Chapter 1: Quality Documentation Overview

Contents:

0) Introduction

The purpose of this chapter is to give an early idea on the QMS documentation for IATF -certified organizations. There are more discussions on document and record control in Chapter 17.

1) 4.4.2 Documentation of QMS) (ISO9001)

(Clause Description-Paraphrase)

As necessary, the organization shall: (a) maintain documented information to support the operation of its processes; b) retain documented information to have confidence that the processes are being carried out as planned.

(Highlights of the Clause)

- (Ref old standard). This is not new as documentation had always been the practice in ISO and IATF systems
- Organization now have more discretion on documentation- what type, how many and the formats to use
- One notable change is there are some changes on the terminology used
- Another notable change is documented information now stands for both document and records. Only the prefix helps to differentiate which is which. 'Maintain' means document and 'retain' means records.

(Compliance Best Practice)

4.4.2 Documentation of QMS
See 7.5.1.1 for a combined discussion

2) 7.5.1.1 QMS Documentation (IATF16949)

(Clause Description-Paraphrase)

QMS shall be documented and shall include a Quality Manual, although it can be a just a collection of key documents. And documentation can be either in hardcopy of electronic copy.

The minimum documented information required for QM are:

a) Scope of QMS, including exclusions and justifications
b) Documented processes established for QMS, or reference to them (e.g a table, a list or a matrix)

c) Processes and interactions, including type and extent of control of any outsourced processes (including process map, interaction, process maps and turtle diagrams). Outsource controls sheets is required, if applicable.
d) CSR and where they are addressed in the QMS documentation.

Matrix can also be used for (b) where the clauses are matrix with the QMS processes. We can use this in place of document master list. The original NOTE has been modified by SI-5 to state the Matrix is an option and not mandatory.

(Highlights of the clause)

- (Ref to old Standards) This a totally new clause.
- ISO9001:2015 had made some drastic changes, which are in some ways controversial e.g. dropping the QM and preventive actions.
- IATF seemed to have reservations and require some omitted items to be added back e.g. manual and preventive actions. IATF however compromised by allowing a simplified version for Quality Manual. See clause description.

Compliance best Practice)

7.5.1.1 QMS Documentation

1. *You are only required to understand ISO's new stand on documentation. There is no need to make any changes. You can keep full documentation and continue to use the old terminologies e.g. 'document' and 'records' instead of 'documented information'.* ***(See Exhibit 1-1).*** *So it is your choice: change or maintain.*
2. *For IATF, the QMS still needs to be documented, with a Quality Manual. The Manual can be a full manual (copy-and-paste from IATF16949:2016 with some modifications), or a simplified manual consisting of key documents and a master list. See Clause Description a) to d). Also see* ***Exhibit 1-2***
3. *It is recommended to use a matrix to summarize your compliance approaches to the various ISO/IATF Clauses. The Compliance Matrix should also link through to your procedures or WI. See* ***Exhibit 1-3.***
4. *Therefore, with a combination of simplified Quality Manual, and a Compliance Matrix, the full QMS is documented*

3. SI & FAQ

SI No	IATF Clause	Description
5	**7.5.1.1 Quality management system documentation**	The quality manual shall include, at a minimum, the following: a) the scope of the quality management system, including details of and justification for any exclusions; b) documented processes established for the quality management system, or reference to them; c) the organization's processes and their sequence and interactions (inputs and outputs), including type and extent of control of any outsourced processes; d) a document (~~**i.e., matrix**~~ **for example, a table, a list, or a matrix**) indicating where within the organization's quality management system their customer-specific requirements are addressed. ***Rationale for change:*** *Some CBs and organizations wanted clarification that a matrix was not a mandatory document. A matrix is just one of multiple methods that are acceptable. The format used is up to the organization.*

