

ISO/TS 16949:2009-06 (E)

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

Contents

	Page
Foreword.....	vii
<i>Remarks for certification</i>	<i>viii</i>
Introduction.....	ix
0.1 General.....	ix
0.2 Process approach.....	x
0.3 Relationship with ISO 9004.....	xii
0.4 Compatibility with other management systems.....	xii
0.5 <i>Goal of this Technical Specification</i>	<i>xii</i>
1 Scope.....	1
1.1 General.....	1
1.2 Application.....	1
2 Normative references.....	2
3 Terms and definitions.....	2
3.1 <i>Terms and definitions for the automotive industry</i>	<i>2</i>
4 Quality management system.....	4
4.1 General requirements.....	4
4.1.1 <i>General requirements — Supplemental</i>	<i>4</i>
4.2 Documentation requirements.....	5
4.2.1 General.....	5
4.2.2 Quality manual.....	5
4.2.3 Control of documents.....	6
4.2.3.1 <i>Engineering specifications</i>	<i>6</i>
4.2.4 Control of records.....	6
4.2.4.1 <i>Records retention</i>	<i>7</i>
5 Management responsibility.....	7
5.1 Management commitment.....	7
5.1.1 <i>Process efficiency</i>	<i>7</i>
5.2 Customer focus.....	7
5.3 Quality policy.....	7
5.4 Planning.....	8
5.4.1 Quality objectives.....	8
5.4.1.1 <i>Quality objectives — Supplemental</i>	<i>8</i>
5.4.2 Quality management system planning.....	8
5.5 Responsibility, authority and communication.....	8
5.5.1 Responsibility and authority.....	8
5.5.1.1 <i>Responsibility for quality</i>	<i>8</i>
5.5.2 Management representative.....	9
5.5.2.1 <i>Customer representative</i>	<i>9</i>
5.5.3 Internal communication.....	9
5.6 Management review.....	9
5.6.1 General.....	9
5.6.1.1 <i>Quality management system performance</i>	<i>10</i>
5.6.2 Review input.....	10
5.6.2.1 <i>Review input — Supplemental</i>	<i>10</i>
5.6.3 Review output.....	10

6	Resource management.....	11
6.1	Provision of resources	11
6.2	Human resources	11
6.2.1	General.....	11
6.2.2	Competence, training and awareness	11
6.2.2.1	<i>Product design skills</i>	11
6.2.2.2	<i>Training</i>	12
6.2.2.3	<i>Training on the job</i>	12
6.2.2.4	<i>Employee motivation and empowerment</i>	12
6.3	Infrastructure.....	12
6.3.1	<i>Plant, facility and equipment planning</i>	12
6.3.2	<i>Contingency plans</i>	12
6.4	Work environment	13
6.4.1	<i>Personnel safety to achieve conformity to product requirements</i>	13
6.4.2	<i>Cleanliness of premises</i>	13
7	Product realization	13
7.1	Planning of product realization.....	13
7.1.1	<i>Planning of product realization — Supplemental</i>	14
7.1.2	<i>Acceptance criteria</i>	14
7.1.3	<i>Confidentiality</i>	14
7.1.4	<i>Change control</i>	14
7.2	Customer-related processes.....	14
7.2.1	Determination of requirements related to the product	14
7.2.1.1	<i>Customer-designated special characteristics</i>	15
7.2.2	Review of requirements related to the product.....	15
7.2.2.1	<i>Review of requirements related to the product — Supplemental</i>	15
7.2.2.2	<i>Organization manufacturing feasibility</i>	15
7.2.3	Customer communication.....	15
7.2.3.1	<i>Customer communication — Supplemental</i>	16
7.3	Design and development.....	16
7.3.1	Design and development planning	16
7.3.1.1	<i>Multidisciplinary approach</i>	16
7.3.2	Design and development inputs	17
7.3.2.1	<i>Product design input</i>	17
7.3.2.2	<i>Manufacturing process design input</i>	17
7.3.2.3	<i>Special characteristics</i>	17
7.3.3	Design and development outputs	18
7.3.3.1	<i>Product design outputs — Supplemental</i>	18
7.3.3.2	<i>Manufacturing process design output</i>	18
7.3.4	Design and development review.....	19
7.3.4.1	<i>Monitoring</i>	19
7.3.5	Design and development verification.....	19
7.3.6	Design and development validation.....	19
7.3.6.1	<i>Design and development validation — Supplemental</i>	19
7.3.6.2	<i>Prototype programme</i>	20
7.3.6.3	<i>Product approval process</i>	20
7.3.7	Control of design and development changes	20

