REFERENCE MANUAL

BEST PRACTICE

COMPLIANCE TO IATF16949:2016 AUTOMOTIVE QMS

With Templates
& Specimens

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STANDARDS

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ISO9001:2015(Black Fonts) IATF16949:2016 (Blue Fonts)

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How to Use This Reference Manual

Timing

If you are preparing for an upcoming surveillance audit, you should browse through the Exhibits section of each chapter first, to see what you can pick up to deal with your immediate concerns. It may be about an OFI raised during the last audit. Or it may be something the auditor had hinted he/she will check this time around. At the bottom of each exhibit, there are notes explaining its usage. If the exhibit notes are not informative enough, you can go to Best Practice section where more explanations are given. Exhibit No's are given in Best Section in bold, for easy identification.

If you have just finished with an audit, and looking for answers to close out some of the NCs, you need to go to the "Clause to Chapter" to trace down the relevant chapter first. When you have found it, you should read through the whole clause, including the Best Practice section, to understand the issue and to formulate your replies.

If you are the QMR, you should ask your process owners to read up their respective sections to understand more, to prepare for the audit. They can download this full manual, or just their sections (chapters) which are separately available on the website.

For those who have no time pressure, you are free. You can read up in any manner, as and when you feel like.

DIY (do-it-yourself) a QMS System

If you are establishing IATF QMS for the first time, you may be tempted to use this reference manual to DIY your system. But hold. You need a certain level of QMS knowledge and experience to piece up the whole thing. If you have them, by all means go ahead. Otherwise, it is advisable to engage a consultant to guide you through. You may propose to him/her to base on this manual, so that you have a permanent reference manual to fall back on, after the project. Or you may take the DIY route, but retain a consultant for advice, with less visits (say start, mid, and end). Besides consulting work, you may also need the person to run the 2 required training (awareness and internal audit), which are normally billed separately. With this method, you should be able to save some money and gain a lot of flexibilities.

I am now contacting my consulting friends around the world to explore the possibility of providing such a package. When it is ready, it will be announced over this website.

Do not construct and ISO9001 system based on this reference manual. You will end up with a seriously-oversize system, which will kill you and your colleagues. I am also planning a similar reference manual on ISO9001 shortly. When it is ready, it will be announced over this website. So, hang in there for a little while.

Manual Organization

All clauses of ISO9001 & IATF16949 are grouped into 35 chapters. Each chapter has a common theme, denoted by the chapter number and name. The clauses within a chapter are related to one another, or to the theme. For example, if you are looking for something concerning changes, you should select Chapter 12, Changes Related; and you will find the information there.

However, if you are approaching from a clause no, you should refer to Clause-Chapter matrix (after the table of contents), to bring you to the relevant Chapter. For example, if you want to understanding

more about compliance method on 8.7.1.4, the Clause-Chapter matrix will show 32, meaning the information is in Chapter 32.

Each Chapter consists of a few headings. If the chapter has only one clause, there are 6 headings. However, if a chapter has more clauses, there will be more headings, as each clause is an additional heading. The 6 headings are explain below:

1. The Clause No and Description
   While a clause number is original, the description is not, due to copyrights. Each clause is paraphrased, and simplified where possible, to be understood more easily. Those who need to see the original text please refer to the respective Standards.

2. Highlights of the Clause
   This section starts with a reference to the older version of ISO9001/TS16949. You can see the before and after picture. Important changes and points are also highlighted to show what and where more attention is needed.

3. Best Practice
   This is based on my personal cumulative experiences as both a consultant and an auditor. Best practice is defined as a method complying to the intent of the standard, and yet not too difficult to implement. Besides, it should have some benefits to the organization, in terms of time saving or financial returns. A best practice usually comes with an illustration, a specimen, or a template.

4. SI & FAQ
   These are from IATF website directly. I tried to paraphrase but they became more complicated and unreadable. So they are just 'copy-and-paste' to the relevant chapters. (Intellectual property rights of ISO and IATF on these materials are fully recognised). Now, you have all relevant information under one roof for convenience. An SI, or Sanctioned Interpretation, actually supersedes the IATF clause mentioned, in part or in whole. You need to read it carefully to ensure you are getting the latest picture. FAQs are relatively less important, as they are mere clarifications on clauses, or replying to frequently-asked-questions raised by users.

5. Supplementary Notes
   To maintain the flow and cohesiveness in understanding the chapters, the Best Practices are given in a concise manner, and not expanded too much and too far-off. In some situations, this approach makes the explanation look cut-and-dry and incomplete. This Supplementary Notes section gives more filler facts, and answers to common questions, so you can get a better understanding of the subject.

6. Exhibits
   This are mainly the illustrations, templates, and specimens. They can save you the trouble of having to create them from scratch. You are free to copy for your own use (including for your organization), without infringing copyrights. However, the exemption does not extend to sharing and re-selling of this materials.
   Most of the specimens and templates given are complete except for some very long ones. An example is QMS Compliance Matrix, which runs into 26 pages; only a few pages are given due

to space constraint. However, the pages needed to portray the concept are there. Only the non-essentials and repeating ones are being truncated off.

Additionally, these specimens come in 'filled-up' state, as far as possible. If your QMS documentation is in English and English is not your native language, you will find the phrases and sentences used in the specimens useful to complete your work.

If time is of the essence, you can purchase the editable copies of Exhibits, at a very affordable price. They are not mandatory but can save you the hassles of drawing complicated forms and formats, and hours and hours of typing time. See the website for details.

Comments & Queries

If you have a comment or question, you may send it to my personal email address: jackchiew4@gmail.com. I will try my best to answer all questions. Please attach a copy of your receipt, together with your question.

Please limit your queries only to clarifications on the manual, or use of formats. Your questions may also be uploaded (anonymously) to this website for the benefits of other readers.

Happy reading, and my fervent hope that your work will be made easier, and IATF QMS will improve. Check with the site, once a while, for new announcements and information.

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.

_____

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.

>> End of Chapter 1 <<

Chapter 2. Risk & Opportunity Analysis

Contents:

0) Introduction

This chapter is on risk and opportunity analysis (R&O), which is the greatest change in ISO's approach to ISO9001for this new version. ISO9001 will no longer be one-size-fits-all. The clauses of the Standards while is still useful, will be implemented in reference to risk and opportunities facing an organization.

1) 4.1 Understanding the organization and its context (ISO9001)

(Clause Description-Paraphrase)
The organization shall determine and analyse external and internal issues that are relevant to its purpose and its strategic direction. In particular it should examine those that can affect its ability to achieve the intended result(s) of its quality management system. The organization shall continue to monitor and review information about these external and internal issues.

3 NOTES are provided to clarify what are external and internal contexts. Issues can be both negative or positive and both shall be considered.

(Highlights of the clause)

- (Ref to old Standards).This is a totally new clause.
- ISO is moving a little into strategic management for quality. Instead of prescribing a set of rules and requirements to be followed, it now allows some priorities to be based on risks and opportunities.
- The risks and opportunities (R&O) will be analysed from both external and internal aspects. Both positive and negative issues shall be captured for analysis.
- The analyses need to be monitored and reviewed. In other words, the analysis is not a one-time affair.

(Compliance Best Practice)

4.1 Understanding the organization and its context

1. *For compliance with this clause, a full analysis is required on external and internal contexts of your organization.*
2. *There are guidelines given under NOTES of the Clause, on how to run the analyses. You are also permitted to use other methods, so long they serve the purpose and lead to accurate conclusions.*
3. *For external analysis, you can use the suggested method (based on PESTEL). There are 2 ways this is done.* ***Exhibit 2-1*** *(Type 1) is used in the traditional strategic sense, with both risks and opportunities seen as they stand,* ***Exhibit 2-2*** *(Type 2) shows another method, where opportunities are improvement opportunities rather than windfall.* ***See SN 2.5 and SN2.6.*** *I recommend Type 2, but you can make your decision.*

4. *For internal analysis, most organizations would use the processes (turtle diagrams) as bases of the analysis, which is very practical and recommended.* ***See Exhibit 2-4***
5. *For internal analyses, you should look at only a few major risks, and not everything. See* ***Exhibit 2 - 5A & Exhibit 2-5B..***
6. *After deciding on the potential risks, scoring should begin on each item. Scoring tables are provided. External analysis have both a risk table and an opportunity table. For internal analysis only the risk table is needed. The risk table is a 4X3 scoring table. See* ***Exhibit 2-6.*** ***Also see SN2.7 and SN2.10*** *for explanations.*
7. *After the scoring, the residual risk of each item is derived. See* ***Exhibit 2-1 & 2-3*** *for External scoring, and* ***Exhibit 2-4*** *for Internal. For actions, see Clause 6.1 below.*
8. *Review is required. I recommend an annual cycle as it is easy to remember. Retain the notes made during Review as evidence. See* ***Exhibit 2-9*** *and* ***Exhibit 2-10*** *on how to document the reviews.*

2) 6. Planning, 6.1 Actions to address risks and opportunities (ISO9001)

(Clause Description-Paraphrase)

After the analysis of external and internal context, interested parties and their needs and expectations, follow-up actions may be needed : (a) to ensure that the QMS can achieve its intended result(s); (b) enhance desirable effects; (c) prevent, or reduce, undesired effects; (d) achieve improvement.

(Highlights and Additional Caution)

- (Ref to old Standards). This is a totally new clause
- This clause flowing down naturally from both 4.1 and 4.2. From the analysis on 4.1 (risks and opportunities), and 4.2 (Interested parties and their needs and expectations), there will be a list of conclusions.
- Final action is we must mitigate against risks and capitalize on opportunities

(Compliance Best Practice)

6. Planning, 6.1 Actions to address risks and opportunities

1. *We need to have a system to decide which R&O to adopt. This had been discussed to some extend in Clause 4.1 above. This section discusses a little further and address the question of 'opportunities'..*
2. *For the suggested system here, only a 'risk' table is used for scoring. See (****Exhibit 2-6****). There is no 'opportunity' table.*
3. *When a final score shows up as H or M+, it is a higher risks, and action shall be taken.*
4. *For scores of M and L, they are the lower risks, and actions are optional. However, if actions are taken, they are considered as improvement, or opportunities for improvement.* ***See SN-2.4, SN-2.5, and SN2.8*** *for more explanations.*
5. *How detail show we document the action plans? 3 types of action plans are commonly used: a) bullet points, b) simple action plan, and b) full project plan. Type a) bullet points, is understood by everyone, and therefore not shown here. The other 2 types are shown in* ***Exhibit 2-7 and Exhibit 2-8.***
6. *For recording, action plans can be on the same document of the analyses, as shown in* ***Exhibit 2-11****. Action plans can also be on separate documents, or other documents*

3) 6.1.2.1 Risk Analysis (IATF16949)

(Clause Description-Paraphrase)

The organization shall include in its risk analysis, at a minimum, lessons learned from product recalls, product audits, field returns and repairs, complaints, scrap, and rework. The organization shall retain documented information as evidence of the results of risk analysis.

(Highlights of the clause)

- (Ref to old Standards). This is a totally new clause
- This clause is meant to capture risks rising not detected earlier. Some of the areas/events where risk are found at: Product recalls, product audits, field returns and repairs, complaints, scrap, and rework etc are events that risks can be found; and therefore must be prevented.
- Retain records on such risk studies

(Compliance Best Practice)

6.1.2.1 Risk Analysis

1. *This is a second net to catch risks which may have escaped from the 'context analyses'. This is activated after each failure. Risks associated with the failure shall be analysed and actions taken. The failure list is given in the Clause Description.*
2. *As this secondary capturing of risks involves many departments, a procedure should (not shall) be prepared for use by all. See* ***Exhibit 2-12***
3. *Once a risk is resolved, lessons learned can be updated to the FMEA, control plan and other lesser documents down the line to prevent recurrence.*

4) SIs and FAQs

None for this Chapter

5. Supplementary Notes

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

Clause	Section	Clarification Subjects
4.1	CBP	**SN2.1 Why do we analyse only a few major items for risk and opportunities? There may be risk missed out in the unchecked areas.**
4.1	CBP	**SN2.2 Why not we use the internal analysis method recommended?**
4.1	CBP	**SN2.3 What do we check for during review of risk and opportunities?**
6.1	CBP	**SN2.4 Does it make sense to use risk table to look for opportunities?**
6.1	CBP	**SN2.5 Any evidence that opportunities for improvement can be accepted as 'Opportunities"?**
6.1	CBP	**SN2.6. Is it better to have action plans placed on the same document together with analysis?**
EXH	EXH 2-3	**SN2.7 Why don't we use SWOT for external analysis?**
EXH	EXH 2-1, 2 -2	**SN2.8 For External analysis, there are 2 options to use. Which one is better?**
EXH	EXH 2-5	**SN2.9 Where do I find the major areas for risk and opportunities for internal analysis?**
EXH	EXH 2-6	**SN2.10 Your scoring table is not 3x3, or 5x5. It is 4X3 which is rather unusual. What is the rationale behind?**

EXH	EXH 2-9	**SN2.11 If R&O review ended with changes and revision of document, do I still have to keep the review notes?**
EXH	EXH 2-12	**SN2.12 The procedure shows we have to update so many document, after a risk is captured and resolved. Are we going a little overboard?**
EXH	EXH 2-1	**SN2.13. How do we file the project plans, especially if another department is the process owner?**
6.1.2 b(1)	Clause	**SN2.14. What does integrating and implementing the actions into is QMS processes?**

SN2.1. Why do we analyse only a few major items for risk and opportunities? There may be risks missed out in the unchecked areas.

It is not the intent of the clause to catch every little fish in the pond. Your QMS which is based on the standard will cater for most of the risks; and you don't have to repeat everything here. This exercise is to focus on major potential risks which have significant impact. Analysing too many items is not only a waste of resources, but it also tend to obscure the critical risks.

SN2.2 For internal analysis, why not we use the method recommended?

The method given in the standard is to analyse internal context is rather academic . Automotive organizations have the turtle diagrams that can provide more tangible analysis and evaluation. We should use what gives us a better handle.

SN2.3 What do we check for, during a review of risk and opportunities?

When conducting a review, we should check on: a) adequacy of the list, b) continued suitability of the assumptions and scoring, and c) the action plans. Revise the document as necessary.

SN2.4 Does it make sense to use risk table to look for opportunities?

Yes. In the analysis of organization contexts, the items being analysed will end up either as H, M or L, which stands for high, medium and low. Only the H items are adopted in most situations. And they are just a handful of them, perhaps 5-10%. The other 90-95% of the items are just left to waste. But they represent opportunities for improvement. If adopted, they can make an organization better, more effective and more efficient. Lower risks are therefore opportunities.