FAQ	IATF Clause	Questions and Answers
1	**Foreword – Automotive QMS Standard**	**QUESTION:** **Why are there two manuals (IATF 16949:2016 and ISO 9001:2015)? Two manuals instead of one manual makes it much more difficult to read and understand the requirements.** **ANSWER:** The IATF and ISO were not able to reach a licensing agreement to publish IATF 16949 in an integrated document. In order to not further delay the launch of the new IATF 16949 standard, the IATF decided to publish in a two-manual format. Prior to release, the IATF did confirm with international accreditation organizations that other industry sectors use a two-manual format model to define their sector specific requirements, and auditing with the two-manual model, while not optimal, is effective. The IATF maintains strong cooperation with ISO by continuing the liaison committee status ensuring continued alignment with ISO 9001.
2	**Foreword – Automotive QMS Standard**	**QUESTION:** **Why are the two manuals (IATF 16949:2016 and ISO 9001:2015) so much more expensive than the ISO/TS 16949 version?** **ANSWER:** Without the co-licensing agreement between ISO and the IATF for the integrated format of IATF 16949, the IATF was not able to negotiate a discount for the ISO 9001:2015 standard. The IATF kept the price of the automotive specific content consistent with prior pricing. Essentially, the difference is the full list price to ISO for their publication of ISO 9001.
8	**7.5.1.1 Quality management system documentation**	**QUESTION:** **Does the document (which could be a table, list or a matrix) have to include non-IATF OEMs and Tier 1s? Do all customer requirements beyond CSR's need to be included in the document?** **ANSWER:** The organization is responsible for evaluating customer requirements, including customer-specific requirements, and including them in the scope of the organization's quality management system, per IATF 16949, Section 4.3.2. A document (which could be a table, a list or a matrix) is required as part of the quality manual, per IATF 16949, Section 7.5.1.1 d). The document shall include <u>all</u> direct customers of the certified organization, which may include IATF OEMs, non-IATF OEMs, and other automotive customers (i.e. tier-1, tier-2, etc.). For example, a tier-2 organization must consider the customer requirements, including customer-specific requirements, of all its customers. The Tier-2 organization does not need to consider the customer requirements of the automotive OEM if the OEM is not its direct customer. It is important to note that the non-IATF OEM customers and other automotive customers may have customer requirements in an internal document that is shared with their suppliers (e.g. such as a supplier quality manual) or in a specific document available to the public (e.g. internet).
8 (cont.)	**7.5.1.1 Quality management system documentation**	Identifying customer-specific requirements may be difficult if the non-IATF OEM or other automotive customers do not clearly link to IATF 16949 clauses in their customer requirement documents. A way to identify if any customer-specific requirements exist is to compare sections of the IATF 16949 standard where the term « if required by the customer » exists and verify if the existing customer requirement document lists any specific requirements that are related to a requirement in the IATF 16949 standard. If yes, that customer and their requirements should be added to the document (which could be a table, a list or a matrix) in the quality manual. Organizations are <u>not</u> expected to take the customer's requirements, including customer-specific requirements, and convert them into a CSR format that aligns with the IATF 16949 clauses similar to what has been published by the IATF OEMs.

FAQ	IATF Clause	Questions and Answers
12	**Throughout the IATF 16949 Standard**	**QUESTION:** **Is it acceptable to document multiple processes in one "documented process"? Or do they each have to be individual documented processes?** **ANSWER:** Yes, it is acceptable for an organization to group multiple documented processes into one (or more) processes. Each documented process does not have to be a standalone process. Organizations should document their processes as it makes sense to their individual business and organizational needs.

4) Supplementary Notes

Legend: HOC= Highlights of Clause, CBP= Compliance Best Practice, S&Q= SIs & FAQ, EXH= Exhibits

Clause	Section	Clarification Subjects
7.5.1.1	CBP	**SN1.1. Why choose a simplified Quality Manual?**
7.5.1.1	CBP	**SN1.2. Why prepare a compliance matrix when it is not compulsory?**
7.5.1.1	CBP	**SN1.3. Is writing a compliance matrix time consuming? Is there a simple solution?**
7.5.1.1	CBP	**SN1.4. When writing the Manual, are the 2 standards i.e. ISO9001 and IATF16949, sufficient as reference?**
7.5.1.1	CBP	**SN1.5. How extensive shall we provide for the lesser documents, such as procedures and work instructions?**
7.5.1.1	CBP	**SN1.6. Can we go 100% paperless for documentation?**
7.5.1.1	CBP	**SN1.7. What is the best way to keep the hardcopies of document and records?**

SN1.1. Why choose a simplified Quality Manual?

