

ISO/TS 16949:2009 Quick Reference

This reference is a quick clause-by-clause summary of the ISO/TS 16949:2009 requirements. The additional ISO/TS 16949:2009 clauses are highlighted by the delta symbol in the + column.

Note: See the actual standard for a complete description of the requirements.

ISO/TS 16949:2009 Clauses	TS +	Summary of Requirements
4. Quality Management System		
4.1 General Requirements		Implement quality system and continually improve it
4.1.1 General Requirements -Supplemental	+	Remain responsible for any outsourced processes
4.2 Documentation Requirements		
4.2.1 General		Include the required documents and records
4.2.2 Quality Manual		Establish and maintain a quality manual
4.2.3 Control of Documents		Ensure documents are at right status in right places
4.2.3.1 Engineering Specifications	+	Conduct timely review of customer specifications
4.2.4 Control of Records		Identify records and keep as evidence of conformity
4.2.4.1 Records Retention	+	Control records for customer and legal requirements
5. Management Responsibility		
5.1 Management Commitment		Show evidence of top management commitment
5.1.1 Process Efficiency	+	Review processes for efficiency and effectiveness
5.2 Customer Focus		Meet the requirements and satisfy your customers
5.3 Quality Policy		Have top management express quality intentions
5.4 Planning		
5.4.1 Quality Objectives		Set measurable targets for products and processes
5.4.1.1 Quality Objectives -Supplemental	+	Define measurements for business plan
5.4.2 Quality Management System Planning		Carry out plans for quality system and its processes
5.5 Responsibility, Authority, and Communication		
5.5.1 Responsibility and Authority		Make sure everyone knows their duties and roles
5.5.1.1 Responsibility for Quality	+	Staff every production shift with quality coordinator
5.5.2 Management Representative		Appoint a manager as focal point for quality system
5.5.2.1 Customer Representative	+	Assign representative for customer requirements
5.5.3 Internal Communications		Keep everyone informed of system effectiveness
5.6 Management Review		
5.6.1 General		Review the quality system at planned intervals
5.6.1.1 Quality Management System Performance	+	Include quality objectives and cost of poor quality
5.6.2 Review Input		Ensure the required agenda topics are covered
5.6.2.1 Review Input -Supplemental	+	Analyze field failures and their impact on quality
5.6.3 Review Output		Record the decisions and actions from reviews
6. Resource Management		
6.1 Provision of Resources		Provide necessary resources to meet requirements
6.2 Human Resources		
6.2.1 General		Ensure everyone working in system is competent
6.2.2 Competence, Training, and Awareness		Train personnel and recognize their contributions
6.2.2.1 Product Design Skills	+	Ensure product designers are skilled and competent
6.2.2.2 Training	+	Maintain documented training procedures
6.2.2.3 Training on the Job	+	Provide OJT for new or revised jobs affecting quality
6.2.2.4 Employee Motivation and Empowerment	+	Motivate employees to meet objectives and improve
6.3 Infrastructure		Provide facilities, equipment, and support services
6.3.1 Plant, Facility, and Equipment Planning	+	Evaluate the effectiveness of existing operations
6.3.2 Contingency Plans	+	Prepare contingency plans in event of an emergency
6.4 Work Environment		Manage combination of human and physical factors
6.4.1 Personnel Safety to Achieve Conformity to Product Requirements	+	Address product safety and risks to employees
6.4.2 Cleanliness of Premises	+	Maintain premises in state of order and cleanliness

