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
Remarks for certification ..... *viii*
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 Goal of this Technical Specification ..... *xii*
1 Scope 1
1.1 General 1
1.2 Application 1
2 Normative references 2
3 Terms and definitions 2
3.1 Terms and definitions for the automotive industry *2*
4 Quality management system 4
4.1 General requirements 4
4.1.1 General requirements — Supplemental *4*
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 Engineering specifications *6*
4.2.4 Control of records 6
4.2.4.1 Records retention *7*
5 Management responsibility 7
5.1 Management commitment 7
5.1.1 Process efficiency *7*
5.2 Customer focus 7
5.3 Quality policy 7
5.4 Planning 8
5.4.1 Quality objectives 8
5.4.1.1 Quality objectives — Supplemental *8*
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 Responsibility for quality *8*
5.5.2 Management representative 9
5.5.2.1 Customer representative *9*
5.5.3 Internal communication 9
5.6 Management review 9
5.6.1 General 9
5.6.1.1 Quality management system performance *10*
5.6.2 Review input 10
5.6.2.1 Review input — Supplemental *10*
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 Product design skills....11
6.2.2.2 Training....12
6.2.2.3 Training on the job....12
6.2.2.4 Employee motivation and empowerment....12
6.3 Infrastructure....12
6.3.1 Plant, facility and equipment planning....12
6.3.2 Contingency plans....12
6.4 Work environment....13
6.4.1 Personnel safety to achieve conformity to product requirements....13
6.4.2 Cleanliness of premises....13
7 Product realization....13
7.1 Planning of product realization....13
7.1.1 Planning of product realization — Supplemental....14
7.1.2 Acceptance criteria....14
7.1.3 Confidentiality....14
7.1.4 Change control....14
7.2 Customer-related processes....14
7.2.1 Determination of requirements related to the product....14
7.2.1.1 Customer-designated special characteristics....15
7.2.2 Review of requirements related to the product....15
7.2.2.1 Review of requirements related to the product — Supplemental....15
7.2.2.2 Organization manufacturing feasibility....15
7.2.3 Customer communication....15
7.2.3.1 Customer communication — Supplemental....16
7.3 Design and development....16
7.3.1 Design and development planning....16
7.3.1.1 Multidisciplinary approach....16
7.3.2 Design and development inputs....17
7.3.2.1 Product design input....17
7.3.2.2 Manufacturing process design input....17
7.3.2.3 Special characteristics....17
7.3.3 Design and development outputs....18
7.3.3.1 Product design outputs — Supplemental....18
7.3.3.2 Manufacturing process design output....18
7.3.4 Design and development review....19
7.3.4.1 Monitoring....19
7.3.5 Design and development verification....19
7.3.6 Design and development validation....19
7.3.6.1 Design and development validation — Supplemental....19
7.3.6.2 Prototype programme....20
7.3.6.3 Product approval process....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 Statutory and regulatory conformity *21*
7.4.1.2 Supplier quality management system development *21*
7.4.1.3 Customer-approved sources *21*
7.4.2 Purchasing information 21
7.4.3 Verification of purchased product 21
7.4.3.1 Incoming product conformity to requirements *22*
7.4.3.2 Supplier monitoring *22*
7.5 Production and service provision 22
7.5.1 Control of production and service provision 22
7.5.1.1 Control plan *22*
7.5.1.2 Work instructions *23*
7.5.1.3 Verification of job set-ups *23*
7.5.1.4 Preventive and predictive maintenance *23*
7.5.1.5 Management of production tooling *24*
7.5.1.6 Production scheduling *24*
7.5.1.7 Feedback of information from service *24*
7.5.1.8 Service agreement with customer *24*
7.5.2 Validation of processes for production and service provision 24
7.5.2.1 Validation of processes for production and service provision — Supplemental *25*
7.5.3 Identification and traceability 25
7.5.3.1 Identification and traceability — Supplemental *25*
7.5.4 Customer property 25
7.5.4.1 Customer-owned production tooling *25*
7.5.5 Preservation of product 26
7.5.5.1 Storage and inventory *26*
7.6 Control of monitoring and measuring equipment 26
7.6.1 Measurement system analysis *27*
7.6.2 Calibration/verification records *27*
7.6.3 Laboratory requirements *27*
7.6.3.1 Internal laboratory *27*
7.6.3.2 External laboratory *27*
8 Measurement, analysis and improvement 28
8.1 General 28
8.1.1 Identification of statistical tools *28*
8.1.2 Knowledge of basic statistical concepts *28*
8.2 Monitoring and measurement 28
8.2.1 Customer satisfaction 28
8.2.1.1 Customer satisfaction — Supplemental *29*
8.2.2 Internal audit 29
8.2.2.1 Quality management system audit *29*
8.2.2.2 Manufacturing process audit *29*
8.2.2.3 Product audit *30*
8.2.2.4 Internal audit plans *30*
8.2.2.5 Internal auditor qualification *30*
8.2.3 Monitoring and measurement of processes 30
8.2.3.1 Monitoring and measurement of manufacturing processes *30*

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