A simplified Quality Manual is better. It tells the gist of the QMS in fewer pages, which is useful for searching information and for training. Your customers, and external auditors would also be happy to see an easy-to-use manual.

SN1.2. Why prepare a compliance matrix when it is not compulsory?

A simplified manual has limited information. How do you show compliance on the rest of the Standard? Yes, you are allowed to provide the minimum, and chances is you will keep the minimum. On audit days, you will find it hard to answer some questions, with so little information noted down. A Compliance Matrix anchors down your compliance methods, concepts, and assumptions, in point form or short phrases. So you can handle questions easier and faster.

SN1.3. Is writing a compliance matrix time consuming? Is there a simpler solution?

Yes, writing a compliance matrix takes time. There are 2 time-consuming parts: a) making decisions on how to comply to all the requirements, b) the writing part of it**.** Part a) is expected of you, whether you write or otherwise. Part b) is little hard if language is not part of your forte. The Compliance Matrix template can help. What you see in **Exhibit 1-2** is a snippet of 2 pages. You can purchase an editable set of exhibits. The editable template of compliance matrix has all 26 pages given, and in semi-finished form. All you need is to edit on them to create your Compliance Matrix (and also the QM) in no time. See back of the Reference Manual for details.

SN1.4. When writing the Manual, are the 2 standards i.e. ISO9001 and IATF16949, sufficient as reference?

No, the two standards are not enough. A peculiar point with IATF16949 is that there are three other reference documents used. They are: a) Rules 5th Ed, b) Sanction Interpretations (SI), and Frequently-

Ask Questions (FAQ). Note that the SI represents official updates. An SI's creation will supersede the corresponding clause (or part of it). Therefore, the Standard is not 100% current now, and you need to check the SI for see the latest picture. At the time of writing, there are already 18 SIs , and 29 FAQs introduced. For your convenience, we have included the relevant SI and FAQ in each chapter.

SN1.5. How extensive shall we provide for the lesser documents, such as procedures and work instructions?

The discretion is yours. However, IATF auditors do need a fair amount of information for reporting. Adequate documentation is appreciated. If you have a lot of information gaps, you need to help out by answering more questions. It can be a lot of legwork too, going round to find people and evidences. It is therefore better to keep adequate documentation for audit.

SN1.6. Can we go 100% paperless for documentation?

Yes, you can. IATF has no objection to that. There is a caveat though: make sure you have enough projectors to use during the audit. I had an experience where there was only 1 projector but 3 auditors queuing to use it. It would be unacceptable as the audit is held up. Also you need to consider your own internal capability. Can paperless be fully implemented throughout the organization, all at once?

SN1.7. What is the best way to keep the hardcopies of documents and records?

All the guiding documents should be in a common binder. You may call it QMS Binder, or something else of your preference. They normally include the QM, its attachments, compliance matrix, procedures and also a copy of the ISO9001 & IATF16949 standards. WIs are normally kept by the respective departments and not in this folder, although you can have a master list here for reference and tracing. To hold all these documents, the binder should be 2 inch thick. Analytical and other reports are bulky and should be kept in other binders, or by process owners. You should have a document guide to show where the documents and records are found.

5. Exhibits

Exhibit 1-1. Annex A1 statement on Changing over to New Terminology

Annex A

(informative)

Clarification of new structure, terminology andconcepts

A.1 Structure and terminology

The clause structure (i.e. clause sequence) and some of the terminology of this edition of this International Standard, in comparison with the previous edition (ISO 9001:2008), have been changed to improve alignment with other management systems standards.

There is no requirement in this International Standard for its structure and terminology to be applied to the documented information of an organization's quality management system.

