ISO/TS 16949:2009 into IATF 16949:2016 - QMS Transition Checklist

This instruction / checklist is intended for use in upgrading your Quality Management System for the transition from the ISO/TS 16949:2009 version to the IATF 16949:2016 revision for Quality management systems used in the automotive production and service parts industries.

The above Quality Management Systems are compatible with each other and have common requirements.

In the Automotive Standard IATF 16949:2016, the requirements are described in:

- Clause 4 Context of the organization
- Clause 5 Leadership
- Clause 6 Planning
- Clause 7 Support
- Clause 8 Operation
- Clause 9 Performance evaluation
- Clause 10 Improvement

Previously in ISO/TS 16949:2009, the requirements were described in:

- Clause 4 Quality management system
- Clause 5 Management responsibility
- Clause 6 Resource management
- Clause 7 Product realization
- Clause 8 Measurement, analysis, and improvement

You have the 2009 version in place and now have the objective of upgrading the system to the 2016 revision. The good news is that since you are familiar with formal management systems, this initiative will be relatively straightforward.

Essentially, the documentation package for the management system will contain:

- One condensed Manual to introduce the documented information required for IATF 16946:2016.
- A group of procedure/system documents in your QMS with updates to reflect a document numbering system related to the new clause numbers and to incorporate the upgrades for the IATF 16949:2016 requirements,
- A group of forms and attachments needed for the documented information and systems.

The documentation will need to be reviewed, upgraded, and implemented. The first step is to assign a person responsible for the QMS, such as with a Management Representative to become familiar with the changes for the 2016 version of the IATF standard. Visit the 16949store.com for training materials, resources, and information on quality management systems requirements.

The following table with detailed instructions focuses on the areas of the documentation required for the IATF 16946:2016 quality management system. As you undertake the task of upgrading your quality management system from the 2009 version to the 2016 version, note that the intent of the main clauses is shown in blue font, and in the 2nd left hand column of the instructions, the text in *italics* indicates where requirements were included in previous ISO/TS 16949:2009.

The new IATF standard incorporates the requirements of ISO 9001:2015, and in the first left hand column of the instructions, the clause numbers highlighted in green indicates where specific IATF 16949 additions are made to ISO 9001:2015.

You will need copies of the IATF, the ISO and ISO/TS standards along with this instruction to pinpoint for your organization the areas that need attention. You may want to make notes and add comments in the space available to the right and the left of the column for reference documentation. Use the upgrade checklist section on the right side of the table to assign the responsibility for the upgrade and to follow up on its completion.

ISO/TS 16949:2009 into IATF 16949:2016 - QMS Transition Checklist

IATF 16949:2016 Clause	Changes to the existing ISO/TS 16949:2009 Quality System	Reference document	Changes in existing documentation	Upgrade Checklist	
				Assigned to:	Date Completed
All	The International Automotive Standard IATF 16949:2016 is restructured and contains 10 sections or clauses numbered 1 through 10. It is important to note that the standard is revised to incorporate the new clause structure and content of ISO 9001:2015. Also, new automotive industry requirements, definitions, and notes are included.	IATF 16949:2016	The requirement clauses of the new standard are the Clause 4 through Clause 10. Your company needs to become familiar with the new structure and the changes and subsequently upgrade the Quality Management System (QMS).		
All	While the specific requirement for a quality manual is not in ISO 9001:2015, the new standard requires a Quality Manual as part of the Documented Information be maintained for the QMS.	Manual	Replace / rework your existing Quality Manual with a condensed version that will introduce the quality system. The format and structure of the quality manual is at your discretion and will depend on the size, culture, and complexity of your company, see also clause 7.5.1.1.		
---	*In ISO/TS 16949, the requirement for a Quality Manual was in clause 4.2.2.*	Manual	In the condensed manual include sections for: • Scope of the Quality Management System (QMS) • Distribution Control List, • Revision Status, • Quality Policy and Objective, Strategic Direction, Corporate Policies • Organization Chart, • Company Background - Products and Services, • Process Flow Diagram, • List of Documented Information, • Records Documentation Matrix.		
---	The specific requirement for documented procedures is not in IATF 16949; however documented information is required to plan, establish, implement, and maintain the QMS processes. *In ISO/TS 16949, the requirement for control of documents was included in 4.2.3, and the requirement for control of records was in 4.2.4.*	Documented information	The QMS documented information may be presented in any suitable format such as in a method, an instruction, a system, a process, a procedure, etc. You will need to add / replace / rework your QMS procedures to incorporate the IATF 16949:2016 requirements. An early consideration is the development of a process for the control of documented information. Replace / rework the documented procedures for Control of Documents and Control of Records with a		

			procedure, (such as P-750) for Documented Information and include it in section 7.5.		
4	**For ISO 9001:2015**, this clause introduces two sub-clauses relating to the context of the organization, (1) understanding the organization and its context and (2) understanding the needs and expectations of interested parties. Together they require that you determine the issues and requirements that can impact on the planning of the QMS. In addition, the scope of the QMS and the QMS processes along with their applicability and interactions need to be determined. **For IATF 16949:2016**, sections are introduced to supplement requirements for the scope of the QMS, customer specific requirements, conformance of products and processes, and product safety.				
4	Clause 4, Context of the Organization is a new requirement in IATF 16949:2016.	Documented information	Your company must determine the issues and requirements that can impact on the planning of the QMS and that can affect the ability to achieve the intended results of the QMS. For typical guidance, see procedure P-400 for Organizational context and worksheet, F-440-002 to identify issues and requirements.		
4.1	Documented information for the QMS sets the stage for an understanding of the requirements and of the international standard.	Procedure	Document the information (in a document P-400, Organizational Context) to outline the process to understand and determine the internal and external issues that are relevant to the QMS.		
4.2	A stakeholder approach provides for an understanding of the requirements of interested parties.		Include (in a document P-400) the process to understand and determine the needs and expectations of interested parties.		
4.3	Clause 4.3 covers the requirement for the scope of the QMS. *In ISO/TS 16949, the scope of the QMS was required to be included in a quality manual per par 4.2.2 a.*		Include P-400, the process to determine the scope of the QMS. Refer to 4.3 a) thru c) and consider the internal and external issues, the requirements of interested parties, and your products and services.		
4.3.1	For IATF 16949, the requirements for determining the scope of the QMS are supplemented.		Include in the scope of the QMS, the supporting on-site or off-site functions, such as design centers, corporate headquarters, and distribution centers.		
4.3.1	For IATF 16949, an exclusion is only permitted for clause 8.3, design and development of products. *In ISO/TS 16949, the application and exclusion of requirements were included in par 1.2 and the only exclusion permitted is clause 7.3, design and development of products and services.*		If your company does not design and develop products or services, include justification for the exclusion of clause 8.3. Note that conformity to IATF 16949 can only be claimed if the exclusion does not affect your ability or responsibility to meet product and service requirements and enhance customer satisfaction.		

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: _____