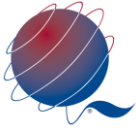


SAE AS9100 Revision C

Requirements beyond ISO 9001:2008

UPDATING YOUR MANAGEMENT SYSTEM

CLAUSE	REQUIREMENTS	SPECIFIC ACTION	OWNER	COMMENTS
3	Terms and Definitions – Ensure awareness and understanding of: <ul style="list-style-type: none"> • Risk • Special Requirements • Critical Items • Key Characteristic 			
4.1	Include process(es) that deploy(s) requirements from: <ul style="list-style-type: none"> • Customers • Applicable Laws • Applicable Regulations 			
4.2.1	Personnel are aware of procedures and have access to the QMS documents			
4.2.4	Bring supplier records under control via QMS or contractually w/suppliers			
4.2.4	Specify contractual rights to retrieve legible records from suppliers			
5.2	Measure product conformity and on-time performance and take action if not achieved per 8.3, 8.2.3 and 8.5.2			
5.5.2d	Authorize Management Representative to resolve quality management issues			
7.1e	Determine configuration management appropriate to your product(s)			
7.1f	Determine the resources to support use and maintenance of the product(s)			
7.1.1	Establish and use project management process			
7.1.2	Establish and use risk management process			



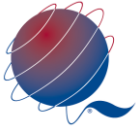
SAE AS9100 Revision C

Requirements beyond ISO 9001:2008

UPDATING YOUR MANAGEMENT SYSTEM

CLAUSE	REQUIREMENTS	SPECIFIC ACTION	OWNER	COMMENTS
7.1.3	Establish configuration management or justify exclusion of this clause			
7.1.4	Establish and use work transfer process or justify exclusion of this clause			
7.2.2d	Determine any special product requirements			
7.2.2e	Identify risks associated with the transaction before committing to meet the requirements (see 7.1.2)			
7.3	Design and development of products			
7.3.1	Manage project (see 7.1.1) design as well			
7.3.1	Plan design for ability to produce, inspect, test and maintain product			
7.3.1	Input safety and functional objectives of product			
7.3.3e	Identify critical items, their key characteristics and specific actions to be taken on these items			
7.3.3	Design output to include information necessary for product to be identified, manufactured, verified, used and maintained			
7.3.4c	Who authorizes release from each design stage?			
7.3.6.1	Plan, document, use and record verification and validation tests (such as prototyping)			
7.3.6.2	Ensure test records demonstrate that the design results in a product that meets requirements of all identified operational conditions			

FOR USE BY:		2 of 7	
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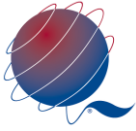


SAE AS9100 Revision C

Requirements beyond ISO 9001:2008

UPDATING YOUR MANAGEMENT SYSTEM

CLAUSE	REQUIREMENTS	SPECIFIC ACTION	OWNER	COMMENTS
7.3.7	Control design change per configuration management process (see 7.1.3)			
7.4.1	Your company is responsible for all purchased product			
7.4.1a	Must have list of approved suppliers indicating what they are approved to supply (incl. verifications)			
7.4.1b	Relate the degree of control specified in purchase order to evals. of supplier performance			
7.4.1c	Define actions to correct supplier nonconformity			
7.4.1d	Specify in PO the use of customer-approved sources of special processing			
7.4.1e	Authorize someone to change approval status and stop use of suppliers			
7.4.1f	Determine and manage purchasing risks per 7.1.2			
7.4.2d	Identify the revision status of the documents that describe the processes, goods & services ordered			
7.4.2e	Specify design, verification and any statistical requirements for critical items/key characteristics			
7.4.2f	Specify requirements for obtaining, identifying, preserving and delivering any test specimens			
7.4.2g	Supplier notification of nonconforming product			
7.4.2g	*ABC accepting nonconforming material			