The structure of clauses is intended to provide a coherent presentation of requirements, rather than a model for documenting an organization's policies, objectives and processes. The structure and content of documented information related to a quality management system can often be more relevant to its users if it relates to both the processes operated by the organization and information maintained for other purposes.

There is no requirement for the terms used by an organization to be replaced by the terms used in this International Standard to specify quality management system requirements. Organizations can choose to use terms which suit their operations (e.g. using "records", "documentation" or "protocols" rather than "documented information"; or "supplier", "partner" or "vendor" rather than "external provider"). Table A.1 shows the major differences in terminology between this edition of this International Standard and the previous edition.

Table A.1 — Major differences in terminology between ISO 9001:2008 and ISO 9001:2015

ISO 9001:2008	ISO 9001:2015
Products	Products and services
Exclusions	Not used (See Clause A.5 for clarification of applicability)

Remarks given in this section explain on the exhibit. Do not include them as part of the form.

- This answers many people's doubt about need to change over to the new terminology.
- Even in the IATF 16949 Standard, suppliers, documents, and records are still mentioned here and there.

Exhibit 1-2. A Simplied Quality Manual

QUALITY MANUAL
Template Technology
In Compliance to ISO9001:2015 & IATF16949:2016

1. The Commitment

Template Technology has made a commitment to institute a Quality Management System based on ISO 9001:2015 & IATF 169494:2016.
Through this document and other communication means, we strive to make known of this intention to all our employees, suppliers and major customers, whose understanding, cooperation and assistance are vital to the success of this project. Any suggestions to improve quality of our services and customer satisfaction will be most appreciated.
This Quality Manual summarizes the key information of our QMS. We also have a Matrix to show how every clause is complied.

2. Organization Profile

Template Technology was formed in 1990, and specializes in the production of precision plastic parts in support of automotive, electrical and electronics and other manufacturing industries.
In general, we have the necessary expertise, manpower, equipment and facilities to carry out our business activities. Our intention to place our operations under the ISO9001:2015 & IATF16949:2016 framework is another effort to maintain a consistently high standard in our products and services.

3. Scope

The scope of our QMS certification is "Precision Plastic Injection Moulded Parts & Assembly".
Product Design is not applicable as customer provides drawings and technical specifications. Hence, Clauses 8.3.3.1, 8.3.2.2 and 8.3.5.1 are not applicable.

Addresses of our sites, remote locations/support functions and sites we support are :
Our manufacturing centre is located at:

Site	Name of Organization & Address	Scope
1	**Template Company** No. 35 Excellent 6 Avenue Excellent Industrial Estate Shah Alam, Selangor, Malaysia	Precision Plastic Injection Moulded Parts & Assembly

Remote Support Sites are:

RL	Name of Organization and Address	Support services Received
	NA	

4. QMS Processes

- Our process map shows the processes and their types. A box- and-line process flow chart shows the sequence and interaction.
- All manufacturing are performed inhouse, and there is no outsourcing for the moment.
- The individual processes are further presented as turtle diagrams. Each process owner has a copy of the turtle diagram.
- Risk and opportunity analysis has been conducted for both external and internal contexts. A full set of the turtle diagrams is maintained by the document controller. Each process owner has his/her own copy.

5. Documentation levels

Our QMS is structured in several categories of documentations, namely:

a) Strategic Studies (Risk and Opportunity Analysis, Scope, Needs and Expectations of Interested Parties. Contingency Plans, Organization Knowledge, Customer Specific Requirements, and other important documented information)
b) Process Maps and Turtle Diagrams, box-and-line process flow chart
c) Quality Manual
d) Quality Procedures,
e) Work Instructions, Checklists, forms and formats

f) Supporting Documents e.g. quality records, external document etc.

A copy of the documented processes are attached to this manual

6 Organization Structure, Roles and Responsibilities

The organization structure of the company can be simply illustrated by the organization chart (Attachment A). To maintain cost competitiveness, many of our employees are multi-taskers doing an assortment of jobs, often from the various departments. Hence our organization structure is very simple. Job Descriptions have been prepare for each job positions, maintained by the HR Department.

