IATF 16949:2016

Quality Management Systems Documentation

Quality Manual / Documented Information

Document No. QM-016

Street Address

City, State, Zip

Tel,

Cell Phone:

Email:

Web Site:

Instructions:

This manual is used as a template in developing your IATF 16949:2016 Automotive Quality Management System.

- Methods and systems used in the development and operation of the QMS vary widely from company to company.
- The blue text and suggestions displayed in the manual are intended to offer some options and to highlight the areas that need attention / update / replacement.
- Review the text and suggestions and at a minimum replace or update them to reflect the unique / customized information of your quality system requirements.
- Delete the blue text after each task is completed.
- Use replace function – enter “Your Company” in find space, enter your company name in replace space – system should make changes throughout the entire document.
- Additional details and instructions in the use of the QM-016 manual template are included in a separate file “QMS-Template-Instructions”.

Additional documentation review.

- Similarly, the blue text and suggestions displayed in the QMS documentation (that will follow) for the procedures, instructions, attachments, forms, and flow diagrams are intended to offer some options and to highlight the areas that require update or replacement.

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1.0 Purpose/Scope

1.1 This procedure describes the quality management system (QMS) processes for ensuring control of the initial release and changes to the documented information essential for the production or services provided by Your Company.

1.2 The procedure applies to all documented information essential to the product or service and to the procedures defined as essential to the operation of the QMS.

2.0 Responsibilities and Authorities

2.1 The Quality manager / Quality team leader / Management representative has the prime responsibility and approval authority for this procedure.

2.2 In support of the Quality manager, the Quality team / ISO steering committee is responsible to ensure that personnel have access to and are aware of relevant QMS documentation and changes.

2.3 Additional responsibilities for the document owner, the document control coordinator, department managers, engineers, employees, and the Management rep are detailed in relevant paragraphs of section 5.0 below.

3.0 References and Definitions

3.1 References.

3.1.1 This document addresses clause 7.5 of the IATF 16949:2016 standard covering, Documented information.

3.1.2 QM-016 Quality Manual.

3.2 The documented information collectively describes the QMS where a typical pyramid-shape documentation structure provides for:

- Tier I - Manual
- Tier II - Procedures (P-xxx)
- Tier III - Work Instructions (WI)
- Tier IV - Quality Records

3.3 Definitions: Definitions related to this procedure are provided in the document numbering instruction WI-750-001.

4.0 Resources

4.1 None, (unless an electronic document control system is used).

5.0 Instructions

5.1 The QMS includes the documented information required by the IATF 16949:2016 international standard and the documented information determined to be necessary for an effective QMS.

1.0 Purpose/Scope

1.1 The purpose of this procedure is to describe the system that provides controlled conditions under which the production processes are performed at Your Company.

1.2 The procedure applies to the release of products and services.

2.0 Responsibilities and Authorities

2.1 The Quality manager has the prime responsibility and approval authority for this procedure.

2.2 In support of the Quality manager, the Quality team / ISO steering committee is responsible to ensure that processes are performed under controlled conditions.

2.3 Additional responsibilities for the Quality manager / quality team are detailed in relevant paragraphs of section 5.0 below.

3.0 References and Definitions

3.1 References: This document relates to clause 8.6 of the IATF 16949:2016 standard, covering release of products and services.

3.2 Definition: Production processes: Processes that contribute or result in the product or service being produced or the product or service being provided.

4.0 Resources

4.1 As listed in the applicable production documentation.

5.0 Instructions

5.1 In support of the procedure P-851 for control of production and service provision, this procedure addresses the control of changes and the post-delivery activities.

5.1.1 The Quality team / ISO steering committee ensures that systems are implemented under controlled conditions.

- The documented information for production and service provision are included in the QMS-Process identification worksheet, F-440-001.

5.2 A suitable infrastructure and process environment include manufacturing equipment where production processes are controlled and managed to achieve product conformance and continual improvement.

5.3 Release of products and services is performed after the verification activities at the appropriate stages ensure that product and service requirements are met. An example of a typical inspection report, form F-910-004 can document results.

5.3.1 Product release criteria and product release authority are documented on

5.1.3 Executive Management may require that the performance of certain processes be monitored using statistical techniques to ensure the required level of performance.

5.1.4 Statistical Techniques may be applied, as necessary, to the following:

- Control of process performance.
- Corrective and preventive action analysis and effectiveness.
- Customer complaints.
- Customer perception survey feedback.
- Establishment of sampling plans for inspection and testing.
- Evaluation of non-conformance defect categories.
- Evaluation of the measurement system.
- Set up of process equipment.
- Testing and validation of processes.
- Testing and validation of produce / service designs.
- Any other company wide situations that require statistical monitoring.

5.2 Statistical Sampling.

5.2.1 When specified, statistical sampling is used for new product or service design, verification of those designs, incoming inspection, in-process inspection, and final inspection.