SN2.5 Any evidence to support their theory, that opportunities for improvement can be accepted as 'Opportunities'?

We are all conditioned by the SWOT in thinking, and interpreting Opportunities as the opposite of Risks. But that is not the intent of ISO. It did not mention SWOT and did not suggest opportunities must be opposite of risks. Risks and opportunities can be on the same side of the coin. In my model, higher risk are 'risks", lower risks when acted on are 'opportunities'. The model is in no way, in conflict with ISO's definition. See ISO's definitions on opportunities below:

- IATF16949:2016 Clause 0.3.3 states: "Opportunities can arise as a result of a situation favourable to achieving an intended result, for example, a set of circumstances that allow the organization to attract, develop new products and services, **reduce waste or improve productivity**" <author: the favourable situation can be anything, including a weakness, that leads to actions taken>
- ISO9001:2015. 6.1.2 NOTE2. Opportunities <author: opportunity can be anything, including a weakness, that leads to actions taken> can lead to the adoption of new practices, launching new products, opening new markets, addressing new markets, building partnerships, using new technology and other desirable and viable possibilities to address organization's or its customer's needs.

Other ISO Management Systems are even clearer of ISO' bent towards my improvement argument:

- ISO45001:2018. Clause 3.22. OH&S opportunity: "circumstances or set of circumstances that can lead **to improvement of OH&S**…
- ISO22000:2018. NOTE at 6.1.3. Opportunities can lead to the adoption of new practices (modification of products or processes) using new technology and other desirable and viable possibilities **to address the food safety of** the organization or its customers.

ISO14001: 2015. 3.2.11 risks and opportunities. Potential adverse effects (threats) and **potential beneficial effects** (opportunities)

One final point to note is for both ISO9001 and IATF16949, the core theme is quality, and not about investments or business strategies. Hence opportunities should refer to opportunities for improvement within the QMS context. The strategic tools of SWOT or PESTEL if used in the conventional method, is for investments and business strategies.

SN2.6. Is it better to have action plans placed on the same document together with analysis?

There is no right or wrong here, but a matter of personal preference. Personally, I prefer all information on the same page, so I don't have to look elsewhere for the information and data.

SN2.7 Why don't we use SWOT for external analysis?

ISO touches on the elements of SWOT but did not specifically mention the tool. Instead it suggests a method close to PESTEL for external analysis. For internal analysis, it also did not mention about SWOT but 4 angles to study risk and opportunities. Yes, you can use SWOT but you need to use it in a way to show risks and opportunities in sufficient depth, to allow actions to be formulated and implemented.

SN2.8 For external analysis, there are 2 options to use. Which one is better?

Both can be used, so it is a matter of personal preference. Type 1 is based on mainstream strategic approach, and may tangent you off to investment and business strategy mode. Type 2 stays on the subject of QMS risk and improvement, which is the core concern of ISO9001 and IATF16949. There are people who are not comfortable with Type 2, and they can go to Type 1.

SN2.9 For internal analysis, where do I find the major areas for risk and opportunities for internal analysis?

Major or primary risks and opportunities should be concentrating in the output and the KPI areas. Only sparingly can you find a major risk, here and there in the rest of the places. See **Exhibit 2-5A.** You can also start with the purpose of a process, and think of 3-5 major obstacles as the primary risks. See **Exhibit 2-5B**.

SN 2.10 Your scoring table is not 3x3, or 5x5. It is 4 X 3, which is rather weird. What is the rationale behind?

A 4x3 is better than a 3x3 table. The latter results in far too many M (medium risks) that requires further decisions on adoption, as 'M' is an optional area. Since it is an optional area, most people will opt for the easy way-no actions. No action means no benefits to the QMS and the organization. In this 4 X 3 method, there are M+ as well as M in the risks . M+ is higher risk and actions must be taken. M is somewhat safe and actions remain optional. When actions taken on M, it is Opportunity (for Improvement). More action items is the result.

4x3 is better than a 5 X 5. A 5 X 5 tends to split things too fine and more time taken to complete the analysis. In this head-count world, time use should be guarded jealously.

SN2.11 If R&O review ends with changes and revision of document, do I still have to keep the review notes?

No, no need. The revised document is your evidence of review.

SN2.12 The procedure shows we have to update so many document, after a risk is captured and resolved. Are we going a little overboard?

That is the requirement of IATF. You need to monitor, review and update on risk management. There are many areas with R&O, starting with internal and external contexts, interest parties, and contingency plans. The procedure ropes them all in for the review. If you do them in good time, it will be not taxing and every minute spent here is worth it.

SN2.13. Why is a scenario used to analysing external environment?

An external analysis based on current situation is history by the time it is done. You will miss opportunities and be troubled by threats when they appear. I advocate people to look a little into the future when doing external analysis. 12 months planning is very reasonable. Standard strategic management would look into 5 years or more.

SN2.13. How do we file the project plan, especially if another department is the process owner?

This has to follow your organization's practices. But the suggested method below should not be in conflict with most organizations. Project papers should be kept by the respective process owners. QMR should be informed, or allowed to review with the process owner periodically as a monitoring activity. For audit purpose, a copy should be provided to the QMR. It will speed up the audit, as IATF auditors may accept this copy and move on, without calling in the process owner.

Tracking is still an issue though. It is good to have a dashboard view of all ongoing projects. Your analysis documents can be dashboard. Records the external files and folders here link you to the responsible department. **(Exhibit 2-11)**

SN2.14. What does integrating and implementing the actions into is QMS processes?

It means that actions should really link to the functional departments. They should not be done by the QMR for the purpose of completing the risk analysis, for audit purposes only. The corrective or improvement actions must be truly implemented in the relevant departments to derive the benefits.

6) Exhibits

Exhibit 2-1 External Analysis PESTEL (conventional)

External Factors	(Scenario) Expected Changes in 0-1 years & Impact	Risk				Opportunity			
		S	P	R	Action/ Project No	A	E	0	Project No
Legal	Minimum wage will be increased (Negative: will increase operating costs a lot since we have 1000 workers)	M+	H	H	R1. EXTP-01	NA			NA
Economic & market	Economy is picking up very well. (Positive: more sales expected, and we have excess capacity to handle)	NA	NA	NA	None	M	M	M	NA
Technological	No change (We are in precision injection moulding serving E&E and automotive sectors)	NA	NA	NA	None	NA	NA	NA	NA
Competition	News that a China competitor is setting a subsidiary in the country (Negative: not a direct competitor immediately but can be in the future)	M	M	M	R2. EXTP-02	NA	NA	NA	NA
Social	Not Applicable (Our industry is not directly affected by changes in consumer behaviour)	NA	NA	NA	None	NA	NA	NA	NA
Cultural	Not Applicable (Our industry is not directly affected by cultural issues)	NA	NA	NA	None	NA	NA	NA	NA

(Action Plan)

Action Code	Risk/ Opportunities	Actions	Responsibility	Due Date	Action Plan Location
R1. EXT-01	Risk	• Outsource some low value-added processes • Adopt some automation	Top Management	Refer to detail project	Top Management
R2. EXT-02	Risk	• Carry an impact study on the China company's intended activities on our business	Marketing HOD	Mar 2018	Marketing

Legend:
Risk: H (High, Must Take Action), M (Mid, Action Optional), L (Low, Action Not Required)
Opp: H (High, Should Adopt), M (Mid, Adoption Optional), L (Low, Adoption Not Required)

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

- This analysis is based on the suggested method given in ISO9001:2015 Clause 4.1. NOTE 2 , and according to conventional method of PESTEL
- In projecting risk and opportunity, a scenario within the year is used.
- Action plans in this example are given just below the analysis so they can be seen together. Sometimes the plan needs to be in greater detail, and this has to be done outside of the form due to space constraint. And the last column "Action Plan Location" links you to where you can find the detail plans and records
- In this example, a simple scoring method is based on the score tables given

Exhibit 2-1 External Analysis PESTEL (conventional)- Page 2

Risk Ranking Table

Severity (S)

Category	Description
Low Impact (L)	Impact to interested parties is low. The effect is minor, mainly as inconveniences
Mid Impact (M)	Impact to interested parties is moderate. The effect can be moderate financial losses (can handle without much hardship)
Mid Plus Impact (M+)	Impact to interested parties is moderate but nearing High. The effect can be moderate to high financial losses (can handle with some hardship)
High Impact (H)	Impact to interested parties is high. The effect can be heavy monetary losses causing jeopardy, injury or fatality, or seriously affecting the organization's reputation

Probability (P)

Category	Description
Low Probability (L)	Very remote probability to occur, or 0-25 %% chance to occur
Mid Probability (M)	Has not occurred before, but chance to occur is moderate e.g. 25-50%
High Probability (H)	Has occurred before, is occurring or >50% probability will occur
% given above is rough estimates only. There is no requirement for exact data as evidences	

Risk Evaluation

Severity	Probability		
	Low probability	Mid probability	High probability
Low Impact (L)	L	L	M
Mid Impact (M)	L	M	M+
Mid Impact Plus (M+)	M	M+	H
High Impact (H)	M	H	H

Action Guide

Risk Level	Description	Corrective Actions
H	High Risk	Remedial actions needed
M	Moderate Risk	Remedial actions are optional
M +	Moderate Plus Risk	Remedial actions encouraged
L	Low Risk	Remedial actions

Opportunity Evaluation Table

A. Opportunity Evaluation

Attractiveness	Ease of Implementation		
	Low (L) (Difficult)	Mid (M) (moderate)	High (H) (Easy)
Low (L)	L	L	M
Mid (M)	L	M	H
High (H)	M	H	H

B. Action Guide

Opportunity Level	Description	Actions
L	Low Opportunity	Generally not to consider
M	Moderate Opportunity	Can consider
H	High Opportunity	Case should be adopted

C. Attractiveness

Category	Description
Low Attractiveness	Project requires lot of work for very little return. Or ROI >5 years.
Mid Attractiveness	Moderate work relative to the acceptable returns. ROI is 2-5 years
High Attractiveness	Return is very good relative to work load. ROI <2 years. Or the project has strategic importance to the Organization

D. Ease of Implementation

Category	Description
Low Ease (difficult)	Requires a lot of resources and may cause some disruption to the main business line
Mid (Moderate)	Requires some additional resources and training required, but within the means and control of the Organization.
High Ease (Easy)	Easy to implement, resources are largely in place and people able to implement without much training

Exhibit 2-2. External Analysis. Risk and Improvement

External Analysis. PESTEL Risk & Improvement

Ext Factors	(Scenario) Expected Changes in 0-1 years	Impact	S	P	Risk	Actions
Legal	Minimum wage will be increased	Will increase operating costs by a lot since we have 1000 workers	M+	H	H	EXT-01-19
Economic & market	Economy is picking up very well.	Pressure to retain employees with good offers around	M+	M	M+	EXT-02-19
Technological	No new technology required from customers	No new risk	NA	NA	NA	NA
Competition	News that a China competitor is setting a subsidiary in the country	Heard they are very competitive at costing. May force us to lose margin	M	M	M	EXT-03-19
Social	Not Applicable	Our industry is not directly affected by changes in consumer behaviour)	NA	NA	NA	NA
Cultural	Not Applicable	(Our industry is not directly affected by cultural issues)	NA	NA	NA	NA

(Action Plan)

Action Code	Risk/ Opportunities	Actions	Responsibility	Due Date	Action Plan Location
EXT-01-19	Risk	• Outsource some low value-added processes • Adopt some automation	Top Management	Refer to detail project	Top Management
EXT-02-19	Risk	• Improve our industrial relationship	HR/ HOD	Mar 2018	HR
EXT-03-19	OPP (OFI)	• Understand more about the competitor	Marketing HOD	Mar 2018	Marketing

Legend:
Risk: H & M+ (High, Must Take Action), M &L: (medium and Low-When actions taken on M&L, it is opportunity for improvement.

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

- This analysis is based on the suggested method given in ISO9001:2015 Clause 4.1. NOTE 2 , but focusing on risk and opportunity for improvement.
- For this type, only scoring table is used. H and M+ are considered high risks and actions shall be taken. M and L are lower risks, but when actions taken are considered as opportunity, opportunity for improvement

Exhibit 2-3. External Analysis - SWOT

SWOT Analysis (2018)

Strength	Weakness
○ Unique taste ○ Quality Ingredients ○ Friendly Staff	○ Low profits ○ No business website ○ Competition has more offerings
Opportunities	**Threats**
○ Market boom ○ Could expand to add pastries ○ can implement loyalty program	○ Gluten-free societal trends ○ Drought ○ Negative reviews

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

- Actually SWOT is both internal and external analyses. Strength and Weakness are internal, while opportunities and threats are external.
- Thus some overlap work exist in the internal & external analysis. The tool may be good for a pastry shop, but not for automotive plants.
- The information is what you see on the grid. There is no further analysis of the risk and opportunity. You need to have other documents to record your final conclusion and actions.