7. Quality Policy and Objectives

The Management has undertaken a strategic study on the Organization to understand the key issues and problems concerning the operations. Based on these findings and our own vision, we have decided on a Quality Policy which is subject to review from time to time.

7.1 Quality Policy

We are committed to:

a) maintain high quality products and services to our customers
b) review the suitability of the QMS, the Quality policy and Quality objectives at least once a year
c) applicable requirements of interested parties shall be complied to
d) apply the principles of continual improvement

This Policy has been prepared as Posters and displayed at strategic places of the company to promote awareness.

7.2 Quality Objectives

The Quality Objectives (called KPI) are prepared on a annual basis for each process based on the processes and also to deploy the Quality Policy.

8. Customer Specific Requirements

Customer Specific Requirements are prepared from customers' supplier quality manuals. In the absence of SQM, CSR is prepared from the transaction history or knowledge gained from interactions with the relevant customers.

9. Language

This QMS documentation was originally written in English. Subsequent translations in any other languages shall be treated as reference copies only. In case of contradictions, the English version shall prevail.

9. Separate Revision Control

Attachments are on a separate revision control basis, and not fully tied with that of the Quality Manual. Any updates (changes) on the attachments would only affect the revision status of relevant attachment, and not that of the Quality Manual.

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John E Long
Managing Director

Attachments :

A. Organization Chart
B. QMS Team
C. KPI list
D. Matrix between ISO IATF16949:2016 and our QMS
E: Process Maps
F: Turtle Diagram Master List
G. Quality Procedures Master List
I: Quality Records, Retention Period and Filing Details
J Quality Policy Poster
K. Strategic Analysis Master List
L: CSR Master List

Exhibit 1-3. A Compliance Matrix

ISO16949:2016 Adequacy Matrix
ISO9001:2015(Black Fonts(IATF16949:2016 (Blue Fonts)

