
1	SCOPE
QS 9000: new:	Introduction, applicability In addition to the applicability for supplier sites for production and services and their subcontractors for: <ul style="list-style-type: none">- parts or materials, or- services like heat and surface treatment, the customers may extend the applicability to specified products, throughout the automotive supply chain.
4	QUALITY SYSTEM REQUIREMENTS
4.1	Management responsibility
4.1.1	Quality policy
4.1.1.1	Quality policy - ISO 9001:1994
QS 9000: new:	Element: 4.1.1 No change.
4.1.1.2	Objectives
QS 9000: new:	Element: 4.1.1 Originating from the quality policy, measurable goals are to be established for all functions. The goals are to be included in the company's business plan.
4.1.1.3	Customer satisfaction
QS 9000: new:	Elements: 4.1.6; 4.1.6.1 The comparison of competitor data or appropriate benchmarks as well as a review by senior management has been removed. Also, the requirement to notify the certification body/registrar when a customer was placed into negative status was removed.
4.1.1.4	Continuous improvement
QS 9000: new:	Elements: 4.2.5; 4.2.5.1: 4.2.5.3 The quality policy shall include the continuous improvement of quality, service, cost and technology. Improvement projects to increase quality and productivity shall be initiated, where possible. The list of situations, which might lead to improvement projects, is not included in ISO/TS 16949.

4.1.2	Organization
4.1.2.1	Responsibility and authority
4.1.2.1.1	Responsibility and authority - ISO 9001:1994
QS 9000: new:	Element: 4.1.2.1 Sub item f) has become a separate section (4.1.2.1.2).
4.1.2.1.2	Customer representative
QS 9000: new:	Element: 4.1.2.1 f) No change.
4.1.2.1.3	Quality responsibility
QS 9000: new:	Elements: 4.1.2.5; 4.1.2.a) Following note: "Personnel responsible for quality should have the responsibility to stop production, if necessary to correct quality problems" has been changed to a requirement.
4.1.2.2	Resources
4.1.2.2.1	Resources - ISO 9001:1994
QS 9000: new:	Element: 4.1.2.2 No change.
4.1.2.2.2	Shift resources
new:	During all shift operations, especially in production processes, personnel in charge off or with delegated responsibility and authority for quality control shall be present.
4.1.2.3	Management representative
QS 9000: new:	Element: 4.1.2.3 No change.
4.1.2.4	Organizational interfaces
QS 9000: new:	Element: 4.1.2.4 All customer manuals are referenced instead of only APQP. Necessary information is to be transmitted in a language used by the customer (waiver is possible). The note with the typical functions has been dropped.
4.1.3	Management review

4.1.3.1	Management review - ISO 9001:1994
QS 9000: new	Element: 4.1.3 No change.
4.1.3.2	Management review - supplement
QS 9000: new:	Element: 4.1.3.1 The review is considered an important subject of the continuous improvement process. Beyond strategic quality goals, the periodic reporting of quality related losses/costs shall be part of the review. (See also 4.2.8). In the notes, the multidisciplinary approach has been deleted and the conduct of the review in appropriate intervals has been added.
4.1.4	Business plan
QS 9000: new:	Element: 4.1.4 No change. (Quality goals see 4.1.1.2)
4.1.5	Analysis and use of company level data
QS 9000: new:	Element: 4.1.5 The supplier needs to have an information system for timely reporting of product information arising from usage. The comparison of the data with those of other companies is no longer a requirement but a note.
4.1.6	Employee motivation, empowerment and satisfaction
new:	Motivation of personnel and the introduction of a process to measure employee satisfaction and their understanding of the quality goals.
4.1.7	Impact on society
4.1.7.1	Product safety
QS 9000 new:	Element: 4.2.3.4 Includes product safety and minimization of potential risk for personnel, customers, users and the environment, especially in design control and process control.
4.1.7.2	Regulations
new:	It shall be ensured that safety and environmental constraints are satisfied, including those concerning handling of dangerous materials.
4.2	Quality system