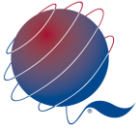


SAE AS9100 Revision C

Requirements beyond ISO 9001:2008

UPDATING YOUR MANAGEMENT SYSTEM

CLAUSE	REQUIREMENTS	SPECIFIC ACTION	OWNER	COMMENTS
7.4.2g	Supplier notification of changes to process/product for *ABC approval			
7.4.2g	Suppliers to deploy requirements to their suppliers			
7.4.2h	Specify supplier record retention requirements			
7.4.2i	Provide right of access to suppliers' facilities/records			
7.4.3	Keep track of incoming product not known to conform (per 7.5.3)			
7.4.3	Maintain a log of verification requirements delegated to suppliers (see 7.4.1a)			
7.5.1g	Name person accountable for conforming/nonconforming product during its manufacture			
7.5.1h	Record that all steps and checks have been made			
7.5.1i	Prevent/detect and remove foreign objects			
7.5.1j	Reliable supply of compressed air and other utilities			
7.5.1k	Maintain standards and samples to communicate acceptance criteria to technicians			
7.5.1	Ensure production plan or quality plan (see 7.1) covers critical items and specifies process controls for key characteristics			
7.5.1	Plan and conduct verifications while it can be done – before assembly, for example			

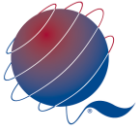


SAE AS9100 Revision C

Requirements beyond ISO 9001:2008

UPDATING YOUR MANAGEMENT SYSTEM

CLAUSE	REQUIREMENTS	SPECIFIC ACTION	OWNER	COMMENTS
7.5.1.1	Verify conformity to process and product acceptance criteria (FAI)			
7.5.1.2	Control changes to production processes			
7.5.1.3	Control production hardware and software			
7.5.1.4	Control service operations unless excluded			
7.5.3	Identify any differences in actual and specified configuration			
7.5.3	Prevent unauthorized use of approval devices			
7.5.5a	Provide cleaning			
7.5.5b	Prevent/detect and remove foreign objects			
7.5.5c	Provide special handling of sensitive products			
7.5.5d	Provide marking, labeling and warnings			
7.5.5e	Control stock			
7.5.5f	Provide special handling of hazardous materials			
7.6	Keep list of device type, ID, location, check frequency and methods, device recall method, device acceptance criteria and environmental conditions			
8.2.1	Monitor: <ul style="list-style-type: none"> • Product conformity • OTD performance • Customer complaints • SCARs ...and take corrective action per 8.5.2			
8.2.3a	Take action to correct a nonconforming process			
8.2.3b	Evaluate if process nonconformity has led to product nonconformity			



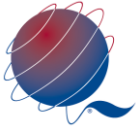
SAE AS9100 Revision C

Requirements beyond ISO 9001:2008

UPDATING YOUR MANAGEMENT SYSTEM

CLAUSE	REQUIREMENTS	SPECIFIC ACTION	OWNER	COMMENTS
8.2.3c	Determine if process nonconformity has impacted other processes or products			
8.2.3d	Control nonconforming product per 8.3			
8.2.4	Document product acceptance measurement requirements (see 7.1c)			
8.2.4a	Specify acceptance criteria			
8.2.4b	When to perform conformity verifications			
8.2.4c	Records to be kept			
8.2.4d	Measurement devices to be used and instructions for use			
8.2.4	Ensure accompanying test certificates/records are present at delivery			
8.3	Include product returned by customer and process for approving personnel authorized to disposition nonconforming product			
8.3	Ensure procedure for control of NC product authorizes competent people (see 6.2.1) for dispositioning of said NCs			
8.3	Use-as-is and repair dispositions require OEM/designer approval unless conforming to OEM specifications			
8.3	Use-as-is and repair dispositions require customer approval if deviating from contract			
8.3	Error-proof removal of scrap and render unusable			

FOR USE BY:		6 of 7	
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SAE AS9100 Revision C

Requirements beyond ISO 9001:2008

UPDATING YOUR MANAGEMENT SYSTEM

CLAUSE	REQUIREMENTS	SPECIFIC ACTION	OWNER	COMMENTS
8.5.1	Monitor and evaluate implementation of improvements			
8.5.2g	Involve suppliers in removing the root causes of nonconformity			
8.5.2h	Expedite/escalate corrective action			
8.5.2i	Investigate extent of other nonconforming products			
8.5.3	Consider use of FMEAs during product or process design to manage risk and drive preventive actions			

*ABC = Your organization

For information on leading, developing, auditing and improving your management system, please visit www.aworldofquality.com early and often!

FOR USE BY:		7 of 7	
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