement and implement appropriate improvement projects.

The supplier shall use appropriate continuous improvement measures and methodologies (see 4.2.7).

NOTE 1 The following list shows examples of possible techniques which might be used. There may be many other methods which meet specific supplier needs more appropriately:

- control charts (variables, attributes, CUSUM),
- design of experiments (DOE),
- theory of constraints,
- overall equipment effectiveness,
- parts per million (PPM) analysis to achieve zero defects,
- value analysis,
- benchmarking,
- analysis of motion/ergonomics,
- mistake-proofing.

NOTE 2 Guidelines for quality improvement are given in ISO 9004-4.

4.1.2 Organization

4.1.2.1 Responsibility and authority

4.1.2.1.1 Responsibility and authority – ISO 9001:1994

The responsibility, authority and the interrelation of personnel who manage, perform and verify work affecting quality shall be defined and documented, particularly for personnel who need the organizational freedom and authority to:

- a) initiate action to prevent the occurrence of any nonconformities relating to the product, process and quality system;
- b) identify and record any problems relating to the product, process and quality system;
- c) initiate, recommend or provide solutions through designated channels;
- d) verify the implementation of solutions;
- e) control further processing, delivery or installation of nonconforming product until the deficiency or unsatisfactory condition has been corrected.

4.1.2.1.2 Customer representative

The supplier shall assign responsibility to appropriate individuals to represent the needs of the customer in internal functions in addressing quality requirements, such as selection of special characteristics, setting quality objectives, training, corrective and preventive actions, product design and development.

4.1.2.1.3 Quality responsibility

Management with responsibility and authority for corrective action shall be promptly informed of products or processes which become noncompliant with specified requirements.

Personnel responsible for quality shall have the authority to stop production to correct quality problems.

4.1.2.2 Resources

4.1.2.2.1 Resources – ISO 9001:1994

The supplier shall identify resource requirements and provide adequate resources, including the assignment of trained personnel (see 4.18), for management, performance of work and verification activities including internal quality audits.

NOTE Subclause 4.18 in ISO 9001:1994 is 4.18.1 in this Technical Specification.

4.1.2.2.2 Shift resources

Especially concerning the production process, all the shifts shall be staffed with personnel in charge of, or delegated responsibility for quality.

4.1.2.3 Management representative

The supplier's management with executive responsibility shall appoint a member of the supplier's own management who, irrespective of other responsibilities, shall have defined authority for

- a) ensuring that a quality system is established, implemented and maintained in accordance with this International Standard, and
- b) reporting on the performance of the quality system to the supplier's management for review and as a basis for improvement of the quality system.

NOTE The responsibility of a management representative may also include liaison with external parties on matters relating to the supplier's quality system.

4.1.2.4 Organizational interfaces

The supplier shall have systems in place to ensure management of appropriate activities during concept development, prototype and production according to customer advanced product quality planning and control plan manual or project management manual (see bibliography).

The supplier shall use a multidisciplinary approach for decision making and have the ability to communicate necessary information in a language used by the customer, unless waived by the customer, and data in the customer-prescribed format.

4.1.3 Management review

4.1.3.1 Management review – ISO 9001:1994

The supplier's management with executive responsibility shall review the quality system at defined intervals sufficient to ensure its continuing suitability and effectiveness in satisfying the requirements of this International Standard and the supplier's stated quality policy and objectives (see 4.1.1). Records of such reviews shall be maintained (see 4.16).

NOTE Subclauses 4.1.1 and 4.16 in ISO 9001:1994 are 4.1.1.1 and 4.16.1 in this Technical Specification.

4.1.3.2 Management review – supplemental

These reviews shall include all elements of the quality system and its performance (see 4.2.8) over time as an essential part of the continuous improvement process.

Part of the management review shall be the monitoring of strategic quality objectives, and the regular reporting and evaluation of the cost of poor quality.

NOTE Management review should be conducted with sufficient frequency to ensure that the established quality system is effective.

4.1.4 Business plan

The supplier shall utilize a formal, documented, comprehensive business plan. The business plan shall be a controlled document.

NOTE 1 The content of the business plan is not subject to third-party audit.

Goals and plans shall cover short-term (1 to 2 years) and longer-term (3 years or more). The goals and plans shall be based on analysis of competitive products, where available, and on benchmarking inside and outside the automotive industry and the supplier's commodity. Methods to determine current and future customer expectations shall be in place. An objective process shall be used to define the scope and collection and analysis of information, including the frequency and methods of collection.

Methods to track, update, revise and review the plan shall be documented to ensure that the plan is followed and communicated throughout the organization, as appropriate.

NOTE 2 This plan may typically include as applicable:

- market-related issues including customer satisfaction plans,
- financial planning and cost objectives,
- growth projections including plant/facilities plans,
- human resource development,
- R & D plans, projections, and projects with appropriate funding,
- operational performance objectives, measurables and improvement plan,
- health, safety and environmental issues.

4.1.5 Analysis and use of company level data

The supplier shall document trends in quality, operational performance (productivity, costs of poor quality, efficiency, effectiveness) and current quality levels for key product and service features.

NOTE These should be compared with those of competitors and/or appropriate benchmarks.

Trends in data and information shall be compared with progress toward overall business objectives and lead to action to support the following:

- a) development of priorities for prompt solutions to customer-related problems;
- b) determination of key customer related trends and correlation to support status review, decision making and longer term planning;
- c) an information system for the timely reporting of product information arising from usage.

4.1.6 Employee motivation, empowerment and satisfaction

The supplier shall have a process for motivation of employees to achieve quality objectives and to make continuous improvements. The process shall include promotion of quality awareness on all levels.

NOTE Quality reviews should be conducted to provide appropriate information, such as "plan/actual" comparison and improvement suggestions.

The supplier shall have a process for measurement of employee satisfaction and employee understanding of appropriate quality objectives.

4.1.7 Impact on society

4.1.7.1 Product safety

Due care regarding product safety and means to minimize potential risks to employees, customers, users and the environment shall be addressed in the supplier's quality policy and practices, especially in design control (see 4.4) and process control (see 4.9) procedures and practices. The supplier shall promote internal awareness of safety considerations relative to the supplier's product.

4.1.7.2 Regulations

The supplier shall have a process to ensure compliance with all applicable government, safety and environmental regulations, including those concerning storage, handling, recycling, eliminating or disposing of materials.

4.2 Quality system

4.2.1 General

The supplier shall establish, document and maintain a quality system as a means of ensuring that product conforms to specified requirements. The supplier shall prepare a quality manual covering the requirements of this International Standard. The quality manual shall include or make reference to the quality system procedures and outline the structure of the documentation used in the quality system.

NOTE 1 Guidance on quality manuals is given in ISO 10013.

NOTE 2 All the quality system documents should be controlled. See Figure 2.