4.2.1	General
QS 9000 new:	Element: 4.2.1 No change.
4.2.2	Quality system procedures
4.2.2.1	Quality system procedures - ISO 9001:1994
QS 9000 new:	Element: 4.2.2 No change.
4.2.2.2	Quality system documentation
new:	The requirements of ISO/TS 16949 are to be included in the quality system documentation, but not necessarily in individual procedures (previously part of QS-9000 Introduction).
4.2.3	Quality planning
4.2.3.1	Quality planning - ISO 9001:1994
QS 9000 new:	Element: 4.2.3 No change.
4.2.3.2	Quality plan requirements
new:	A quality plan with customer requirements and relevant technical specifications shall be available.
4.2.4	Product realization
new:	Note: " Product realization " includes all quality planning activities or a project management system, based on defect prevention and continuous improvement.
4.2.4.1	General
QS 9000 new:	Elements: 4.2.3.1; 4.4.11 Introduction of a process to ensure timely compliance with customer requirements (quality, cost and delivery). For reference to APQP see 4.2.4.5.
4.2.4.2	Measurements
new:	During process development, indicators like quality risks, costs, lead times, critical paths and others, as appropriate, must be defined, analyzed and reported to management.

4.2.4.3	Review cycle
new:	The process of product realization is to be reviewed (coordinate with design phases and include process development).
4.2.4.4	Multidisciplinary approach
QS 9000	Element: 4.2.3.1
new:	No change.
4.2.4.5	Tools and techniques
QS 9000	Elements: 4.2.3.1; 4.2.3.5; 4.2.3.6
new:	For product quality planning and control plans, general reference is given to the customer manuals (bibliography). New processes shall be analyzed for process capability and to identify additional requirements for process control. Goals for process capability, reliability, maintainability and availability as well as acceptance criteria shall be documented.
4.2.4.6	Computer-aided design (CAD)
QS 9000	Element: 4.4.4.1
new:	The requirement for CAD has to be contractually agreed upon. The supplier shall be able to use numerical design and drawing data for the manufacture of production tools and prototypes.
4.2.4.7	Special characteristics
QS 9000	Element: 4.2.3.2
new:	Suitable methods for the identification of special characteristics (product characteristics or process parameters) shall be applied.
4.2.4.8	Feasibility reviews
QS 9000	Element: 4.2.3.3
new:	Reference to APQP and the Team Feasibility Commitment Form have been removed.
4.2.4.9	Management of process design
4.2.4.9.1	General
QS 9000	Element: 4.2.3 / APQP
new:	Documented procedures have to be used for development and verification of production processes.
4.2.4.9.2	Process design input
QS 9000	Element: 4.2.3 / APQP

new: Requirements for process design are to be identified, documented and reviewed including:

- results of the product design,
- goals for productivity, process capability and cost,
- experience from earlier developments, and
- others.

4.2.4.9.3 Process design output

QS 9000 Element: 4.2.3 / APQP

new: The process design output must be expressed in terms that can be verified and validated against process design input requirements. The results must include:

- specifications and drawings,
- process-FMEAs,
- acceptance criteria for process release, and
- others.

4.2.4.9.4 Process verification

QS 9000 Element: 4.2.3 / APQP

new: The process design output requirements must be verified against process design input requirements and must be recorded.

4.2.4.10 Control plan

QS 9000 Element: 4.2.3.7

new: Pre-launch control plans must be developed using an interdisciplinary approach (also valid for prototype phase, if contractually agreed upon).
Reference to PPAP has been removed.

4.2.4.11 Product approval process

QS 9000 Elements: 4.2.4.1; 4.2.4.2; 4.2.4.3; 4.4.9.1

new: The supplier shall comply with the procedure recognized by the customer. This process shall also be applied to subcontractors. If there is no customer requirement, the supplier should use one of the customer manuals listed in the bibliography.
All changes are to be reported to the customer and may require customer approval.
All changes, including those from subcontractors, shall be validated.
When required, additional customer requirements for verification/identification shall be met.