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7. Product Realization		
7.1 Planning of Product Realization		Plan and develop processes for product realization
7.1.1 <i>Planning -Supplemental</i>	+	<i>Consider customer requirements in quality plans</i>
7.1.2 <i>Acceptance Criteria</i>	+	<i>Define acceptance criteria</i>
7.1.3 <i>Confidentiality</i>	+	<i>Ensure confidentiality of customer products</i>
7.1.4 <i>Change Control</i>	+	<i>Control changes that impact product realization</i>
7.2 Customer-Related Processes		
7.2.1 Determination of Product Requirements		Define customer, regulatory, and own requirements
7.2.1.1 <i>Customer-Designated Special Char.</i>	+	<i>Demonstrate conformity for special characteristics</i>
7.2.2 Review of Product Requirements		Review requirements before committing to customer
7.2.2.1 <i>Review -Supplemental</i>	+	<i>Waiver of review requires customer authorization</i>
7.2.2.2 <i>Organization Manufacturing Feasibility</i>	+	<i>Confirm and document manufacturing feasibility</i>
7.2.3 Customer Communication		Talk to customers about products and complaints
7.2.3.1 <i>Customer Communication -Supplemental</i>	+	<i>Communicate in customer format, e.g. CAD, EDI</i>
7.3 Design and Development		
7.3.1 Design and Development Planning		Plan design stages, activities, and responsibilities
7.3.1.1 <i>Multidisciplinary Approach</i>	+	<i>Involve appropriate functions in planning process</i>
7.3.2 Design and Development Inputs		Identify and review input requirements for design
7.3.2.1 <i>Product Design Input</i>	+	<i>Document and review product design inputs</i>
7.3.2.2 <i>Manufacturing Process Design Input</i>	+	<i>Document and review mfg. process design inputs</i>
7.3.2.3 <i>Special Characteristics</i>	+	<i>Include all special characteristics in control plan</i>
7.3.3 Design and Development Outputs		Prepare design outputs and approve before release
7.3.3.1 <i>Product Design Outputs -Supplemental</i>	+	<i>Express for V&V of product design</i>
7.3.3.2 <i>Manufacturing Process Design Output</i>	+	<i>Express for V&V of manufacturing process design</i>
7.3.4 Design and Development Review		Review ability of design results to meet requirements
7.3.4.1 <i>Monitoring</i>	+	<i>Report measurements at design stages</i>
7.3.5 Design and Development Verification		Verify the design outputs meet input requirements
7.3.6 Design and Development Validation		Validate the product is okay for application or use
7.3.6.1 <i>Validation -Supplemental</i>	+	<i>Perform validation per customer requirements</i>
7.3.6.2 <i>Prototype Program</i>	+	<i>Include prototype program, if required by customer</i>
7.3.6.3 <i>Product Approval Process</i>	+	<i>Use approval procedure recognized by customer</i>
7.3.7 Control of Design and Development Changes		Review, verify, and validate any design changes
7.4 Purchasing		
7.4.1 Purchasing Process		Evaluate, select, monitor, and control your suppliers
7.4.1.1 <i>Statutory and Regulatory Conformity</i>	+	<i>Use products conforming to applicable regulations</i>
7.4.1.2 <i>Supplier QMS Development</i>	+	<i>Develop suppliers with goal of conformity to TS</i>
7.4.1.3 <i>Customer-Approved Sources</i>	+	<i>Purchase from approved sources, if in contract</i>
7.4.2 Purchasing Information		Create purchase orders describing supplier products
7.4.3 Verification of Purchased Product		Check purchases to ensure they meet requirements
7.4.3.1 <i>Incoming Product Conformity to Requirements</i>	+	<i>Assure quality by one or more of accepted methods</i>
7.4.3.2 <i>Supplier Monitoring</i>	+	<i>Monitor supplier performance</i>
7.5 Production and Service Provision		
7.5.1 Control of Production and Service Provision		Plan and control production and service activities
7.5.1.1 <i>Control Plan</i>	+	<i>Develop control plans and update for changes</i>
7.5.1.2 <i>Work Instructions</i>	+	<i>Document work instructions and make accessible</i>
7.5.1.3 <i>Verification of Job Setups</i>	+	<i>Make work instructions available for setup personnel</i>
7.5.1.4 <i>Preventive and Predictive Maintenance</i>	+	<i>Implement a total preventive maintenance system</i>
7.5.1.5 <i>Management of Production Tooling</i>	+	<i>Implement system for managing production tooling</i>
7.5.1.6 <i>Production Scheduling</i>	+	<i>Schedule production to meet customer requirements</i>
7.5.1.7 <i>Feedback of Information from Services</i>	+	<i>Establish process to communicate service concerns</i>
7.5.1.8 <i>Service Agreement with Customer</i>	+	<i>Verify service effectiveness, if agreement exists</i>