Exhibit 2-4. Internal Analysis-Process based

Internal Analysis 2019

(Process: Purchasing)

Table 1. Analysis

No	Major Risks/Deviations (What can go Wrong)	Impact	Current Controls	S	P	Risk Level	Additional Controls	Action Code
1	Not maintaining a good base of suppliers to support the operations	Cost and quality may not be well controlled	Procedure for selection and evaluation of suppliers (not well implemented)	M+	M	M+	• Qualify for more suppliers • Implement multisource purchasing	RP-PUR-01
2	Purchasing incorrectly-type and quality	Affect quality and delivery	Procedure for purchasing and incoming inspection (gen no mistake)	H	L	M	Not Required	None
3	Supply not on time	Affect delivery	Monitoring system for incoming control and provide forecast to assist suppliers (Generally no problem)	H	L	M	Visit critical suppliers often to ensure they are controlling inventory well	None
4	No evaluation on suppliers	Supplier may not be performing at their best	Procedure for evaluation of suppliers available and implemented (Service and indirect type suppliers not evaluated)	M+	M	M+	Include service type of suppliers and indirect suppliers	RP-PUR-02

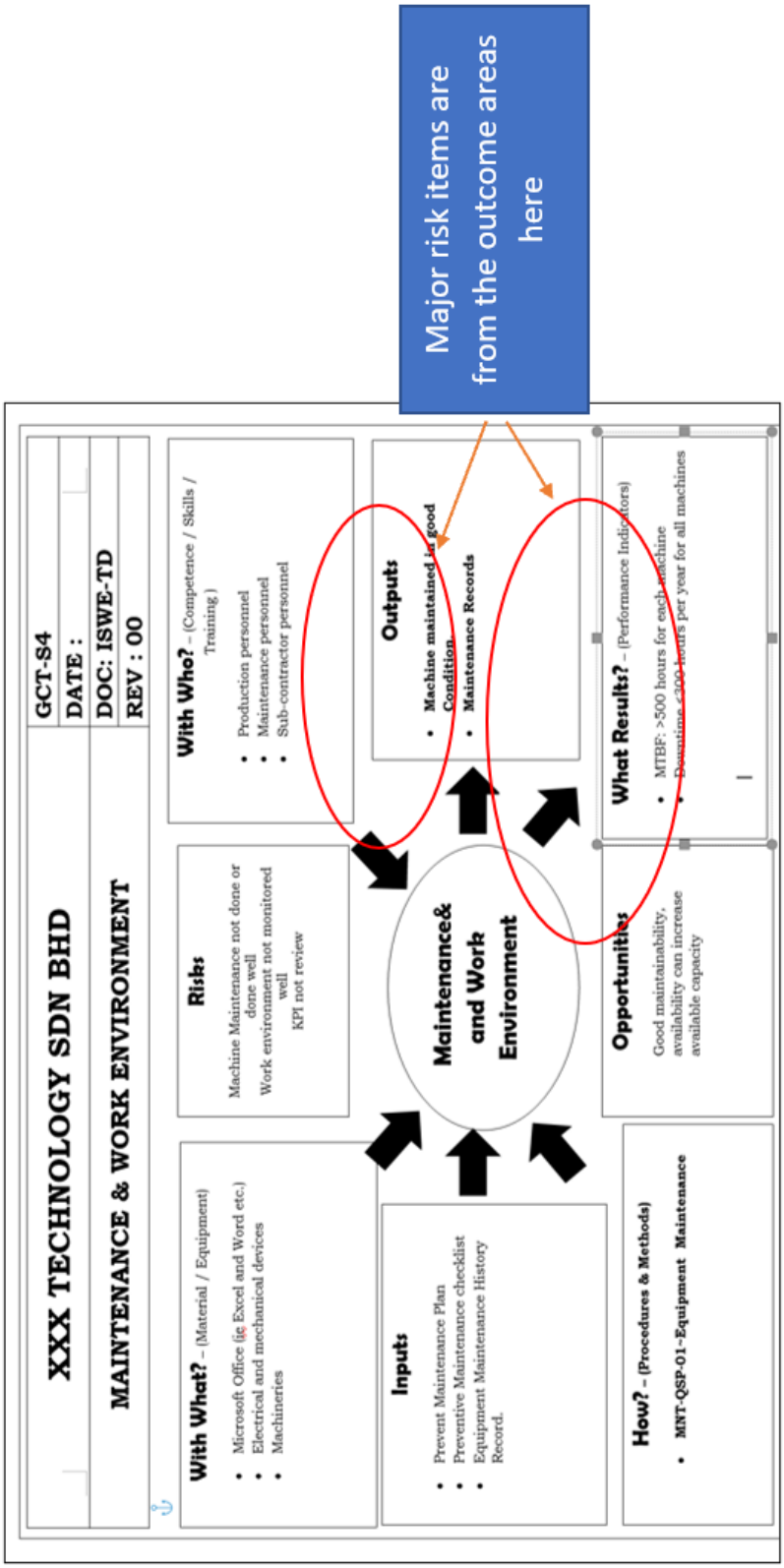
Table 2: Action Summary

Action Code	Risk/ Opportunity	Action	Due date	Doc Information Location	Effective?	Evidence
RP-PUR-01	Risk	Qualify for more suppliers and implement multisource purchase	Jun 2018	Purchasing		Purchasing
RP-PUR-02	Risk	Include service type of suppliers and indirect suppliers	Sep 2018	Purchasing		Purchasing
OP-PUR-01	OPP	Training Purchasing Personnel to negotiate price and also practice multi-sourcing, where applicable	30 Dec 2018	Purchasing		HR/ Purchasing

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

1. Internal analysis method here is based on 'process'. The analysis shown here is only 1 process- purchasing. Other processes shall be analysed the same way.
2. But it is important is to limit the analysis to only a few major items. Otherwise you are overloading without an equivalent payback.
3. Only a single scoring table is used for both risk and opportunity. The scoring table use is a 4 X 3 (not 3 X 3). I found that 3 X 3 ends up with too many M, which requires more thinking and decisions. Organizations normally take the easy way by choosing no action. While it is technically correct, it is not helpful.
4. 3 X 4 will end up with M & M+. Items ending as M+, like H are higher risks and actions shall be taken. That is for risk mitigation.
5. Unlike external analysis, there is no special column to analyse opportunity in internal analysis. For internal analysis, opportunity will be construed as "opportunity for improvement", which are risk ratings of M and L. See Supplementary Notes for more explanations.

Exhibit 2-5A. Critical Internal Risks Areas



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

- This is to answer the question where are the major potential risks found. There are normally found at output and Performance Indicator. Very rarely they are found elsewhere
- This is one way to look for potential risks. Another method is to define the purpose of the process, and think of the obstacles to achieve the purpose. Settle for a few major ones. See next Exhibit. I prefer the second method

Exhibit 5B. Internal analysis (based on risks to purpose)

15. Storage & Receiving

Purpose of Process	Major Potential Risk
To control material receiving, identification, storage and preservation to ensure production can take place on time.	Identification, Traceability, FIFO and Storage not well carried out
Also ensure traceability of materials for problem solving	Inventory not well control
To control on materal obsolence to ensure product quality	Shelf-life not well control

16. QAQC

Purpose of Process	Major Potential Risk
To conduct quality checks and inspection to ensure conformity of products and processes as per quality plan	Not preparing Inspection Plan or Inspection Plan not tally with customer agreement or requirement
	Not performing IQA on incoming materials
Internal lab complies to IATF requirement	First piece not performed or late to authorize production
	In process QC not conducted according to quality Plan
	FQA not conducted according to quality Plan
	Internal lab does not fully comply to IATF requirement e.g competence, methods, equipemnt and environment

17. Delivery / FG Store

Purpose of Process	Major Potential Risk
To deliver products ontime and acoording to customer requirement, and premium freight under control	Delivery wrong parts or not on time
	Damage to product during transportation
	Not delivered as per customer instructions
	Premium freight exceeding allowable limits

18. Customer Feedback

Purpose of Process	Major Potential Risk
Customer feedback, including satisfaction, complain, scorecards and portal data are studied and understood. Any shortfall shall be responded with improvement actions	Customer complaints/claims not handled well
	Customer complaints takes too long to resolve

18. Customer Feedback

Purpose of Process	Major Potential Risk
Customer feedback, including satisfaction, complain, scorecards and portal data are studied and understood. Any shortfall shall be responded with improvement actions	Customer complaints/claims not handled well
	Customer complaints takes too long to resolve
	Customer scorecard not studied and responded to
	Customer portals not studied and responded to

19. NCP, CAPA

Purpose of Process	Major Potential Risk
Control Nonconforming output to prevent unintedend use	Does not contain an NCP well to prevent intended use
Manage noncoformity to correct them and to prevent their recurrence	Does not conduct Root Cause Analysis well
Also learning lesssons to prevent occurrence of nonconformity in similar or potential situations	Corrective action plans not effective
	Did not check on horizontal processes to prevent potential problems
	Suspect product not well control
	Scrapped product are not well control to prevent recylcing or uninteded use

20. Calibration

Purpose of Process	Major Potential Risk
Ensure measuring equipment is suitable for use, calibrated on time and result traceable to international standards or national equivalent. Independent labs shall be certified to ISO/IEC17025 or equivalent national standard	Calibration not done/ not done ontime
	Internal verification is not traceable to international standard
	Some calibration is not peformed by labs with ISO/IEC17025

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

- This is another way to look for R&O. They should relate to the purpose of a process, and we just think of the major obtacles to this purpose for your risks and opportunities
- There is always the temptation to list out everything. But the extra analysis is not necessary. Your QMS will take care of the minor obstacles, and so you do not need to repeat them here.
- What is seen above is only 2 out ot 7 pages of the original document, dut to space constraint

Exhibit 2-6. The 4X3 Risk table

Severity (S)

Category	Description
Low Impact (L)	Impact to interested parties is low. The effect is minor, mainly as inconveniences
Mid Impact (M)	Impact to interested parties is moderate. The effect can be moderate financial losses (can handle without much hardship)
Mid Plus Impact (M+)	Impact to interested parties is moderate but nearing High. The effect can be moderate to high financial losses (can handle with some hardship)
High Impact (H)	Impact to interested parties is high. The effect can be heavy monetary losses causing jeopardy, injury or fatality, or seriously affecting the organization's reputation

Probability (P)

Category	Description
Low Probability (L)	Very remote probability to occur, or 0-25 %% chance to occur
Mid Probability (M)	Has not occurred before, but chance to occur is moderate e.g. 25-50%
High Probability (H)	Has occurred before, is occurring or >50% probability will occur
% given above is rough estimates only. There is no requirement for exact data as evidences	

Risk Evaluation

Severity	Probability		
	Low probability	Mid probability	High probability
Low Impact (L)	L	L	M
Mid Impact (M)	L	M	M+
Mid Impact Plus (M+)	M	M+	H
High Impact (H)	M	H	H

Action Guide

Risk Level	Description	Corrective Actions
H	High Risk	Remedial actions needed
M	Moderate Risk	Remedial actions are optional
M +	Moderate Plus Risk	Remedial actions encouraged
L	Low Risk	Remedial actions

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

- This is Severity x Probability (S X P) risk table. It is a 4 x 3 rather than 3 X 3, or 5 X 5
- A 3X3 produces too many M, which is optional. Any most organizations would just ignore them because there are optional. Usually no actions will be taken
- A 5 X 5 is ok, but takes too much time to do
- A 4 X 3 is a happy compromise. 2 types of M will be produce, the normal M and M+. M+ needs to take action

Actions taken on red circle M+ items are mandatory for risk mitigation, just like for any H items

Actions taken on blue circle M items and Green L items are not mandatory. When actions are taken, they are for improvement (opportunities for improvement)

Exhibit 2-7. Simple Action Plan

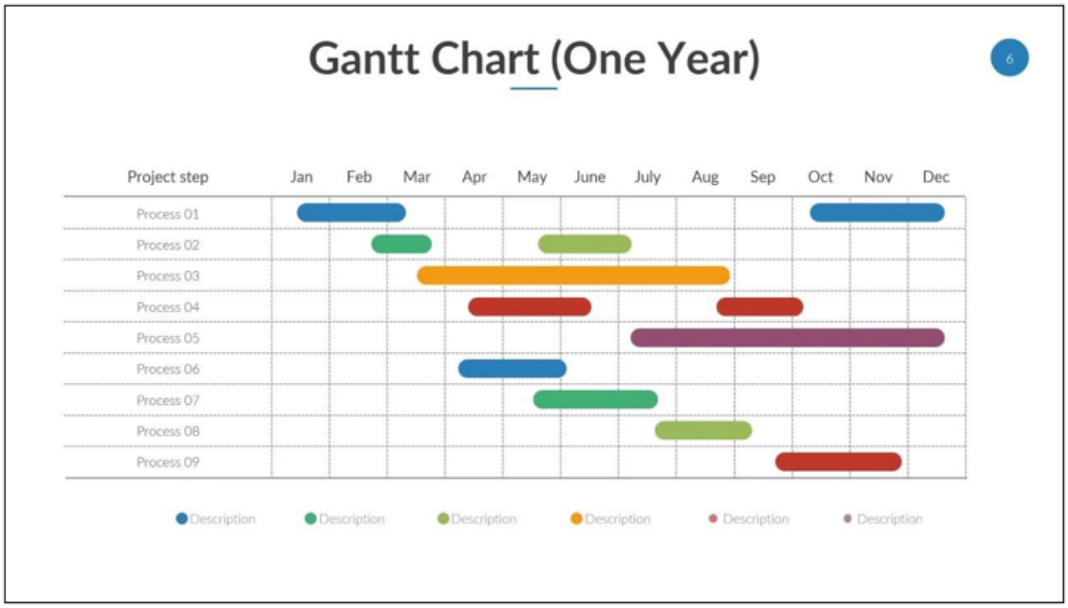
Project Title: To reduce the temperature at the mixing platform by installing air turbines Objective: • To reduce discomfort and therefore work errors • To reduce medical leave	Doc No. PDN-2/2019	Year 2019
	Completion Date 1 Apr 2019	Compiled by[Date
Project Team Members: Project Leader: Mr M Team members: XXX, XXX	Relevance/Integration QMS/EMS	Approved by/Date

Step	Program/Tasks	Person Responsible	Due Date	Completed on	Outcome	Status (Monthly)
1	Meeting to finalize decision	Proj Team 23	15 Jan 19	15 Jan 19	Proposed idea accepted	
2	Quotations for installing air turbines	Mr R, Purchasing	20 Jan 19			
3	Get approval from MD	Mr M, Proj Leader	25 Jan 19			
4	Project implementation, installation by supplier XXX	Mr S, Mtn	30 Jan 19			
5	Operate the system	Mr P, Production	20 Feb 19			
6	Review meeting, evaluating data and effectiveness	Project Team	20 Mar 19			

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

- This type of plan is by far the most popular method. It is easy to use and provides sufficient information on a single page.
- It shows the plan direction and work scope, due dates, responsibilities, and outcome.
- It can also be checked at any time on progress. The last column status is used to record updated status, which can be on pencil, until closed out

Exhibit 2-8. Project Plan with Gantt Chart



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

- When an action plan gets too complex, bullet points and simple action plans may not be suitable. A proper project plan is required. This can be internally prepared or by project contractors.
- A Project Plan shows a lot of details that are omitted in the simpler systems. A detail project plan can be a stack of document, or even a proper project paper. You often see: project title and project umber, description of outcome, project budget, time frame, reporting requirements, stakeholders, qualifications etc. A Gantt Chart showing phases is also a common item in a Project Plan.