4.2.5 Plant, facility and equipment planning,

QS 9000 Elements: 4.2.6; 4.2.6.1

new: No change.

4.2.6	Tooling management
QS 9000 new:	Element: 4.2.6; 4.2.6.2 Tasks were added: <ul style="list-style-type: none">- documentation of changes to tool design including engineering change level,- identification of tool status, e.g. production, repair or disposal.
4.2.7	Process improvement
QS 9000 new:	Elements: 4.2.5; 4.2.5.1 refer to 4.1.1.4.
4.2.8	Performance of the quality system
new:	The supplier shall evaluate the performance of the quality system to verify effectiveness of its operation, record the results and provide evidence of achievement of: <ul style="list-style-type: none">- objectives specified in the quality policy,- objectives specified in the business plan,- customer satisfaction. (refer also to 4.1.3.2)
4.3	Contract review
4.3.1	General
QS 9000 new:	Element: 4.3.1 No change.
4.3.2	Review
4.3.2.1	Review - ISO 9001:1994
QS 9000 new:	Element: 4.3.2 No change.
4.3.2.2	Review - Supplement
QS 9000 new:	Element: 4.3.2 Cost elements or price shall be considered during preparation of quotes.
4.3.3	Amendment to a contract
QS 9000 new:	Element: 4.3.3 No change.
4.3.4	Records

Comparison
ISO/TS 16949 (1999) to QS 9000, 3rd edition (1998)

QS 9000 new:	Element: 4.3.4 No change.
4.4	Design control
4.4.1	General
QS 9000 new:	Element: 4.4.1 No change. (for QS 9000, element 4.4.1.1 refer to 4.4.4.3)
4.4.2	Design and development planning
4.4.2.1	Design and development planning - ISO 9001:1994
QS 9000 new:	Element: 4.4.2 No change.
4.4.2.2	Required skills
QS 9000 new:	Element: 4.4.2.1 No change.
4.4.2.3	Research and development
new:	The supplier shall have access to research and development facilities, to ensure the innovation of products and processes.
4.4.3	Organizational and technical interfaces
QS 9000 new:	Element: 4.4.3 No change.
4.4.4	Design input
4.4.4.1	Design input - ISO 9001:1994
QS 9000 new:	Element: 4.4.4 No change. (for QS 9000, element 4.4.4.1 refer to 4.2.4.6).
4.4.4.2	Reliability objectives
QS 9000 new:	Element: 4.4.10 Goals for product life, reliability and durability are no longer listed under prototype support, but they are still required for design input. Maintainability has been added to these objectives.
4.4.4.3	Use of information
QS 9000	Element: 4.4.1.1

Comparison
ISO/TS 16949 (1999) to QS 9000, 3rd edition (1998)

new: Information gained from analyses of competitive products or other sources shall also be used.

4.4.5 Design output

4.4.5.1 Design output - ISO 9001:1994

QS 9000 Element: 4.4.5
new: No change.

4.4.5.2 Design optimization

QS 9000 Element: 4.4.5.1
new: No change.

4.4.6 Design review

QS 9000 Element: 4.4.6
new: No change.

4.4.7 Design verification

QS 9000 Element: 4.4.7
new: No change.

4.4.8 Design validation

4.4.8.1 Design validation - ISO 9001:1994

QS 9000 Element: 4.4.8
new: No change.

4.4.8.2 Design validation – supplemental

QS 9000 Element: 4.4.8.1
new: No change.

4.4.8.3 Prototype program

QS 9000 Element: 4.4.10
new: No change. (refer also to 4.4.4.2).

4.4.9 Design changes

4.4.9.1 Design changes - ISO 9001:1994

QS 9000 Element: 4.4.9
new: No change. (suppliers own design is included).