7.4	Purchasing.....	20
7.4.1	Purchasing process.....	20
7.4.1.1	<i>Statutory and regulatory conformity</i>	21
7.4.1.2	<i>Supplier quality management system development</i>	21
7.4.1.3	<i>Customer-approved sources</i>	21
7.4.2	Purchasing information.....	21
7.4.3	Verification of purchased product.....	21
7.4.3.1	<i>Incoming product conformity to requirements</i>	22
7.4.3.2	<i>Supplier monitoring</i>	22
7.5	Production and service provision.....	22
7.5.1	Control of production and service provision	22
7.5.1.1	<i>Control plan</i>	22
7.5.1.2	<i>Work instructions</i>	23
7.5.1.3	<i>Verification of job set-ups</i>	23
7.5.1.4	<i>Preventive and predictive maintenance</i>	23
7.5.1.5	<i>Management of production tooling</i>	24
7.5.1.6	<i>Production scheduling</i>	24
7.5.1.7	<i>Feedback of information from service</i>	24
7.5.1.8	<i>Service agreement with customer</i>	24
7.5.2	Validation of processes for production and service provision	24
7.5.2.1	<i>Validation of processes for production and service provision — Supplemental</i>	25
7.5.3	Identification and traceability	25
7.5.3.1	<i>Identification and traceability — Supplemental</i>	25
7.5.4	Customer property.....	25
7.5.4.1	<i>Customer-owned production tooling</i>	25
7.5.5	Preservation of product	26
7.5.5.1	<i>Storage and inventory</i>	26
7.6	Control of monitoring and measuring equipment	26
7.6.1	<i>Measurement system analysis</i>	27
7.6.2	<i>Calibration/verification records</i>	27
7.6.3	<i>Laboratory requirements</i>	27
7.6.3.1	<i>Internal laboratory</i>	27
7.6.3.2	<i>External laboratory</i>	27
8	Measurement, analysis and improvement.....	28
8.1	General.....	28
8.1.1	<i>Identification of statistical tools</i>	28
8.1.2	<i>Knowledge of basic statistical concepts</i>	28
8.2	Monitoring and measurement.....	28
8.2.1	Customer satisfaction.....	28
8.2.1.1	<i>Customer satisfaction — Supplemental</i>	29
8.2.2	Internal audit.....	29
8.2.2.1	<i>Quality management system audit</i>	29
8.2.2.2	<i>Manufacturing process audit</i>	29
8.2.2.3	<i>Product audit</i>	30
8.2.2.4	<i>Internal audit plans</i>	30
8.2.2.5	<i>Internal auditor qualification</i>	30
8.2.3	Monitoring and measurement of processes.....	30
8.2.3.1	<i>Monitoring and measurement of manufacturing processes</i>	30

8.2.4	Monitoring and measurement of product	31
8.2.4.1	<i>Layout inspection and functional testing</i>	31
8.2.4.2	<i>Appearance items</i>	31
8.3	Control of nonconforming product	32
8.3.1	<i>Control of nonconforming product — Supplemental</i>	32
8.3.2	<i>Control of reworked product</i>	32
8.3.3	<i>Customer information</i>	32
8.3.4	<i>Customer waiver</i>	32
8.4	Analysis of data	33
8.4.1	<i>Analysis and use of data</i>	33
8.5	Improvement	33
8.5.1	Continual improvement	33
8.5.1.1	<i>Continual improvement of the organization</i>	33
8.5.1.2	<i>Manufacturing process improvement</i>	34
8.5.2	Corrective action	34
8.5.2.1	<i>Problem solving</i>	34
8.5.2.2	<i>Error-proofing</i>	34
8.5.2.3	<i>Corrective action impact</i>	34
8.5.2.4	<i>Rejected product test/analysis</i>	34
8.5.3	Preventive action	35
<i>Annex A (normative) Control plan</i>		36
<i>A.1 Phases of the control plan</i>		36
<i>A.2 Elements of the control plan</i>		36
Bibliography		38