Exhibit 2-9. Review Evidence Type 1. Notes on the document

Internal Analysis 2019
(Process: Purchasing)

Reviewed on 17 May 2019
By XXX, XXX, XXX

Table 1. Analysis

No	Major Risks/Deviations (What can go Wrong)	Impact	Current Controls	S	P	Risk Level	Additional Controls	Action Code
1	Not maintaining a good base of suppliers to support the operations	Cost and quality may not be well controlled	Procedure for selection and evaluation of suppliers (not well implemented)	M+	M	M+	• Qualify for more suppliers • Implement multisource purchasing	RP-PUR-01 OK
OK2	Purchasing incorrectly-type and quality	Affect quality and delivery	Procedure for purchasing and incoming inspection (gen no mistake)	H	L	M	Not Required	None OK
3	Supply not on time	Affect delivery	Monitoring system for incoming control and provide forecast to assist suppliers (Generally no problem)	H	L	M	Visit critical suppliers often to ensure they are controlling inventory well	None OK
4	No evaluation on suppliers	Supplier may not be performing at their best	Procedure for evaluation of suppliers available and implemented (Service and indirect type suppliers not evaluated)	M+	M	M+	Include service type of suppliers and indirect suppliers	RP-PUR-02 OK
5	(added 21 Jan 2019) Suppliers are not aware of statutory and regulatory requirements	Some customer requirement not fulfilled	Stated requirement on PO	M+	M	M+	Brief suppliers in person, rather than rely on document	RP-PUR-02 New

Table 2: Action Summary

Action Code	Risk/ Opportunity	Action	Due date	Doc Information Location	Effective?	Evidence
RP-PUR-01	Risk	Qualify for more suppliers and implement multisource purchase	Jun 2018	Purchasing	Yes	Purchasing OK
RP-PUR-02	Risk	Include service type of suppliers and indirect suppliers	Sep 2018	Purchasing	Yes	Purchasing OK
OP-PUR-01	OPP	Training Purchasing Personnel to negotiate price and also practice multi-sourcing, where applicable	30 Dec 2018	Purchasing	Yes	HR/ Purchasing OK
RP-PUR-03	Risk	Brief suppliers in person, rather than rely on document	2 May 2019	SQE/Purchasing		New

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

- This is an example of reviewing the risk analysis. Line by line, and point by point.
- Check for inadequacy as well as changing conditions and factors. In other words, you should check if the items are sufficient, and also the assumptions are still valid. You may need to add new items, delete items, re-score the risks etc.
- Hand written notes are as acceptable. For review with changes, document change shall follow and that itself is evidence of review.

Exhibit 2-10. Review Evidence Type 2. Recording on Doc change History

Document Change History

Type of Doc	Process Owner
Internal Analysis-Purchasing	Purchasing

Date	Document Title and No	Revision	Changes
1 Jul 18	Internal Analysis-Purchasing	00	Newly created
23 Feb 19		01	Added a new risk- customer statutory and regulatory requirement not followed by supplier.

Record review results on the Doc Change History

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

- This is another type of recording analysis reviews.
- However, to use this, your organization should have a practice of using document change history for this type of document.
- In most organizations, I see document change history for quality manual, procedures, and forms, but not for technical and analytical document

Exhibit 2-9. Project Linkage Management

External Analysis
Template Technology

External Factors	Scenario Expected Changes in 0-3 years & Impact	Risk			Opportunity		
		Risk Level	Action ?	Project No	Oppo Level	Action ?	Project No
Legal	Minimum wage will be increased (Negative: will increase operating costs a lot since we have 1000 workers)	H	Yes	R1. EXTP-01	None	None	None
Economic & market	Economy is picking up very well. (Positive: more sales expected, and we have excess capacity to handle)	None	None	None	M	None	None
Technological	No change	None	None	None	None	None	None
Competition	News that a China competitor is setting a subsidiary in the country (Negative: not a direct competitor immediately but can be in the future)	M	None	R2. EXTP-02	None	None	None
Social	Not Applicable (Our industry is not directly affected by changes in consumer behaviour)	None	None	None	None	None	None
Cultural	Not Applicable (Our industry is not directly affected by cultural issues)	None	None	None	None	None	None

(Action Plan)

Action Code	Risk/ Opportunities	Actions	Responsibility	Due Date	Action Plan Location
R1. EXT-01	Risk	• Outsource some low value-added process • Adopt some automation	Top Management	Refer to detail program	Top Management
R2. EXT-02	Risk	• Carry an impact study on the China company's intended activities on our business	Marketing HOD	Mar 2018	Marketing

Legend:

Accessibility: Investigate

Focus

This is your dashboard. Use this area to track the locations of information and responsible persons to get updates

Exhibit 2-12. Risk analysis following a failure

Activity Flow	Description	PIC
	1. Failure occurs • Failure can occur in any part of the value-add chain, including after delivery to customer 2. Containment • Actions shall be taken immediate to contain the fallout of the failure • Containment shall include impact on safety and environment 3. Problem Solving Problem solving shall include : - root cause analysis - corrective actions - horizontal application to similar or potential problems 4. Impact on Safety and Env • Analyse impact on safety and environment • Relevant action plans should be implemented 5. Update Risk & Oppo Analyses • Enter the incident into the risk and analysis, with score representing the latest picture • If the final picture still does not achieve reasonable residue risk, further actions are needed 6. Standardize IPNE • Enter the incident into IPNE analysis, with scores representing the latest picture • If the final picture still does not achieve reasonable residue risk, further actions are needed 7. Standardize Contingency Plan • Enter the incident into Contingency Plan, with scores representing the latest picture • If the final picture still does not achieve reasonable residue risk, further actions are needed	Relevant Process Owner/ Contingency Team QMR to assist

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

- This chart links up all the problem-solving steps and updating of related documentation
- Use this as a checklist after a failure to make sure none of the steps and risks are missed out

>>End of Chapter 2 <<

Chapter 3. Contingency Plans

Contents:

0) Introduction

There is only one applicable clause in this chapter. The reason why a whole chapter is devoted to this is because the Clause is often misunderstood and poorly catered for. Many NCs have been written on this clause alone.

1) 6.1.2.3 Contingency Plans (IATF16949)

(Clause Description-Paraphrase)

The organization shall ensure some critical points on contingency planning: (a) identification of emergencies that can interrupt production and delivery. (A list of potential emergencies is given by IATF), (b) Evaluation of the risks and provide appropriate preventive actions and countermeasures. (c) conduct test out and annual review of these action plans, (d) for actual emergencies, notification of customer and interested parties, (d) validation of product conformity after re-start, following an emergency and improper shutdown. (Author: There is another item added 'Cyber-attack', via SI-5)

(Highlights of the clause)

- (Ref to old Standards) There has been a similar clause (6.3.2) of the same title, in the old version of ISO/TS16949. The previous clause was skin deep. It only required the organization to "prepare contingency plans to satisfy customer requirements in the event of an emergency"
- Now IATF provides 9 potential emergencies to be evaluated for contingency planning. Then there is another item added -Cyber-attack, via SI-5.
- Total list therefore is: key equipment failures; interruption from externally provided products processes, and services (shortage or nonconforming quality); recurring natural disasters; fire (outbreak); utility interruptions; labour shortages; or infrastructure disruptions cyber-attack.
- The above list is minimum, you can add more items pertaining to your specific situation.

(Compliance Best Practice)

6.1.2.3 Contingency Plans

1. *To comply with this clause, you need to list out all the potential emergencies. It shall include the 10 items given in Clause Description + SI-5. See* ***Exhibit 3-1.***
2. *Priority for action shall be based on production and delivery impact to customers (not those of your organization).*
3. *These potential emergencies shall be analysed. You should use your operating history, and your current preventives as the baseline for residual risks. You can use the 4X3 risk table for the scoring, to derive the residual risks. See* ***Exhibit 2-6.***

4. *List out the response actions for each item at the extreme right column of the form. To save time, bullet points can be used for most cases. Simple action plans or full project plan should be used only in more critical cases.*
5. *Please note that point 4 above is referring to RESPONSE plan, not improvement plan. Many such mistakes have been spotted in field practices.*
6. *For improvement and corrective actions, they shall be managed outside this form, as an continual improvement plan etc.*
7. ~~*Annually*~~*Annual review of the contingency plan is required, with involvement by Top Management. See* ***Exhibit 3-4.***
8. *Testing (sometimes called simulation) for the high-risk emergencies is also needed. See* ***Exhibit 3-2 and Exhibit 3-3.***
9. *Notify customer and interested parties as appropriate, when emergencies occur*
10. *Contingency Plans must include product conformity validation after the emergencies (where applicable). The testing form has a space to record this point and point 9.*

2) SI & FAQ

SI Nbr	IATF Clause	Description
3	**6.1.2.3 Contingency plans**	The organization shall: a) – b) (...) c) prepare contingency plans for continuity of supply in the event of any of the following: key equipment failures (also see Section 8.5.6.1.1); interruption from externally provided products, processes, and services; recurring natural disasters; fire; utility interruptions; **cyber-attacks on information technology systems;** labour shortages; or infrastructure disruptions; ***Rationale for change:*** *Organizations need to address the possibility of a cyber-attack that could disable the organization's manufacturing and logistics operations, including ransom-ware. Organizations need to ensure they are prepared in case of a cyber-attack.*
17	**6.1.2.3 Contingency plans**	**a) – d) (...)** **e) periodically test the contingency plans for effectiveness (e.g. simulations, as appropriate);** **cybersecurity testing may include a simulation of a cyber-attack, regular monitoring for specific threats, identification of dependencies and prioritization of vulnerabilities. The testing is appropriate to the risk of associated customer disruption;** **Note: cybersecurity testing may be managed internally by the organization or subcontracted as appropriate** ***Rationale for change:*** *Cybersecurity is a growing risk to manufacturing sustainability in all manufacturing facilities, including automotive. Contingency testing has also been identified by organizations and CBs as an area in need of clarification. This update provides details of what is to be tested as part of a cyber-attack contingency plan validation.*

FAQ	IATF Clause	Questions and Answers
29	**6.1.2.3 Contingency Plans**	**QUESTION** **What is meant by the use of the term "cyber-attack" for contingency plan testing?** **ANSWER** A Cyber-attack is an attempt to gain illegal access to a computer or computer system for the purpose of causing damage or harm. A cyberattack is often a deliberate exploitation of weaknesses in the security of computer systems or networks to gain access to data, alter computer code, logic or data. These actions may have disruptive consequences that can compromise confidential data and lead to cybercrimes, such as information and identity theft, automation-caused operational interruptions, encryption of company critical data or illegal remote controlling of systems or data. Cyber-attacks and cybercrimes are not always a result of a sophisticated series of actions to guess passwords using powerful computer programs run by teams of people from a remote location. They are often actions designed to convince individual persons to release sensitive or private information through email notes (typically phishing), pretexting (impersonating a trusted person or government official), phone calls announcing fake emergencies getting personal information, visual reading of typed passwords, infecting popular websites with malware, text messages with links to sites installing malware, USB drives left on desks, appearing to be legitimate, which are plugged into PCs, and theft of discarded materials containing confidential computer information, etc. Additionally, a cyber-criminal, after gaining access to a company's system, could encrypt company's critical data and demand a ransom to unencrypt the data. Also, GDPR (General Data Protection Regulation) in Europe or similar requirements in other regions specify that organizations are responsible to ensure that personal data retained by the organization is protected and kept secure at all times, reinforcing the importance of being prepared in the case of cyber-attacks. Additional details regarding information technology security techniques is available through ISO/IEC 27001.

3) Supplementary Notes

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

Clause	Section	Clarification Subjects
6.1.2.3	CBP	**SN3.1 What do you mean by "according to risk and impact to the customers'?**
6.1.2.3	CBP	**SN3.2 Can I change the baseline (current controls), after doing some improvement?**
6.1.2.3	CBP	**SN3.3 Can I use Business Continuity Plan, instead of contingency plan?**
6.1.2.3	CBP	**SN3.4 Must I use the exact wording for the various types of emergencies, or am I allow to use my own description?**
6.1.2.3	CBP	**SN3.5 If there is an emergencies that does not occur, will not occur, do I still score the risks?**
6.1.2.3	CBP	**SN3.6 If the final risk is low, do I still need to provide action plans?**
6.1.2.3	CBP	**SN3.7 Why is there a need to score the final risk, when it is not mentioned in the clause?**
6.1.2.3	CBP	**SN3.8 Can I combine this analysis with Risks and Opportunities analysis?**
6.1.2.3	CBP	**SN3.9 Why are we concerned with response and not improvement in this exercise?**
6.1.2.3	CBP	**SN3.10 You said manage the additional improvement or preventive measures outside the contingency form. How do I do that?**
6.1.2.3	CBP	**SN3.11 What is meant by testing, or simulation?**
6.1.2.3	CBP	**SN-3.12 Can actual incident be used for testing? How do we do that?**
6.1.2.3	CBP	**SN3.13 Is testing not same as review? Do I need to do both?**
6.1.2.3	CBP	**SN-3.14 Do Top Management really need to be present in the review?**
6.1.2.3	CBP	**SN3.15 When to inform customer in the event of an emergency?**

6.1.2.3	CBP	**SN3.16. What is meant by "contingency Plans must include product conformity validation after the emergencies"?**

SN3.1 What do you mean by "according to risk and impact to the customers'?

It means prioritization shall be based on risk and impact to the customers, not to your own organization. When you do risk scoring, this will be the criteria to use.

SN3.2 Can I change the baseline (current controls), after doing some improvement?

Of course you can. IATF expects you to do that too. If you have improved, then the document (contingency planning sheet) shall be revised, and the final risks re-scored. Remember it has to be a document revision so changes are tracked.

SN3.3 Can I use Business Continuity Plan (BCP), instead of contingency plan?

There is no prescribed form to use. **Exhibit 3-1** is just an example of how to tabulating the contingency plans. Business Continuity Plan tends to have a wider scope and has a slightly different meaning from the Contingency Plan of IATF. But you can use it so long the requirements of IATF are included into your BCP. There are some organizations doing so, and quite neatly too.

SN3.4 Must I use the exact wording for the various types of emergencies, or am I allow to use my own description?

You only need to comply to the requirement in gist, not necessarily in the exact wordings used in the Standard. Manpower shortage and workers-on-strike can mean roughly the same thing. You can use either.

SN3.5 If there is an emergencies that does not occur, will not occur, do I still score the risks?

An emergency is something you cannot predict for sure. The big flood in Ayutthaya of Bangkok was never expected, yet it happened, and flooding out thousands of factories there. The Covid-19 pandemic had never cross anybody's mind yet it happened. You must still do the scoring for the risks listed. You can score either 'Low' or even 'NA'. The heading however, cannot be removed.

SN3.6 If the final risk is low, do I still need to provide action plans?

You can decide on this. It is not important and IATF auditors won't split hair over a low risk finding.

SN3.7 Why is there a need to score the final risk, when it is not mentioned in the clause?

Rating the risk is not directly mentioned as such, but it is implied. 6.1.2.3 (a) states 'identify and evaluate internal and external risks…' So you have to evaluate (score) the risks.

Another supporting point is that scoring the risks is good for you. With the final scores, you only have to focus on the higher risks for simulation. Otherwise you have to do simulation on all risks, since there is no indication which ones are important and which ones, not.

SN3.8 Can I combine this analysis with Risks and Opportunities analysis?