4.4.9.2 Evaluation of design change

Comparison
ISO/TS 16949 (1999) to QS 9000, 3rd edition (1998)

QS 9000 new:	Element: 4.4.9.2 No change. (refer also to 4.2.4.11)
4.5	Document and data control
4.5.1	General
QS 9000 new:	Element: 4.5.1 No change.
4.5.2	Document and data approval and issue
4.5.2	Document and data approval and issue - ISO 9001-1994
QS 9000 new:	Element: 4.5.2 No change.
4.5.2.2	Engineering specifications
QS 9000 new:	Element: 4.5.2.1 No change.
4.5.3	Document and data changes
QS 9000 new:	Element: 4.5.3 No change.
4.6	Purchasing
4.6.1	General
4.6.1.1	General - ISO 9001:1994
QS 9000 new:	Element: 4.6.1 No change.
4.6.1.2	Customer approved subcontractors
QS 9000 new:	Elements: 4.6.1.1; 4.6.2.1 The reference to the customer list of approved subcontractors has been removed. Products, materials and services must be purchased from approved subcontractors (e.g., specified in the customer drawings or specifications), if contractually agreed upon. Other subcontractors can only be used if approved by the customer.
4.6.1.3	Regulatory compliance
QS 9000	Element: 4.6.1.2

**Comparison
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new:	No change.
4.6.2	Evaluation of subcontractors
4.6.2.1	Evaluation of subcontractors - ISO 9001:1994
QS 9000	Element: 4.6.2
new:	No change.
4.6.2.2	Subcontractor development
QS 9000	Element: 4.6.2.1
new:	Development shall be performed with the goal subcontractor compliance with the requirements of TS 16949 or other customer quality manual (bibliography). Note 1 states that -subcontractor's audits used for this of development activity shall be performed by a 2 nd or 3 rd party accepted by the customer.
4.6.2.3	Scheduling subcontractors
QS 9000	Element: 4.6.2.2
new:	No change.
4.6.3	Purchasing data
QS 9000	Element: 4.6.3
new:	No change.
4.6.4	Verification of purchased product
4.6.4.1	Supplier verification at subcontractor's premises
QS 9000	Element: 4.6.4.1
new:	No change.
4.6.4.2	Customer verification of subcontracted product
QS 9000	Element: 4.6.4.2
new:	No change.
4.7	Control of customer supplied product
4.7.1	Control of customer supplied product - ISO 9001:1994
QS 9000	Element: 4.7
new:	No change.
4.7.2	Customer owned tooling

Comparison
ISO/TS 16949 (1999) to QS 9000, 3rd edition (1998)

QS 9000 new:	Element: 4.7.1 The note regarding identification has been removed.
4.8	Product identification and traceability
QS 9000 new:	Element: 4.8 No change.
4.9	Process control
4.9.1	General
4.9.1.1	General - ISO:1994
QS 9000 new:	Element: 4.9 No change.
4.9.1.2	Cleanliness of premises
QS 9000 new:	Element: 4.9.b.1 No change.
4.9.1.3	Contingency plans
QS 9000 new:	Element: 4.9.b.2 No change.
4.9.1.4	Designation of special characteristics
QS 9000 new:	Element: 4.9.d.1 No change.
4.9.1.4	Preventive maintenance
QS 9000 new:	Element: 4.9.g.1 No change.
4.9.2	Job instructions
QS 9000 new:	Element: 4.9.1 No change.
4.9.3	Maintaining process control
QS 9000 new:	Elements: 4.9.2; 4.9.3; 4.9.5 No change. (section 4.9.3 of QS 9000 was removed, with no effect on this clause)
4.9.4	Verification of job set-ups
QS 9000	Element: 4.9.4

Comparison
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new:	No change.
4.9.5	Appearance items
QS 9000	Element: 4.9.6
new:	No change.
4.10	Inspection and testing
4.10.1	General
4.10.1.1	General - ISO 9001:1994
QS 9000	Element: 4.10.1
new:	No change.
4.10.1.2	Acceptance criteria
QS 9000	Element: 4.10.1.1
new:	No change.
4.10.2	Receiving inspection and testing
QS 9000	Elements: 4.10.2; 4.10.2.1; 4.10.2.2; 4.10.2.3
new:	No change (including 4.10.2.1; 4.10.2.2 and 4.10.2.3.).
4.10.2.4	Incoming product quality
QS 9000	Element: 4.10.2.4
new:	The possibility of a customer waiver with regard to the listed methods was added.
4.10.3	In-process inspection and testing
QS 9000	Element: 4.10.3
new:	No change.
4.10.4.	
4.10.4.1	Final inspection and testing - ISO 9001:1994
QS 9000	Element: 4.10.4
new:	No change.
4.10.4.2	Layout inspection and functional testing
QS 9000	Element: 4.10.4.1
new:	The frequency of inspection and testing must be outlined in the control plan by the supplier.