ISO16949:2016 Requirement	Compliance Details	Relevant Document Location
1. Scope	Title Only	
1.1 Scope-Automotive supplement to ISO9001	Scope is defined in the QM. Our remote support sites and services provided are also given	QM Clause XX
2. Normative references	As per ISO9001:2015 Fundamentals and vocabulary. Understood, However, some of the old terms such as suppliers, document and records are used in synonymously until further decisions	
2.1 Normative and informative references	Annex C control plan is part of the standard. Annex E is only for information. Shall comply	IATF16949:2016 Standard. Annex Section
3. Terms and Definitions	Abbreviations and definitions given in ISO9001: 2015 and additional ones given in IATF below. Shall comply	
3.1 Terms and Definition for automotive	Additional abbreviations and definitions for automotive use. Shall comply	IATF16949:2016 Standard
4. Context of Organizations	Title only	
4.1 Understanding the organization and its context	External Analysis and Internal Analysis have been carried out. External is based on the model recommended by ISO9001:2015. Internal analysis is based on each QMS process.	Attachment XX
4.2 Understanding the needs and expectations of interested parties	Interested parties and their needs and expectations (IPNE) has been carried out	Attachment XX
4.3. Determining the Scope of QMS	Scope of registration, addresses of sites, addresses of remote location/support functions are given in QM Section XXXX	QM Section XXXX
4.3.1 Determining the scope-supplemental	See 4.2 above	QM Section XXXX
4.3.2 Customer-specific requirement	CSR Summaries have been compiled for each customer	QM Section XXX, Attachment XX
4.4, 4.4.1 QMS and its processes	Our Process Map is based on the MP-COP-SP Process Mapping. There is also a business flow chart to show how all the processes, their sequence and interactions. Each process is represented by a turtle diagram.	QM Section XXX, Attachment XX
4.4.1.1. Conformance of product and processes	Understood and will be complied to. Service parts will be given equal attention as production parts. Outsourcing will be controlled including compliance to all customer, statutory and regulatory requirements.	QP7-2
4.4.2.1 Product Safety	Currently not applicable	NA
4.4.2 (Documentation of QMS)	6 categories of documented information involved. Level 1 Context & interested Party Analysis, Level 2. Quality Policy & Objectives, Level 3:Quality Manual, Level 4: procedures, Level 5 Work instructions, Level 6. Forms, Level 5	QP2-1
5. Leadership	Title only	
5.1, 5.1.1 Leadership and Commitment	New requirement fully complied to. Stated in QP 5-1, Management Commitment. Also mentioned in parts in QM	QP 5-1
5.1.1.1 Corporate responsibility	Antibribery and Whistle Blowing Policies available. Displayed at notice board	QM Attachment XXX
5.1.1.2 Process Effectiveness & Efficiency	Annual study (sampling) of process effectiveness and efficiency.	Special report
5.1.1.2 Process Owners	Defined in QMS Team Chart	QM Attachment XXX
5.1.2 Customer Focus	Starts from Management to the lowest member of the company has embraced this concetp	QP 5-1
5.2. Policy	Set and subject to annual review. If appropriate revised	QM Attachment XX
		As posters and displayed at strategic places
5.2.1 Establishing the Quality Policy	Set annually and called 'List of KPI'	QM Attachment XX
5.2.2 Communicating the Quality Policy	Via QM, Policy Posters, Awareness training materials	QM Attachment XX As posters and displayed at strategic places, HR Orientation Materials
5.3 Organizational Roles, Responsibilities, and Authorities	QM, Organization Chart, QMS Team Chart	
5.3.1 Organizational Roles... supplemental	Job Descriptions, List of Process Owners	JD with HR List of Process Owners-QMR/DCC
5.3.2 Responsibility and authority for product requirement and corrective actions	Persons have been appointed to be responsible for taking corrective actions over quality issues. Responsibilities for normal shift hours rest with the production and quality managers. They may assign their assistances e.g engineers, to be responsible. For night shifts, the assigned responsible are usually supervisors or shift/line leaders.	Check with Production and quality as instructions may need to be fluid
6. Planning	Title only	
6.1, 6.1.1 Actions to address risks and opportunities	EXTAN, INTAN, QAP. Achievement and review records	EXTAN-QM Attachment XX INTAN-QM Attachment XX QAP- as directed by EXTAN, INTAN IPNE Review Records
6.1.2 Action Plan	As above	QPXXX
6.1.2.1 Risk Analysis	Requirements are summarized QPXXX	QPXX Form No
6.1.2.2 Preventive Actions	QPXXX NCP, CAPA	No case at present
6.1.2.3 Contingency Plans	Contingency Analysis and Action Plans. Simulation and Review Records	
6.2, 6.2.1 Quality Objectives and planning to achieve them	Process KPI. Adhoc Quality Objectives (ADO)	QM Attachment XX KPI List (with QMR & DCC) ADO (with QMR & DCC)
6.2.1.1 Quality Objectives and planning to achieve them	See above. Tracking progress reports prepared by relevant HOD and submitted to MD	As above Tracking progress reports-HOD, QMR, MD
6.3 Planning of Changes	QP XXX Management Responsibility. Actual records of change projects.	QPXXX Actual projects records: QMR, Engineering, relevant department
7 Support	Title only	
7.1 Resources	Title only	
7.1.1 General	Title only	
7.1.2 People	The headcount is controlled by Top Management. It may vary from time to time. Adequacy can also be judged at a particular point in time, in the manners the various processes are managed	Top Management
7.1.3 Infrastructure	Infrastructure for our operations are buildings, telecommunications, computers and software, working space, production and support equipment. Their status generally decided by Management in consultation with multifunctional teams. They are also reviewed annually, and during reviews of business feasibility.	Equipment changes (acquisition, replacement, overhaul etc)- Top Management & Maintenance Dept Annual review: ISWE review (Maintenance, QMR, Management Review) Project Review: Feasibility Study, including capacity study- BD Dept (Business Development)
7.1.3.1 Plant, facility, and equipment planning	As above	See above

Remarks given here explain on the Exhibit. Do not include them as part of the document

- The Compliance Matrix shown above is only the first 2 out of 26 pages, due to space
- However the 2 pages should give an idea on how a compliance matrix looks like.