This is quite commonly done, presumably due to the creativity of some consultants. However, that is not the intent of ISO. If it is, ISO would have used a single clause to cover the 2 requirements. Although there are similar elements in both the analysis, their purposes are different. Risk and Opportunity analysis is to understand where the R&O are, and then provide improvement where applicable. Contingency plan, on the other hand, is about response to emergencies. Therefore the 2 exercises are meant to be done on separate platform and documentation.

SN3.9 Why are we concerned with response and not improvement in this exercise?

Contingency plan is meant to deal with an emergency, despite of all the preventives and preparedness in place. It is not about improvement at that particular point in time. What the customer wants is: you

continue to deliver the supplies on time, whatever happens. You have to figure out how you would do that, and that is the response we are talking about. Investigation and improvement can come later, after the customer's key concern is addressed.

SN3.10 You said manage the additional improvement or preventive measures outside the contingency form. How do I do that?

You can carry out the improvement as a continual improvement project. Alternatively, you can go back to R&O and use the format there to manage areas of weaknesses. See 4.1 and 6.1**.**

SN3.11 What is meant by testing, or simulation?

Testing means to test out the response plan. It is usually done by means of simulation, similar to the concept of fire-drill in EMS, or OHSMS, or a recall in FSMS. Organizations often show IATF auditors a fire-drill, pull out directly from EMS as an evidence of Contingency Plan simulation. They missed the point totally. Fire-drills are to primarily to protect lives and properties. The drill does not attempt to review continued supply to customers, despite of the fire.

SN3.12 Can actual incident be used for testing? How do we do that?

Yes, actual incident can be used for testing. In fact it is more superior than a simulation. It has actually occurred; and the response and results can be used to compare with the response plan to gauge effectiveness. Improvements can then be suggested.

SN3.13 Is testing not same as review? Do I need to do both? How to I review a contingency plan?

Yes you have to do both. Let's look at the clauses first. Review is 6.1.2.3f, and testing is 6.1.2.3e, which state both are required. Most organizations do not carry out the review, thinking simulation conducted will automatic cover this requirement. This is incorrect. Testing is only on 1-2 emergency items, but the contingency plan has minimum 10 potential emergencies.

The best method for contingency plan review is to run a review meeting. You gather the relevant people to make up the multi-disciplinary team required, and review through the contingency plan, point by point. To save time, you may also ask each PIC to review on his/her own area and come to the meeting to present the findings and conclusions. The group can then help to give feedback and finalize the review. The conclusion of review may result in revisions to the contingency plans. In the event there are no changes, evidence in the form of minutes taken, or remarks on the review contingency plan copy retained. If you keep a document change history, changes and conclusions can also be recorded here.

SN3.14 Do Top Management really need to be present in the review?

Yes, according to the Clause. But in reality, some flexibilities are allowed. This would be a little over-killing to insist top management to sit through such a meeting. IATF Auditors do understand top management is hard pressed for time. Requesting Top Management to approve the revised documentation should suffice. It will be better if QMR can do a debriefing, in particular, on the changes. It will even be best, if Top Management can be present for some parts of the review meeting to get a feel how this is done.

SN3.15 When to inform customer in the event of an emergency?

This is according to the contractual agreement you have with the customer. Generally speaking, if you are more confident of handling, you can take a longer time to inform. If you are not so confident, you should inform the customer as early as possible. This is to allow them to make other arrangements or assist you in some way. Otherwise you may be slapped by a big claim.

SN3.16. What is meant by “contingency Plans must include product conformity validation after the emergencies”?

This does not apply to all situations. It is only applicable where the production run is interrupted e.g. by machine break down, workers on wildcat-strike. The product in process may be deteriorated due to extended exposure, a change of operating conditions, and processed not according to plan. Under the circumstances, the product must go through the first piece buy-off again.

Continuing

4) Exhibits

Exhibit 3-1. Contingency Plan

Exhibit 3-1.Contingency Plan

Contingency Plan 2019

S/N	Type	Impact to Customer	Current Controls	S	P	R	Response and Mitigation	Detail Procedure
1	Key Equipment Failure	Production interrupted, may affect OT Delivery	Have excess capacity and spare machines.			L	• Switch over to another machine	None
2	1250 ton machine has no substitute	If problem, production interrupted, OT delivery affected. Heavy penalty will be imposed	Agreement with XXX to mutually assist each other in times of emergencies	H	M	H	• Activate the emergency plan CW101	CWI 101
3	External Supply Problem	Production interrupted, may affect OT Delivery	Multisource purchasing already practiced	M+	L	M	• Can buy from another source.	None
4		Transporter failure cause delivery problem	Currently 2 outsourced transporters. We also own 2 trucks	M+	L	M	• Own truck can be used in the event of supplier problem	None
4	Recurring Natural Disaster-flood	Can disrupt total operations	Never happened in the last 70 years	NA	NA	NA	• NA	None
5	Fire outbreak	Production facilities destroyed, affecting production and delivery	Fire safety system is available and well maintained.	M+	L	M	• Keep inventory as per customer specifications	None
6	Utility Interruption-power	Production interrupted, may affect OT Delivery	Backup generator available for light use Additional generators can be rented easily	H	L	M	• The genset will automatically cuts in when failure • Major failure contact rental company. Contact XXX, Tel XXXXXXXX	None
7	Water disruption	Production interrupted, may affect OT Delivery	Can ferry the water in, treated	H	L	M	• Contact contractor to ferry in water. Contact XXX, Tel XXXXXXXX	None
8	Labor Shortage	Production interrupted, may affect OT Delivery	We maintained a safe application quota from the department (direct). Also can use contract workers	M+	M	M+	• Call the labor supply agencies. Contact XXX,	None
							Tel XXXXXXXX, or XXX, Tel XXXXXXXX	
9	Cyber Attack	Can disrupt total operations	Firewall, anti-virus at every terminal. Back up	H	L	M	• Contact XXX, Tel XXXXXXXX • Inform HQ for additional backup	None
10	Typhoon in Thai supplier for fabric	Can delay shipment of fabric from Thailand and affecting our OTD to customers	Safety stock by customer and organization. HQ also keep stock. Keep tight monitoring of weather forecast	H	M	M	• Activate backup stock-points • Contact HQ XXX, Tel XXXXXXXX	None

Legend: Risk Level. H= High (details needed), M=Mid (Min bullet point guide), L= Low (bullet point guide)

Remarks:

Example of Emergency Plan

CWI-101: 1250 T machine Failure Respond Plan

1. Inform affected customers: Marketing (within 4 hours)
2. Contact equipment maker for assessment on repair: Purchasing (within 4 hours)
3. Contact Partner (XXX company) to get assistance. Management (within 2 hours)
4. To work on detail coordination plan with Partner: Planner/QA/Production (within 1 day)
5. Meeting of relevant internal department head and personnel on situation: Chief Coordinator/Management, within 1 day)

Remarks given in this section explain on the Exhibit. Do not include them as part of your document

- Risk coring is based on SXP Risk Evaluation Table. the 2 arrows above show the connections. Exhibit 2-6
- Conduct simulation for the H and M+ emergencies over 3-year cycle, do a schedule to show planning
- Bullet points are expected for each case. But for High risk items, a detail WI should be established and be adjunct to this plan. See case above
- Annual review is required of this contingency plan, top management is expected to be involved.

Exhibit 3-3. Contingency Plan Testing - Simulation

Contingency Plan Testing 2019

Contingency Plan Test	
☐Actual case ☑ Simulation Case	Date: 17 Sep 2019
Emergency Tested. Transportation failure	People involved XXX, XXX, XXX

Case Study

Requirement:
Delivery to Honda Assembly Melaka by 5pm before warehouse close

Response Actions given in Contingency Plan:

- If breaks down on highway, send a spare truck to transfer and continue

Scenario (Simulation)

1. This is a stimulated case, conducted in meeting room
2. Consider breakdown at 3.30PM at Seremban
3. Plant is 50 km away, but takes 1.5 hours for spare truck to arrive
4. To transfer the goods to spare truck takes about 2 hour manually (forklift not available)
5. Continue journey another 1.5 hours.
6. By the time of arrival to Honda Melaka, it would be 8:30 pm

Conclusion:
Outcome cannot meet customer requirement. Not OK

Improvement options:
1. start journey in the morning, and not after lunch
2. prepare some tools to transfer from truck to truck.
3. tighten controls on truck maintenance

New Response Measures:

- Driver to inform HQ immediately
- Response team shall despatch soonest, with transfer equipment and manpower required
- Appoint a ERP leader to control onsite
- Inform customer if appropriate on expected delivery time

Management Decision

Adopt fully the recommendations.
Run through risk management flow and update as required

Submitted by	Approved by

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

- This is a simulated case, and not based on real occurrence.
- Most simulated case can be conducted on the side lines, without disrupting the operations. But data and information should be as realistic as possible

Exhibit 3-2. Contingency Testing-Real Occurrence

Contingency Plan Testing 2019

Contingency Plan Test

☑Actual case ☐Simulation Case Date: 30 Apr 2019

Emergency Tested.	People involved
Water Supply Failure	XXX, XXX, XXX

Case Study

Requirement:

To continue to deliver to customer ontime

Response Actions given in Contingency Plan:

- Supply form 3 buffer stock
- If advance information given, calculate and produce ahead

Scenario (Simulation)

1. This is a real case, that had happened, with notice from the water authority
2. It was informed that there will be imposed 3 day interruption of water supply between 24-27 Apr 2019
3. Use BZXXX case for study. It requires 384 sets per day.
4. 3 day buffer stock means: 1152 sets required.
5. Our water tank can supply 2.5 days of operation, or 960 set.
6. Total available inventory is 1152+960 = 2112 sets
7. Customer requirement for 4 days = 1536 sets.
8. Therefore inventory and production quantify can supply with an excess of 576 sets
9. On 27 Apr 2019, it was checked on site and view delivery document, the plan could be executed as plan.

Conclusion:

The customer demand can be fulfilled with inventory and production quantities. Actual checked on site on the last day of water disruption confirmed delivery in full. Therefore the plan is effective.

Improvement options:

1. The 3 day buffer is sufficient and can be maintained
2. We should look into alternative water supply by containers, if water disruption is getting frequent
3. Alternatively, install more water tanks
4. Run through risk management flow and update as required

New Response Measures:

- Response to include water supply contractor contact No

For Actual Occurrence Cases

1. Have we notified and provide information as required by customers ☑yes☐No
2. If production was stopped not in accordance to normal procedure, has the product been verified in full conformity to requirement ☑yes☐no. Doc No: FPBO. XXX date 28 Apr 2019

Management Decision

.1. Start to contact water supply contractors, and understanding costing etc
2. Also look at cost of installing extra water tanks

Submitted by	**Approved by**

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

- This is a real case, with advance notice of emergencies.
- The contingency team did the calculation well in advance and found they could handle the situation with good safety margin
- The contingency team actually check implementation at the end of the water disruption, to see if the plan actually worked out.
- The outcome was good. But as the tendency of water disruption was getting frequent, contingency recommends to adopt some preventive measures.
- This is an excellent case of using contingency plan to ensure smooth operation, despite failure of other parties.

Exhibit 3-4. Contingency Plan Review. Page 1

Contingency Plan 2019

Review on 20 Mar 2019
Reviewer: XXX, XXX

No	Emergency Type	Impact	Current Controls	Risk Eval			Response and Mitigation
				S	P	R	
1	Key Equipment Failure	Production interruption, affecting delivery (OK)	• Currently excess capacity, plenty of idling equipment • Approved subcon available (Excess capacity is decreasing as business is picking up)	H (OK)	L M	M H	• Switch over to another machine if a machine breaks down, if available • Contact subcons to process • Maintenance to improve reliability
2	External Supply Interruption	Production interruption, affecting delivery (OK)	• Multi-sourcing practised (OK) • Safety inventory of 2 days (OK) • Subcon A for plating having quality issue later-resolving (resolved) • Subcon B to come on line (came on and OK)	H (OK)	M L	H M	• Get from other approved sources if supply is uncertain (OK to continue) • ~~To source another plating subcon by June (Purchasing)~~
3	Transport Equipment Failure	Delivery affected (OK)	• Outsourced to contractor who promise backup within 2 hours • Org also has own trucks that can be used • So far no issue of transport • Store assistant Mr XXX who has licence for driving truck has resigned (OK- continue)	H (OK)	L (OK)	M (OK)	• ~~Ensure the replacement has the truck licence (HR)~~ • ~~Alternative, get one of other store assistance to get such a licence (HR & Store Manager)~~ • Mr XXX came back to work as driver
4	Recurring Natural Disaster-Flood	Delivery affected The external roads flooded. (OK)	• Build extra inventory during the monsoon months (Oct-Dec) • Request customer to keep extra inventory for the 2-3 months (customer accepted)	H (OK)	L (OK)	M (OK)	• Current measures good enough • In the event of uncertainty, inform General Manager

Exhibit 3-4. Contingency Plan Review. Page 2

5	Fire outbreak	Production facilities damaged, affecting production and delivery. (OK)	• Fire safety system fully in place • Electrical consultant checks on system every 3 months • No incident so far. (OK)	H (OK)	L (OK)	M (OK)	• To increase checks by electrical consultant every (2)month, as plastic is a high hazard industry for fire.
6	Utility Failure (power)	Production interruption, affecting delivery (OK)	• Standby generator can run some machines • If inform earlier, can build inventory • Catch up with over time, or weekend running (new)	H (OK)	L (OK)	M (OK)	• ~~Find contacts to rent large generator if require (Production Manager and Purchasing)~~ • Contact production manager immediately to authorize overtime or weekend running
7	Utility Failure (water)	Production interruption, affecting delivery (OK)	• If inform earlier, can build inventory • Catch up with over time, or weekend running (new)	H (OK)	L (OK)	M (OK)	• ~~Build backup water storage tank~~ . Done • ~~Find contacts to purchase water in tanker loads (Production Manager and Purchasing)~~ • Contact production manager immediately to authorize overtime or weekend running
8	Manpower interruption	Production interruption, affecting delivery (OK)	• Approved subcon available • Catch up with over time, or weekend running • Get more contract workers from manpower supplier • Manpower shortage experience in month of June	H (OK)	L M	M H	• Contact XXX or XXX • Develop a better system of estimating demand to have advance notice for recruitment
9	Infrastructure failure	Production interruption, affecting delivery	• Approved subcon available • Catch up with over time, or weekend running	H	L	M	• See above
		(OK)	• Get more contract workers from manpower supplier (OK)				
10	Computer affected by Cyber Attack or virus	Operation interruption, affecting delivery (OK)	• Computer data backed up every day, automatic • Antivirus at all terminals • Duplicate system available as redundancy, can kick in when the main system fail (OK)	H (OK)	L (OK)	M (OK)	• HOD to ensure compliance by checking monthly (Admin & Finance Manager)

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

- This is one way to conduct Contingency Plan review. A copy of the Contingency Plan is required for the team to review, line by line
- Pencil marking is acceptable. If there is no change, this is your evidence.
- However, if there are changes, the original document shall be revised to show changes. This will be the evidence of review instead
- Not only response plan can change, the current controls may also subject to change and so are the scoring
- Get the top management to sign or request his/her input, as the standard requires their participation

>>End of Chapter 3 <<

Chapter 4. Interested Parties & their Needs and Expectations

Contents:

0) Introduction

There is only one applicable clause (4.2) in this chapter. Clause 2.2 is just a supporting clause to clarity the meaning of 'interested parties'. The reason why a whole chapter is devoted to this is because the Clause is not commonly misunderstood and poorly catered for.