4.10.5	Inspection and test records
QS 9000 new:	Element: 4.10.5 No change.
4.10.6	Laboratory requirements
QS 9000 new:	Elements: 4.10.6; 4.10.7; 4.11.2.b.1 Internal laboratories have to comply with the requirements ISO/IEC 17025 or national equivalent and must have a laboratory scope. Details of QS-9000 have been dropped. External laboratories have to be accredited to ISO/IEC 17025 (or equivalent).
4.11	Control of inspection, measuring and test equipment
4.11.1	General
4.11.1.1	General – ISO 9001:1994
QS 9000 new:	Element: 4.11.1 No change.
4.11.1.2	Measuring system analysis
QS 9000 new:	Element: 4.11.4 No change. A note with regard to the knowledge of measuring system, etc. was added.
4.11.2	Control procedure
QS 9000 new:	Element: 4.11.2 QS-9000 4.11.2.b.1 and the note with regards to calibration by the manufacturer have been removed. See also 4.10.6.
4.11.3	Records
QS 9000 new:	Element: 4.11.3 Records of customer owned inspection, measuring and test equipment were added. The term calibration was expanded to calibration/verification.
4.12	Inspection and test status
QS 9000 new:	Elements: 4.12; 4.12.1 QS-9000 clause 4.12.1 regarding supplemental verification has been removed.

**Comparison
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4.13	Control of nonconforming products
4.13.1	General
4.13.1.1	General - ISO 9001:1994
QS 9000 new:	Element: 4.13.1 No change.
4.13.1.2	Suspect material or product
QS 9000 new:	Elements: 4.13.1.1; 4.13.1.2 No change.
4.13.1.3	Corrective action plan
QS 9000 new:	Element: 4.13.2.1 Customers are to be immediately informed when nonconforming products have been shipped.
4.13.2	Review and disposition of nonconforming product
QS 9000 new:	Element: 4.13.2 No change.
4.13.3	Control of reworked product
QS 9000 new:	Element: 4.13.3 The requirement for no rework visible on the exterior of products supplied for service applications has been removed.
4.13.4	Engineering approved authorization
QS 9000 new:	Element: 4.13.4 No change.
4.14	Corrective and preventive action
4.14.1	General
4.14.1.1	General - ISO 9001:1994
QS 9000 new:	Element: 4.14.1 No change.
4.14.1.2	Problem solving
QS 9000 new:	Element: 4.14.1.1 Problem solving methods have been clarified.

4.14.1.3	Mistake proofing
QS 9000 new:	Element: 4.14.1.2 No change.
4.14.2	Corrective action
4.14.2.1	Corrective action - ISO 9001:1994
QS 9000 new:	Element: 4.14.2 No change.
4.14.2.2	Corrective action impact
QS 9000 new:	Element: 4.14.2.2 No change.
4.14.2.3	Returned product test/analysis
QS 9000 new:	Element: 4.14.2.1 The cycle time for the analysis process shall be minimized.
4.14.3	Preventive action
QS 9000 new:	Element: 4.14.3 No change.
4.15	Handling, storage, packaging, preservation and delivery
4.15.1	General
QS 9000 new:	Element: 4.15.1 No change.
4.15.2	Handling
QS 9000 new:	Element: 4.15.2 No change.
4.15.3	Storage
4.15.3.1	Storage - ISO 9001:1994
QS 9000 new:	Element: 4.15.3 No change.
4.15.3.2	Inventory
QS 9000	Element: 4.15.3.1