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7.5.2 Validation of Production & Service Processes		Examine the process if you can't check the product
7.5.2.1 <i>Validation -Supplemental</i>	+	<i>Apply to all production and service processes</i>
7.5.3 Identification and Traceability		Identify the product and its inspection and test status
7.5.3.1 <i>Identification & Traceability -Supplemental</i>	+	<i>Apply traceability in all cases</i>
7.5.4 Customer Property		Exercise care with any customer property
7.5.4.1 <i>Customer-Owned Production Tooling</i>	+	<i>Permanently mark all customer-owned tooling</i>
7.5.5 Preservation of Product		Handle, store, package, and protect the product
7.5.5.1 <i>Storage and Inventory</i>	+	<i>Assess product condition in stock at planned interval</i>
7.6 Control of Monitoring and Measuring Equipment		Calibrate measuring equipment for valid results
7.6.1 <i>Measurement Systems Analysis</i>	+	<i>Conduct statistical studies to analyze variation</i>
7.6.2 <i>Calibration/Verification Records</i>	+	<i>Include required items in the calibration records</i>
7.6.3 <i>Laboratory Requirements</i>	+	
7.6.3.1 <i>Internal Laboratory</i>	+	<i>Define scope for capability of own internal laboratory</i>
7.6.3.2 <i>External Laboratory</i>	+	<i>Use accredited lab or one approved by customer</i>

8. Measurement, Analysis, and Improvement		
8.1 General		Plan, measure, analyze, and improve processes
8.1.1 <i>Identification of Statistical Tools</i>	+	<i>Determine needed tools and include in control plan</i>
8.1.2 <i>Knowledge of Basic Statistical Concepts</i>	+	<i>Understand variation, stability, and over adjustment</i>
8.2 Monitoring and Measurement		
8.2.1 Customer Satisfaction		Ask customers what they think about your products
8.2.1.1 <i>Customer Satisfaction - Supplemental</i>	+	
8.2.2 Internal Audit		Evaluate conformity and effectiveness of system
8.2.2.1 <i>Quality Management System Audit</i>	+	<i>Audit system for conformity to TS requirements</i>
8.2.2.2 <i>Manufacturing Process Audit</i>	+	<i>Audit each manufacturing process for effectiveness</i>
8.2.2.3 <i>Product Audit</i>	+	<i>Audit products at stages of production and delivery</i>
8.2.2.4 <i>Internal Audit Plans</i>	+	<i>Include all processes and shifts in annual plan</i>
8.2.2.5 <i>Internal Auditor Qualification</i>	+	<i>Ensure auditors are qualified to audit TS</i>
8.2.3 Monitoring and Measurement of Processes		See if processes are achieving planned results
8.2.3.1 <i>M & M of Manufacturing Processes</i>	+	<i>Perform studies on new manufacturing processes</i>
8.2.4 Monitoring and Measurement of Product		Verify products meet acceptance criteria
8.2.4.1 <i>Layout Inspection and Functional Testing</i>	+	<i>Perform for each product in control plan</i>
8.2.4.2 <i>Appearance Items</i>	+	<i>Provide, maintain, and control appearance masters</i>
8.3 Control of Nonconforming Product		Prevent use or delivery of nonconforming product
8.3.1 <i>Control of NC Product -Supplemental</i>	+	<i>Classify unidentified or suspect product as NC</i>
8.3.2 <i>Control of Reworked Product</i>	+	<i>Make rework and re-inspection instructions available</i>
8.3.3 <i>Customer Information</i>	+	<i>Promptly inform customer if NC product is shipped</i>
8.3.4 <i>Customer Waiver</i>	+	<i>Seek waiver if process different than approved</i>
8.4 Analysis of Data		Analyze effectiveness and identify improvements
8.4.1 <i>Analysis and Use of Data</i>	+	<i>Compare performance trends to quality objectives</i>
8.5 Improvement		
8.5.1 Continual Improvement		Continually improve effectiveness of quality system
8.5.1.1 <i>Continual Improvement of Organization</i>	+	<i>Define a process for continual improvement</i>
8.5.1.2 <i>Manufacturing Process Improvement</i>	+	<i>Focus on reduction of product and process variation</i>
8.5.2 Corrective Action		Fix detected problems and prevent recurrence
8.5.2.1 <i>Problem Solving</i>	+	<i>Use defined process for problem solving</i>
8.5.2.2 <i>Error-Proofing</i>	+	<i>Use error-proofing in corrective action process</i>
8.5.2.3 <i>Corrective Action Impact</i>	+	<i>Apply actions to similar processes and products</i>
8.5.2.4 <i>Rejected Product Test/Analysis</i>	+	<i>Analyze rejected parts and act to prevent recurrence</i>
8.5.3 Preventive Action		Avoid potential problems by preventing occurrence

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