1) 2.2 Fundamental concepts (ISO9000:2015)

(Clause Description-Paraphrase)

Clause 2.2.4 Interested Parties. The concept of interested parties extends beyond a focus solely on the customer. It is important to consider all relevant interested parties.

Part of the process for understanding the context of the organization is to identify its interested parties. The relevant interested parties are those that provide significant risks to organizational sustainability if their needs and expectations are not met. Organizations define what results are necessary to deliver to those relevant interested parties to reduce that risk.

Organizations attract, capture, and retain the support of the relevant interested parties they depend upon for their success.

(Highlights of the clause)

- (Ref to old Standards). This is a totally new clause.
- Interested parties are risks to organizational sustainability, if their needs and expectations are not met. (ISO9000:2015. Clause 2.2.4)
- Any of the interested parties can cause an interruption to the organization, thus affecting on-time delivery, and customer satisfaction.

2) 4.2 Interested parties and their needs and expectations

(Clause Description-Paraphrase)

Due to their potential effect on an organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, the organization shall determine the interested parties that are relevant to the quality management system and their requirements. The organization shall continue to monitor and review the analysis results.

(Highlights of the clause)

- (Ref to old Standards) This is a totally new clause.
- It talks about interest parties and their needs and expectations.
- The organization shall identify, study and manage the interested parties, in order to ensure smooth operations, achieve its objectives and avoid conflicts

- The organization shall continue to monitor and review the analysis results.

(Compliance Best Practice)

4.2 Interested parties and their needs and expectations

1. *To fully comply with this clause, you need to:*
   a) identify who are your interested parties, for QMS
   b) understand their needs and expectations,
   c) assess to what extend these needs and expectations are being met,
   d) decide which areas to improve,
   e) ensure actions taken are effective
2. *You can carry out the analysis on a single form, see* ***Exhibit 4-1.***
3. *A annual review shall be conducted. See* ***Exhibit 2-9*** *for review method*

3) SIs & FAQs

No SIs & FAQs for this Chapter

4) Supplementary Notes

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

Clause	Section	Clarification Subjects
4.2	CBP	**SN4.1 Who are the interested parties? Why are they significant?**
4.2	CBP	**SN4.2 How do we know their needs and expectations? Do we run interviews, conduct surveys etc?**
4.2	CBP	**SN4.3 How do we know we are meeting their needs and expectations?**
4.2	CBP	**SN4.4 How do we determine what kind of actions we should take?**
4.2	CBP	**SN4.5 Do we have to agree to everything specified/requested?**
4.2	CBP	**SN4.6 How to know if the actions taken is effective?**
4.2	CBP	**SN4.7 Can I combine this exercise with risk and opportunity analysis (external and internal analysis)?**
4.2	CBP	**SN4.8 Why do we need to run reviews?**

SN4.1 Who are the interested parties? Why are they significant?

Interested parties are those that pose risks to organizational sustainability, if their needs and expectations are not met. They pose various degree of risks to this sustainability, depending on prevailing situations.

Generally, interested parties are: customers, regulators, suppliers, employees, neighbours and local communities. Depending on your situations, you may further break them up into finer entities e.g. suppliers can be suppliers of commodities, or onsite subcons, transporters etc. internal interested parties can be further classified as shareholder, management, departments, individual employees etc.

SN4.2 How do we know their needs and expectations? Do we run interviews, conduct surveys etc?

There is no rules written on how you collect data and info. ISO/IATF did not say you must objectively interview or survey the target groups. So you can do the whole exercise without the involving any of the interested parties. But do get the right sources or channels to give an unbiased and reliable picture. Example: employee sentiments should come from HR. Customer satisfaction perception is best from sales & marketing. Community relations can be judged by the admin person who is in contact with

them. ISO just wants you to be aware of these risks, and take reasonable actions to keep things under control.

SN4.3 How do we know we are meeting their needs and expectations?

From the sources and channels you use, see SN4.2. You can follow up with a meeting with interested parties concerned. Some organizations interpreted the clause in the reverse manner. They listed down demands on the interested parties! This is totally the opposite of the intent of ISO.

SN4.4 How do we determine what kind of actions we should take?

You need to run an evaluation of the expectations from you current offerings, and consider the feedback from your sources/channels. You also have to consider the nature of the threats, urgency and your own capabilities, before you make further commitments.

SN4.5 Do we have to agree to everything specified/requested?

The answer is yes and no. For some of the interested parties, their expectations are non-negotiable. Enforcement agencies, for example, expects compliance to the relevant laws. You comply or be litigated. Customers are almost in the same category. It is always their way or the highway. Other expectations are generally negotiable. Auditors will judge on your agreement or consensus reached with the interested parties. Once you have agreed, you need to deliver.

SN4.6 How to know if the actions taken is effective?

You get feedback from the interested parties directly, or via your sources or channels.

SN4.7 Can I combine this exercise with risk and opportunity analysis (external and internal analysis)?

This is quite common, presumably due to the creativity of some consultants. It saves them work, but that is not the intent of ISO. If it is, ISO and IATF would have used a single clause rather than two different clauses. Although there are common elements, their purposes are different. R&O analysis is a general analysis and provides a picture where the risks and opportunities are. Risks from Interested Parties, on the other hand, can blow up quite suddenly, sometimes without any warning. The next thing is your operations are interrupted. Therefore interested parties deserve another analysis from another angle. Lumping the analysis with other studies can lead to the danger of negligence.

SN4.8 Why do we need to run reviews?

Analysis is based on a particular point in time with a particular set of factors and conditions. Risk is obtained by studying the interactions of these factors and conditions. With the passage of time, things change, conditions change. Risk will automatically change. To be in control, review is needed. The frequency of review will depend on the dynamics of the changes. But for practicality, review of interested parties can be done once a year, to coincide with risks and opportunities, or when a big change occurs.

5) Exhibits

Exhibit 4-1. Interested Parties Analysis

Interested Parties	Needs & Expectations	Counter Measures Provided	Degree of Meeting IPNE. Good/OK/OFI	Improvement Action
Customers: Include Immediate Customers, and Final Customers	Good & safe Products, on-time delivery, reasonable pricing, good services	Ongoing control on quality and delivery. Pricing and costing is managed by Management, Finance, Purchasing and Operations. Services are overseen by Management. Customer visit annually to review business	Good	NA
Regulators: Include Government Agencies & ISO/IATF	**Govt Agencies**: Comply to legislations, and regulations. **ISO/IATF**: Comply to the Standards .	**Govt Agencies**: For our industry only environmental and OSHA apply for regulators. Our company has ISO14001 and we comply to government regulations on OSHA **ISO/IATF**: Audits for last few years showed we are generally complying	Govt Agencies: Good ISO/IATF: Good	NA
Internal Stakeholders: Include Shareholders, Department and Functions, and individual employees	**Shareholders**: Fair returns for investments **Dept & Function**s: Smooth operation, not overly stressful for department staff **Employees**: Reasonable remuneration. Opportunities for career advancement. Job not overly stressful and low occupational hazards	**Shareholder**: Our company is a privately-funded company belong to a few shareholders. Our current returns rate had been acceptable by shareholders, in view of current business conditions **Dept & Functions:** Our operations are systematic and procedures govern most things. If problem, depts should get back to QMS team to resolve. Recently found QC inspectors workload getting too stressful due to customer demanding additional controls.	Shareholders: OK. Dept & Function: OFI.	NA IPNE-1
		Individual Employee. We provide package that are reasonable and fair. We are willing to listen to any request and respond accordingly. So far OK	Employees: OK	NA
External Providers: Include material Suppliers, Onsite Subcon, Transporter and other service providers	**Material Suppliers**: reasonable profits, prompt payment **Onsite subcons**: similar to suppliers above, plus occupational safety on site, no illegal activities **Transporter:** Similar to suppliers above, and free of hazards from organization's products. **Other Service Providers:** similar to suppliers above, plus occupational safety on site, no illegal activities.	**Material Suppliers/Other service providers:** We allow a reasonable pricing to suppliers and pay them promptly according to the agreed terms, with some flexibilities. **Onsite contractors.** both parties are required to play a part to ensure safety and environmental care. The company has done its part. **Transporters:** Our products do not pose any safety, health nor environment risks to them in making the deliveries. We also provide training to these contractors on how to comply to customers' requirement on their sites, and hazards to avoid.	Material and other service providers. Good Onsite contractors Good Transporters: Good	NA NA NA
Communities: Immediate neighbours	Free of harmful emissions from the organization's activities. Village head recently requested RM10000 to help maintain the road system, due to traffic passing their areas on the way to our plant	Our ISO14001 handles this part of emission. Details are provided in our EMS. Management met their delegation and agreed on RM5000/year until further notice, starting from next year.	Community. Good	NA IPNE-2

Action Code	Risk	Opportunity	Action	Due date	Action Plan Locations
IPNE-1	x		Increase 2 more QC inspectors as the current workload is getting too stressful. Job fatigue is setting in, leading to flow out of rejects to customers	June 2018	Manpower request/HR
IPNE-2	x		Financial controller to include this into next year budget	Dec 2018	Finance

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

- The list given are the common interested parties. You can add bankers, hospital, fire brigade etc., if applicable. On the other hand, you can also cut off some of the irrelevant ones given.
- Some organizations provide a list, but stop short of telling how they satisfy these needs and expectations. The exercise has practically lead them to nowhere. Some conclusions must be reached, so that actions can be taken if not satisfactory
- Not all needs and expectations have to be complied. Some are non-negotiable (e.g. regulators) but most are. But once an agreement is reached between the organization and a particular interested party e.g. community, then compliance to the agreement is expected.

>>End of Chapter <<

Chapter 5. Scope determination

Contents:

0) Introduction

There are only two related- applicable clauses in this chapter. The reason why a whole chapter is devoted to them is because scope determination is now a responsibility of the organization. When the scope is incorrectly defined, it may lead to registration issues, findings and negative audit conclusions.

1) 4.3. Determining the Scope of QMS (ISO9001)

(Clause Description-Paraphrase)

The organization shall determine the boundaries and applicability of the quality management system to establish its scope. When determining this scope, the organization shall consider: (a) the external and internal issues, (b) the requirements of relevant interested parties, (c) the products and services. All the requirements of this International Standard are applicable within the determined scope. The scope of the QMS shall be a documented information. Any omission from the scope affecting the organization's ability or responsibility to ensure conformity of its products and services and the enhancement of customer satisfaction, will invalidate the claims of conformity to this standard.

(Highlights of the clause)

- (Ref to old Standards). This is a totally new clause
- ISO now requires the organization to be responsible for defining the scope.
- It also warned that if an exclusion made which is not justified, the whole QMS is deemed not conforming to the international standard.

(Compliance Best Practice)

4.3. Determining the Scope of QMS
See Clause 4.3.1 for a combined discussion

2) 4.3.1 Determining the scope-supplemental (IATF16949)

(Clause Description-Paraphrase)

Supporting functions, whether on-site or remote (such as design centres, corporate headquarters, and distribution centres), shall be included in the scope of the Quality Management System (QMS). Any exclusion shall be justified. For design, only product design can be excluded, but manufacturing process design is still required in all cases.

(Highlights of the clause)

- (Ref to old Standards) This is a totally new clause.

- For automotive application, there is an additional requirement to record the addresses of all the manufacturing sites, remote locations, HQ etc, on the QMS documentation, as part of the scope.
- Exclusion need to be justified
- Finally the clause states that manufacturing process design cannot be excluded, which had always been the case.

(Compliance Best Practice)

4.3.1 Determining the scope-supplemental

1. *This clause and 4.3, are on how to define the scope. See **Exhibit 5-1 & 5-2.***
2. *The scope statement is a documented information. It can be listed in the Quality Manual or some other documents as an evidence of compliance.*
3. *Although not stated, review of scope is necessary. Notify your CB, by returning their request for updates. If you wish to retain a road map of your review for future reference, an example is given in **Exhibit 5-3.***
4. *Your certification body (CB) will help you to frame the scope during registration stage. They have to ensure the correct information are submitted for approval.*
5. *Subsequently. IATF auditors will also review the scope during each audit, to make sure it is still suitable. Therefore, on the whole, scope determination is not a major issue.*
6. *Request all your remote locations to include in their certificates, that they are supporting your site, and list out the services provided. See **Exhibit 5-4A & 5-4B**.*
7. *If your remote location is not an IATF-certified organization, they should include the information on their QM. Otherwise there will be complications. **See SN-5.4** for explanations.*

3) SIs & FAQs

No SIs & FAQs for this Chapter

4) Supplementary Notes

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

Clause	Section	Clarification Subjects
4.3	CBP	**SN5.1 Why are organizations asked to define the scope with this new version?**
4.3	CBP	**SN5.2 According to the example give, there are a lot of work. Do we have to do so much of spadework to define the scope?**
4.3	CBP	**SN5.3 Why remote locations must put the main site's particulars on their Certificates, or QM? What complications can arise?**
4.3	CBP	**SN5.4 What should the remote locations write in their QMs?**
4.3	CBP	**SN5.5 What happen if a IATF auditor find the scope is no longer suitable? What happens next?**
4.3	CBP	**SN5.6 How do I inform CB on changes of scope?**
4.3	CBP	**SN5.7 Must the scope written on my QM same as given on the certificate or audit notification issued by the CB?**
4.3	CBP	**SN5.8. Is review on scope statement necessary? And how do we do that?**

SN5.1 Why are organizations asked to define the scope with this new version?

The purpose of a correct scope is to ensure the QMS is adequately designed to support the operations. In the past, there were organization claiming activities in the scope which is not available e.g. assembly.

There were also organizations hiding activities from the scope because they wanted to simplify the registration process. Frequent disputes amongst CB, organizations and the auditors occur, when things go wrong. By making the organization responsible for the scope definition, chances of getting the correct scope is better.

SN5.2 According to the example give, there are a lot of work. Do we have to do so much of spadework to define the scope?