Comparison
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new:	The requirement for minimizing inventory levels has been removed. Products that are obsolete are to be controlled as nonconforming products.
4.15.4	Packaging
4.15.4.1	Packaging - ISO 9001:1994
QS 9000	Element: 4.15.4
new:	No change.
4.15.4.2	Customer packaging standards
QS 9000	Element: 4.15.4.1
new:	No change.
4.15.4.3	Labelling
QS 9000	Element: 4.15.4.2
new:	No change.
4.15.5	Preservation
QS 9000	Element: 4.15.5
new:	No change.
4.15.6	Delivery
4.15.6.1	Delivery - ISO 9001:1994
QS 9000	Element: 4.15.6
new:	No change.
4.15.6.2	Performance monitoring of supplier delivery
QS 9000	Element: 4.15.6.1
new:	No change.
4.15.6.3	Production scheduling
QS 9000	Element: 4.15.6.2
new:	The QS-9000 Notes have been revised and incorporated in the basic statement
4.15.6.4	Electronic communication
QS 9000	Element: 4.15.6.3
new:	The computerized system can be substituted by another method agreed with the customer.

4.15.6.5	Shipment notification system
QS 9000 new:	Element: 4.15.6.4 The computerized system can be substituted by another method agreed with the customer.
4.16	Control of quality records
4.16.1	Control of quality records - ISO 9001:1994
QS 9000 new:	Element: 4.16 No change.
4.16.2	Records retention
QS 9000 new:	Element: 4.16.1 To meet governmental and customer requirements, retention time for documents and records must be defined. The specific retention periods of QS-9000 (e.g., PPAPs) have been eliminated.
4.17	Internal quality audits
4.17.1	Internal quality audits - ISO 9001:1994
QS 9000 new:	Element: 4.17 No change.
4.17.2	Internal quality audits – supplement
4.17.2.1	General
QS 9000 new:	Element: 4.17.1 An audit plan must be established in accordance with ISO 10011-1. The Note states that for each function, area or process audited, a specific checklist should be used.
4.17.2.2	System audit
QS 9000 new:	Elements: 4.17: 4.17.1 All activities are to be audited. An audit plan must be established on a yearly basis. Compliance with the requirements of the standard as well as any additional system requirements must be verified.
4.17.2.3	Process audit
new:	The product realization process and the production processes are to be audited to verify effectiveness of process performance.

4.17.2.4	Product audit
QS 9000 new:	Element: 4.10.4.2 Product audits must be done at appropriate stages of production and delivery. QS-9000 note has been eliminated.
4.17.3	Auditor qualification
new:	The customer requirements for the qualification of internal system and process auditors must be complied with.
4.18	Training
4.18.1	Training - ISO 9001:1994
QS 9000 new:	Element: 4.18 Note 1 stresses that this requirement is valid for all members of the supplier's organization.
4.18.2	Training effectiveness
QS 9000 new:	Element: 4.18.2 Customer specific requirements must be considered.
4.18.3	Training on the job
new:	Personnel performing activities affecting quality must be: <ul style="list-style-type: none">- trained on the job for new or modified processes (also includes contract or agency personnel, and- informed about customer consequences if quality standards are not met.
4.19	Servicing
4.19.1	Servicing - ISO 9001:1994
QS 9000 new:	Element: 4.18 No change.
4.19.2	Feedback of information from service
QS 9000 new:	Element: 4.19.1 No change.
4.19.3	Servicing agreement with customer

Comparison
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new: In case there is a servicing agreement with the customer, the supplier needs to verify the effectiveness of:

- supplier service centers,
- special purpose tools,
- training of service personnel.

4. 20 Statistical Techniques

4. 20.1 Identification of need

QS 9000 Element: 4.20.1
new: No change.

4. 20.2 Procedures

QS 9000 Element: 4.20.2
new: No change.

4. 20.3 Identification of statistical tools

QS 9000 Element: 4.20.3
new: No change.

4. 20.4 Knowledge of basic statistical concepts

QS 9000 Element: 4.20.4
new: No change.