5.2.2 The sampling plan to be used for an inspection is documented in the inspection instruction. Where a sampling plan has not been defined, the sampling defaults to C = 0 Sampling Plans.

5.2.3 For attribute data sampling, the acceptable level is zero defects.

5.3 Review of Sampling Methods.

5.3.1 The Management Representative regularly evaluates the suitability and effectiveness of the sampling methods that have been utilized. The evaluation is performed by analyzing trends in product nonconformances, audit findings, customer survey perception feedback, customer complaints and other various feedback information.

5.3.2 If the sampling plans are not effective, they are modified to improve their effectiveness. Regular evaluations may also determine that the statistical techniques in use are no longer of any value and the recommendation to discontinue or modify, would be made.

5.4 Analysis and use of data.

5.4.1 Quality and operational performance trends are compared with progress toward objectives and results in actions to support:

- Development of priorities for prompt resolution of customer-related problems.
- Determination of key customer-related trends and correlation to aid in status review, decision making and longer term planning.
- An information system for timely reporting of product information resulting from actual use.

5.4.2 A method of analysis is provided with procedure P-913 for root cause analysis.

6.0 Forms and Documented Information

6.1 F-911-001 Frequency Distribution Report

6.2 P-720 Competence and awareness

6.3 P-910 Monitoring, measuring, analysis, and evaluation

6.4 P-913 Root cause analysis

6.5 List the forms that you have referred to above. These forms, charts and summaries may be system generated and are typically standard and are controlled.

- Assign form control numbers such as F-911-001 for the Frequency Distribution Report.
- List records that must be maintained and add them to the Quality Records Table.
- Reference input and output requirements for management review meetings.

7.0 Opportunities and Risks

7.1 The planning procedure P-600 for Planning for the Quality management system addresses opportunities and risks (risk-based thinking).

7.2 As applicable to your company, make use of your organizational knowledge, lessons learned and experience with the activities associated with **Statistical techniques** to determine the opportunities and risk that need to be addressed and that can:

- Give assurance that the procedure can achieve its intended result(s).
- Enhance desirable effects, and prevent or reduce undesired effects.
- Achieve improvement.

8.0 Revision History

Revision	Date	Section	Paragraph	Summary of change	Authorized by
A				**Initial issue**	

INSERT YOUR COMPANY LOGO/NAME HERE

F-740-001
Comment and Suggestion Report

Instructions

- You are encouraged to make comments and/or suggestions for the improvement to the QMS known to your supervisor.
- Use the form below to communicate your suggestions and/or comments to ensure are noticed so that prompt reporting and subsequent timely improvement actions can be initiated.
- Your inputs can be reported by filling out this simple form available at the ISO bulletin boards.
- Your inputs can be reported verbally, in which case, your supervisor fills out the form below.
- Thank you; we appreciated your help and efforts in improving our quality performance.

QMS Comment and Suggestion Form	
Name: _____	Date: _____
Location:	
Equipment:	
Description of your observation / comment:	
Suggested improvement action:	
Supervisor remarks:	
Action taken:	

INSERT YOUR COMPANY LOGO/NAME HERE

F-750-006
Document Revision Checklist

Document Name:		**Document Number:**
Changes	Revision approved by supervisor and plant quality control	
	Accept previous changes	
	Update header to current date	
	Date all attachments (new or changes only)	
	Update page numbering	
	Make new changes using revision tool	
	Run spell check	
	Reprint original (white paper), including all attachments	
	Password protect document	
Master List	Update document information in the master list including date, records, attachments, related documents and references.	
	If form, attachment or reference changes, search master lists for other affected documents and issue a document change request form. New references require number identification.	
	If there are related documents, check to see if review or changes are indicated.	
Training	a) Determine level of training required with supervisor (NN, RQ, EM)	
	b) Update training summary date of revision and level of training required for the revision	
	c) Check training summary for list of individuals trained on the document	
	d) For required training send change memo to supervisor listing individuals to be trained	
	e) For employee training send memo to manager or supervisor in charge of employee training	
Approval	Give new original and attachments to supervisor and quality control to sign	
Distribution	a) Check distribution summary for listing of controlled copies	
	b) Copy onto controlled paper.	
	c) Remove obsolete master copy and stamp it “Obsolete”. Attach change request and file in the “Obsolete” binders.	
	d) File new original in master binder	
	e) Distribute controlled copies as indicated by controlled copy list.	
	f) Remove & discard obsolete controlled copies.	

NN=None Needed RQ=Required EM=Employee Meeting O=Original, no revision yet

INSERT YOUR COMPANY LOGO/NAME HERE

EQUIPMENT PROBLEM REPORT

EQUIPMENT DESCRIPTION: _____

LAST TASK PERFORMED: _____

JOB NUMBER: _____

DATE: _____ TIME: _____

OPERATOR: _____

REPORTED BY: _____

DESCRIPTION OF PROBLEM:

ACTION TAKEN

PROBLEM INVESTIGATED BY: _____

PROBLEM RESOLUTION DATE: _____