Exhibit 5-1 is just a diagram showing how the scope is defined, and their elements. There is no work here. **Exhibit 5-2** systematically logs down the decisions that brings out the scope logically. It is there if you should want to use it, but it is not compulsory.

SN5.3 Why remote locations must put the main site's particulars on their Certificate or QM? What complications can arise?

First and foremost, there is an IATF Rule that allows the main site auditor to accept a remote location's report in lieu of onsite audit, under certain conditions. It these conditions are not met, the main site auditor shall conduct onsite audit. If the distance between the 2 entitles are far (e.g. Vietnam Site and Japan HQ), it can be costly. The most common condition not met is the linkage of the two is not established. It is not stated in the audit report, nor on the certificate of the remote location. The result is onsite audit needed for the remote locations.

The best method is to include your site on their certificate. If the main site is on the certificate, there can be no argument. Next best thing is putting your organization as a supported site on the QM of the remote location. It alerts the QMR and the auditor (of remote location) of the existence of a supported site. The audit report can then mention about this support, and it will serve the purpose.

SN5.5 What happen if a IATF auditor finds the scope is no longer suitable? What happens next?

There are 2 scenario here: a) the certificate has not been issued yet, e.g. initial certification or recert, b) certificate has been issued e.g. surveillance audits, or special audits.
In case a), it is a matter of document change to be submitted along with the report. But if the change requires increase of mandays, auditor will seek authorization of regional office to change mandays, there and then. For case b), what is said of a) applies to b). However, the certificate will need to change and there will be some cost to this.

SN5.7 Must the scope written on my QM same as given on the certificate or audit notification issued by the CB?

Technically they should be identical. However, they are often not the same. One reason is due to a lack of checking of the documentation, especially after some modifications for done registration. This is a nonconformity because this is a documented information. It is interesting to note that the 2 statements can never be the same, not 100%. The certificate will only carry the scope statement. Exclusion is there, but in some corners of the certificate. So are the addresses. Your scope statement in your QM tends to be neatly placed in a good, flowing manner. But this is OK and acceptable.

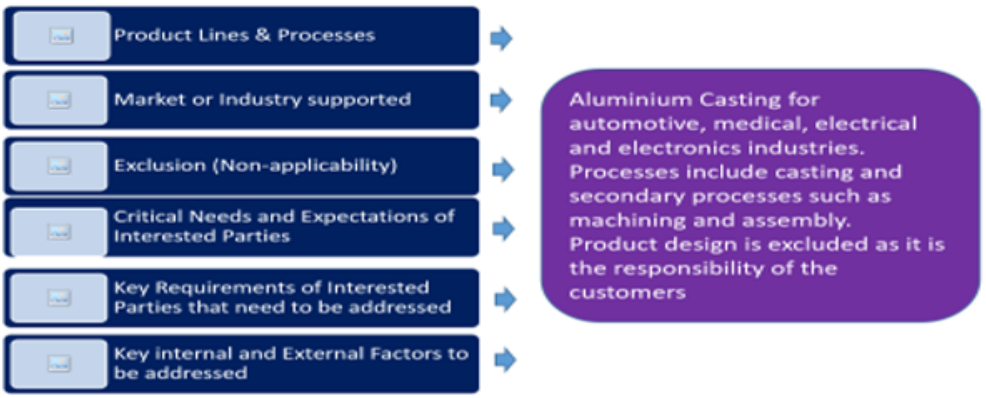
SN5.8 Is review on scope statement necessary? And how do we do that?

Review is not stated as a requirement, but in all intents and purposes, it is a requirement by the CB. That makes it a requirement. If you have derived the scope statement the way given in **Exhibit 5-2**, the review is easy. If not, **Exhibit 5-1** can guide you through, and you can summarize your evidence in **Exhibit 5-3.**

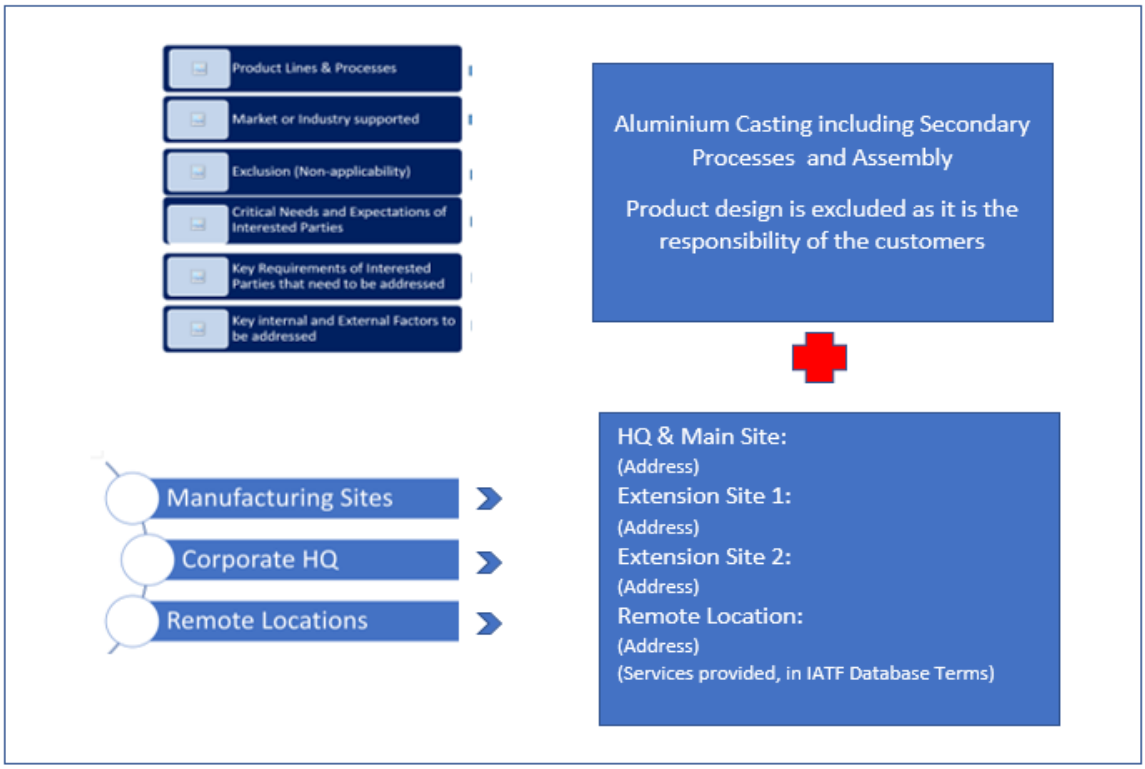
5) Exhibits

Exhibit 5-1. Determining the Scope

1. (ISO9001:2015 Scope Statement)



2. (IATF16949:2016 Scope Statement)



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

- CB will assist you on how to word the scope, but you have to provide the information.
- Note that you are not required to state "for automotive industry". In fact, IATF will not entertain you even if you request.

Exhibit 5-2. Determining Scope, Step-by-Step

<table>
<tr><th>S/N</th><th>Guide</th><th>Actual</th></tr>
<tr><td>1</td><td>a) Current Scope
b) If no current scope, scope is determined by (2) below</td><td>Example Injection Molding and Secondary Processes</td></tr>
<tr><td>2</td><td>Scope Determination
Product, activities/processes, industries supported, Non-applicability /exclusion</td><td>
<table>
<tr><td>Categories</td><td>Specifics</td></tr>
<tr><td>Product</td><td>Plastic parts</td></tr>
<tr><td>Activities/ Processes</td><td>Injection moulding, secondary processes</td></tr>
<tr><td>Industry Supported</td><td>Electrical and Electronics, automotive</td></tr>
<tr><td>Exclusion</td><td>Product Design</td></tr>
</table>
</td></tr>
<tr><td>3</td><td>Any other significant types of interested parties in the scope?
a) Regulators.
b) Suppliers
c) Employees
d) Community
e) Emergency Agency
If yes, provide a phrase to fit into the scope</td><td>
<table>
<tr><td>Interested Parties</td><td>Yes/No</td><td>Remarks</td></tr>
<tr><td>Customers</td><td>Yes</td><td></td></tr>
<tr><td>Regulators</td><td>No</td><td>We have ISO14001 and ISO45000 for EHS</td></tr>
<tr><td>Suppliers</td><td>Yes</td><td></td></tr>
<tr><td>Employees</td><td>Yes</td><td></td></tr>
<tr><td>Community</td><td>Yes</td><td></td></tr>
<tr><td>Emergency Agency</td><td>No</td><td>We do not have processes that can lead to emergency situations</td></tr>
</table>
</td></tr>
<tr><td>4</td><td>Are all significant Internal Issues identified in Internal processes being considered? Any key issues to add to the scope statement?</td><td>Yes. No significant issue to be added to scope statement</td></tr>
<tr><td>5</td><td>Are all External Issues identified being considered? Any key issues to add to the scope statement?</td><td>Yes. No significant issue to be added to scope statement</td></tr>
<tr><td>6</td><td>Final Scope Statement, in 2 parts:
• Scope
• Non-applicability and justification</td><td>(Scope) Manufacture of Plastic Parts for Electrical and Electronics, and automotive.
(Additional statements-if applicable)
Example 1: The product shall be in compliance to XXX Act 2016.
Example 2: The production and related activities shall not create environmental problems to the immediate community
(Non-Applicability and Justification) Product Design is excluded as Organization shall manufacture to Technical Specs and Drawing provided by Customers.</td></tr>
</table>

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

- You may keep a record like this, but it is entirely optional. What is mandatory is the final scope statement is recorded somewhere in the QMS documentation.
- Note the yellow highlight section. ISO9001 actually wants open critical issues of organization context and interested parties issues to be considered for inclusion.
- In practice, CB will not encourage you to do so. You should just tackle them elsewhere in your QMS. Example 1 may be taken as a customer requirement and managed from there. Example 2, on the other hand, can be managed via your ISO14001:2015 EMS.

Exhibit 5-3. Scope Review Records

Scope Review For Year (2019)

Current Scope:

Plastic Injection Moulding for electrical, electronics, medical and automotive industries

A. Considerations

No	Areas of Consideration	Scope Change Needed		If yes, describe change needed
		No	Yes	
1	Product Lines & Processes		✓	Add Assembly
2	Market and Industry Supported	✓		
3	Exclusion (Non-Applicability)	✓		
4	Critical Needs and Expectations of Interested Parties	✓		
5	Key Requirements Risk & Opportunities. need to be addressed	✓		

B. Final Scope Statement of EMS

☐ No Change needed, Remain
☑ Changes as below:
(ISO:9001:2015:)
Plastic Injection Moulding & Assembly for electrical, electronics, medical and automotive industries
(ISO:16949:2016:)
Plastic Injection Moulding & Assembly

Prepared by Approved by

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

- This is another optional document. If you need to have a trail how you reviewed the scope, this is one way.
- This record is good to show evidence. It is just a 'tick' job with a pen, and sign. No elaborate typing or calculations

Exhibit 5-4A Supported Sites on Certificates

CERTIFICATE

kiwa

Reg. Number 8302 - T

First issue date 2018-10-15 Last change date 2018-10-15

Valid Until 2021-10-14 IATF Number 0338345

Quality Management System Certificate

IATF 16949:2016

We certify that the Quality Management System of the Organization:

Simmonds Marshall Ltd.

Is in compliance with the standard IATF 16949:2016 for the following products/services:

Manufacture of Nuts, Bolts, Fasteners and Auto Components of through the process of cold forging and Taping.

Chief Operating Officer
Giampiero Belcredi

Exclusions: 8.3 related to the product design

This certificate is issued in conformity with IATF Rules – Fifth Edition.
Maintenance of the certification is subject to annual survey and dependent upon the observance of Kiwa Cermet Italia contractual requirements.

This certificate is composed of 1 page.

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding Srl
Via Cadriano, 23
40057 Granarolo dell'Emilia (BO)
Tel +39.051.460.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

Simmonds Marshall Ltd.
Certified Sites
- Mumbai Pune Road, Kasarwadi, 411

Place the organizations that you are supported and type of services here

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

- This is the best way to establish the link between you and the remote locations
- Other alternatives include placing remote location details in you QM, and also request them to include your site in theirs
- A third way to via a contract between you and the remotes.

Exhibit 5-4B. Inclusion of supported sites in Remote Location's QM

Quality Manual QMXYZ . Rev XX

… … …

… … …

8. Support Services to Other Plant

No	Name of Organization and Address	Support services Provided
1	XYZ Thailand (Your plant)	Product Design & Testing
2	XYZ Hungary	Product Design & Testing
3	XYZ Poland	Product Design & Testing, Purchasing
4	XYZ Brazil	Product Design & Testing

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

- The best way to link you up to the remote locations is to include your names, addresses, and supported services, on their IATF 16949 certificates.
- The next best thing is to request all your remote locations to include your name in their Quality Manuals like the above example.
- This statement can also be placed on any other QMS documentation instead of the QM, although QM is the easiest and most practical.
- You can also sign a contract with the remote location, and use the contract as evidence.

>>End of Chapter 5 <<

Chapter 6. Customer Specific Requirements

Contents:

0) Introduction

There is only one applicable clause (4.3.2) in this chapter. Clause 9.2.2.1 internal audit is here to show it has some links with Clause 4.3.2, on internal audit. The reason why a whole chapter is devoted to this is because the Clause 4.3.2 is not well understood or poorly presented. Many NCs have been written on this clause alone.

1) 4.3.2 Customer-specific requirement (IATF16949)

(Clause Description-Paraphrase)

Customer-specific requirements shall be evaluated and included in the scope of the organization's quality management system.

(Highlights of the clause)

- (Ref to old Standards) This is a totally new clause.
- Customer specific requirements (CSR) needs to be stated or referred, in/from QMS Documentation
- CSR shall be evaluated for compliance

(Compliance Best Practice)

4.3.2 Customer-specific requirement

1. *Most CSR are contained in Supplier Quality Manuals (SQM), which are given to the suppliers on appointment.*
2. *Some SQM run into hundreds of pages and it is difficult to pick out the CSR at a glance. You should first summarize or extract the key points from the SQM. This step is then followed by an evaluation.*
3. *Evaluation means is gauge whether the CSR are complied. See **Exhibit 4-1** for a specimen.*
4. *A more useful way is to prepare another checklist and 'matrix' the CSRs to the various functions/dept/processes. This list is then shared with all relevant functions/departments, to create better awareness.*
5. *This second list can also be used to conduct internal audit to fulfil 9.2.2.1's requirement of sampling CSR for implementation effectiveness. See **Exhibit 4-2** for the second list.*
6. *Inclusion in the QMS means it should be documented and form part of the QMS. CSR details can be kept in a separate folder, and mentioned in the QM.*
7. *Lastly, CSR can be listed out in any manner, There is no requirement for CSR to be given along the Clauses of IATF16949 standards. This is stated in FAQ 8.*

2) 9.2.2.1 Internal Audit Program (IATF16949)

(Clause Description-Paraphrase) The organization... . Integrated with these audits, the organization shall sample customer-specific quality management system requirements for effective implementation.

(Highlights of the clause)

This chapter only reminds CSR needs to be audited during internal audit.

(Compliance Best Practice)

9.2.2.1 Internal Audit Program

1) Auditing of CSR during internal audit can be done in 2 ways:

a) audit the entire list by a team;

b) split the duties to the various QMS system auditors. Example: the internal auditor auditing purchasing will be asked to audit the CSR concerning purchasing process.

2) The 2nd list comes in very handy as an audit checklist. Audit notes can be taken on it as evidence.

3) SIs & FAQs

No SIs & FAQs for this Chapter

4) Supplementary Notes

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

Clause	Section	Clarification Subjects
4.3.2	CBP	**SN6.1 Is CSR same as technical drawings and specifications?**
4.3.2	CBP	**SN6.2 If there is no SQM given by customer, can I say there is no CSR?**
4.3.2	CBP	**SN6.3 If we do like suggest, extra the important ones only and leave out the rest, are we filtering? Any problem of some CSR got miss out?**
4.3.2	CBP	**SN6.4 Can't we just circulate a copy to all departments and let them do what is needful?**
4.3.2	CBP	**SN6.5 Do we compile one CSR sheet for each customer? Or can I have a general list that include all customer's CSR in the same list?**
4.3.2	CBP	**SN6.6 How to refer for CSR to make it part QMS documentation?**
4.3.2	CBP	**SN6.7 When preparing CSR of a particular customer, must it fit into the IATF clauses?**
9.2.2.1	CBP	**SN6.8 What is meant by sampling for implementation effectiveness?**

SN6.1. Is CSR same as technical drawings and specifications?

No, they are not the same. Customer-specific requirements are something specific to the customer, that may not be found in other customers. This is also not the same as requirements stated on the drawings or technical specs, which are better known as 'technical requirements'. However, it must be stated that some technical requirements are so important that the customers will also include them again as CSR e.g. CPK to maintain as t higher value of 1.67, instead of the common 1.33.

SN6.2. If there is no SQM given by customer, can I say there is no CSR?

Quite often a customer does not have a SQM, and the organization reports there is no CSR. This is not correct. SQM is only a convenient place for customers to list down their specific requirements. A customer not giving out a SQM does not mean it does not have specific requirements. It is the responsibility of the organization to build the list from a variety of sources e.g. meeting and email communications, PPAP, customer audit checklists, audit findings etc.

SN6.3. If we do like suggested here, extract the important ones and leave out the rest, are we filtering, and short-communicating ? Any problem of some CSR being left out?

First, the clarification on extracting. We are not extracting the important ones, but the specific ones relating to the customer, and applicable to you/your industry. It may be just a few items, or it may be a lot. Those requirements already in your general QMS need not be extracted. You can further avoid this possibility of short-communicating, by uploading the entire SQM onto a server or public folder. In doubt, the departments concerned can check on the 'original' document.

SN6.4. Can't we just circulate a copy to all departments and let them do what is needful?

Some SQM run into hundreds of pages. If you just circulate a copy to all the departments, no one will bother to read it. And organization runs the risk of not complying to CSR consistently. You need to do some spadework here, to help out the internal departments

SN6.5. Do we compile one CSR sheet for each customer? Or can I have a general list that include all customer's CSR in the same list?

One CSR checksheet for each customer is the correct way. The requirements will not mix up one with another. Firstly some customers may be sensitive about their requirements being placed onto some common list. Besides, individual list is extremely useful to prepare for customer audit. Individual list allows you to rotate the customers for CSR audit.

SN6.6. How to refer for CSR to make it part of QMS documentation?

You can mentioned this in the body of the QM, or attach a masterlist of CSR of all customers, to the QM.

SN6.7. When preparing CSR of a particular customer, must it fit into the IATF clauses?

No, you don't have to link to the IATF clauses. You should use the customer's reference code for better traceability. See FAQ8.

SN6.8. What is meant by sampling for implementation effectiveness?

Sampling means you don't have to audit every customer's CSR, or all the items. You can select customer A for this year, and Customer B for next year. However, you should show you are auditing all within the certification cycle of 3 years. This 3 year period is not a rule, but generally expected by IATF and CB. If you cannot do so, explain to the auditor. I have seen an audit client doing floor mats, with some 14-15 customers. They use a 5 year-cycle and the audit team accepts as reasonable.

5) Exhibits

Exhibit 6-1: CSR Compilation and Evaluation

Key customer requirement & Evaluation

No	Criteria	Requirement	Complying
0	CSR Document	Alliance Supplier Guide 2.3 (April 2014)	Info only
1	Record Retention Period	A/B/OBD: (Important). 10 years. Normal doc: 3 years	Yes
2	Management Review Frequency	No specs. Follow organization	Yes
3	Internal Audit Frequency	No specs. Follow organization	Yes
4	Complaint Response Format	8D Concern & Countermeasure Report Summary (8D-CCR)	Yes
5	Complaint Response Time	Containment Measure:24 hrs Corrective Actions: 10 Working Days	Yes
6	Customer Special characteristics Identification	A: very Important. B: important, C: Regulatory (OBD)	No. Not included in inspection plan
7	Cpk Requirement	>1.33	Yes
8	Process and Product audit requirement	No specs.	Yes
9	Layout Inspection/ Functional Testing frequency	Once a year, Inspection Report Supplier Test Plan and Report	Yes
10	Part approval process	Refer ASG Section 7.1	Yes
11	PPAP Submission items	Refer ASG Section 7.1	Yes
12	Others		
	Other sources of CSR		
1	Customer audit	Customer requires improvement on Yototen program. 16 Jun 2016	Yes

Action Plan

Item	Action	Due date	Incorporated into (QMS Doc)
6	Inspection plan to include the special characteristics	30 Jun 2017	QA WI XXX

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

- SQM contains a lot of requirement but most are common things. And you would probably have them catered for by your QMS already. To be effective, you should compile just what are the unique or special ones
- The step of evaluation of CSR is a requirement. Most organizations did not do it in the early year of transition

Exhibit 6-2.CSR-Processes Matrix.

No	Criteria	Requirement- Nissan	Management	Sales & Mkt	Process Design	Planning & Orders	Product-ion	Store & deliv	QAQC	MTN & Tooling	HR	Purchase	QMR/ DCC
0	CSR Document	Alliance Supplier Guide 2.3 (April 2014)											
1	Record Retention Period	A/B/OBD: (Important). 10 years. Normal doc: 3 years			x								x
2	Management Review Frequency	No specs. Follow organization	x										x
3	Internal Audit Frequency	No specs. Follow organization	x										x
4	Complaint Response Format	8D Concern & Countermeasure Report Summary (8D-CCR)		x					x				x
5	Complaint Response Time	Containment Measure:24 hrs Corrective Actions: 10 Working Days		x					x				x
6	Customer Special characteristics Identification	A: very Important. B: important, C: Regulatory (OBD)			x				x				x
7	Cpk Requirement	>1.33			x				x				
8	Process and Product audit requirement	No specs.											x
9	Layout Inspection/ Functional Testing frequency	Once a year, Inspection Report Supplier Test Plan and Report											x
10	Part approval process	Refer ASG Section 7.1		x	x				x				x
11	PPAP Submission items	Refer ASG Section 7.1		x	x				x				x
12	Others	None											
	Other sources of CSR												
1	Customer audit	Customer requires improvement on Yototen program. 16 Jun 2016			x		x						x

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

By distributing responsibilities of managing CSR has 2 advantages:
a) the internal departments have no excuse that they are not aware
b) internal auditors can use this matrix to audit for CSR.

>>End of Chapter 6 <<

Chapter 7. QMS & its Processes

Contents:

0) Introduction

There is only one applicable clause in this chapter. The reason why a whole chapter is devoted to this is because the clause in general is not well understood and/or poorly catered for. Many NCs have been written on this clause alone.

1) 4.4, 4.4.1 QMS and its processes (ISO9001)

(Clause Description-Paraphrase)

The organization shall establish a QMS process, to implement the requirements of this standard. The processes shall include input, sequence and interactions, criteria and methods to measure, resources, responsibilities. Risks and opportunities shall also be included. These processes shall be evaluated and implement any changes /improvements needed to ensure that these processes achieve their intended results.

(Highlights of the clause)

- (Ref to old Standards) This is a totally new clause.
- Organization shall defined the processes needed to support the QMS
- Elements that make up a process shall also be identified e.g. input, output, control methods and criteria, performance indicators, responsibility and authority; and the relevant resources (man, machine, materials and methods), sequence and interactions, risks and opportunities etc.
- This ISO9001 clause is describing about process approach. But in practice, ISO is still far from practicing this method. It is very much of clause-based or element-based approach. Getting organizations now to define sequence and interactions, and details of a process. is definitely a good start towards the goal.
- IATF, on the other hand, has make this into an art form by introducing concepts like Turtle diagrams, Octopus Diagrams and Process Mapping, to document the processes. All elements of the processes are active used to enhance and improve the processes

(Compliance best practice)

4.4, 4.4.1 QMS and its processes

1. *To go process approach, you should first identify the processes. One easy way is to amalgamate closely-related procedures into blocks, or 'processes'. See **Exhibit 7-1.***
2. *Next is to link up the newly-created processes, in the actual sequence and interaction, to become a process map for your organization.*
3. *There are several ways to do this. The 3 most-commonly used methods are given below.*
   - *Type 1, MP-COP-SP Process Mapping. See **Exhibit 7-2***
   - *Type 2 , Box-and-line business flow chart. See **Exhibit 7-3.***

- *Type 3, PIOR (process input-output resource) Matrix. See **Exhibit 7-4.***
- *To be complete, you need to use Type 1 + Type 2, or Type 3+ Type 2. **See SN-7.5** for explanations.*

4. *For each individual process, it shall show its elements, which is: a) input-process-output, b) resources i.e. man, machine, method and measurement. One easy way to do this is using the turtle diagram. See **Exhibit 7-5**, and **SN-7.2** for more information*

2) SIs & FAQs

No SIs & FAQs for this Chapter

3) Supplementary Notes

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

S/N	Clause	Section	Clarification Subjects
1.1	4.4.1	CBP	**SN7.1 What is the difference between a process and a procedure?**
1.2	4.4.1	CBP	**SN7.2 How to prepare a turtle diagram?**
1.3	4.4.1	CBP	**SN7.3. Any additional clarifications on turtle diagrams, to guide on compiling them correctly?**
			SN7.4 Is turtle diagrams mandatory?
1.4	4.4.1	CBP	**SN7.5 What are the differences of the 3 types of process mapping? Which one is better?**
1.5	4.4.1	CBP	**SN7.6 Is it mandatory to designate processes as MP-COP-SP?**
1.6	4.4.1	CBP	**SN7.7 What are the criteria to decide MP, COP or SP for processes?**
1.7	4.4.1	CBP	**SN7.8 What is the optimum number of processes to use?**

SN7.1. What is the difference between a process and a procedure?

The two are related, but not identical. The elements of a process include input, process activities, output, resources (man, machine, method, materials etc). Therefore processes tend have a wider scope, which include procedures.

SN7.2. How to prepare a turtle diagram?

The term 'turtle diagram' comes from the configuration formed, when placing the elements of I-P-O, and the 4M together.

The elements are: I (input) is the head, O (output) is the tail, P (process activity) is the shell. The 4M becomes the legs: **M1 (machine), M2 (man), (M3) method and (M4) measurement.** Neat and easy to remember.

I (input): Generally includes things that start the ball rolling. In manufacturing for example, the input is the customer P/O, or a work order from the planner. You should also include other supporting information such as process documents (PFMEA, Control Plan, Packing Instructions etc). Materials, CSR, and legal requirements also go in here as input.

O (Output). Output is what we plan to have. In production, it will be products, which we mean conforming products. Scrap can be included, especially you are controlling it. Note that there is a connection with M4 (measures), and therefore M4 should be found in 'O' directly or implied.

P (Process Activity). This is for writing the process name, as detail activities are given in M3.

M1 (Machine) Basically you record key equipment needed for this process. You should also include special facilties and work environment required.

M2 (Man). Basically is about manpower needed for the process. Focus on 2 areas, type and competency. Special competency should be noted e.g. special grade of welding skill. Note that people outside the department may also be included here.

M3 (Method). This includes guiding documents (SOP, WI, formula lists) etc. You should list them out.

M4 (Measurement). KPI goes in here. It must be the same as what you listed out in the KPI list. However, there is no need to put the quantum here. Reference to current KPI list is acceptable.

There is a tendency to add risk and opportunity to the turtle diagram, which is a good development, since these are new and important requirements of ISO.

SN7.3. Any additional clarifications on turtle diagrams, to guide on compiling them correctly?

- **Why is process document, CSR, legal requirements placed in 'input'?**
  There is no other suitable boxes for them. Besides, they are input
- **Why are guiding documents place in "M3 method" and not in input?**
  These are methods, and there is a special box M3, reserved for them
- **How do we list the competency in M2?**
  First list the type of people needed e.g. tool setter. Place the special skill behind within brackets, if any.
- **Do we list down all the details of SOP etc?**
  No, just list the names or titles of the relevant documents
- **Why not put the KPI quantum in M4?**
  In IATF, objectives setting is annual. Chances for changes are high and you will find a need to revise the turtle diagram. This is a waste that can be prevented.
- **The boxes at risks and opportunities are so small, and insufficient to list down all R&O. What do I do?**
  List the top 1-3 R&O is sufficient. Turtle diagram is a pictorial representation of a process. It is an overview and therefore cannot accommodate all information.

SN7.4. Is turtle diagrams mandatory?

No, turtle diagram is not mandatory. There is no prescribed format and you can use one that suits your preference. IATF certified organizations tend to use the turtle diagrams. In Europe other forms of diagrams are use. The use of PIOR (Process Input-output-Resources) chart actually can do away the turtle diagrams as all the process elements are shown here.

SN7.5. What are the differences of the 3 types of process mapping? Which is still better?

Type 1. It is the (MP-SOP-SP) method, showing how the total processes in some sequence. Interactions however cannot be shown here very clearly. Although not perfect, it is simple to understand and conceptualize. This process map is essentially built on the turtle diagrams , where the resources are clearly shown.

Type 2. It is the Box and line diagram. The process flow is very detail showing the entire value-added flow from RFQ to delivery, to customer feedback. This is basically the version used in old ISO9001. The weaknesses

are a) resources are not seen, b) not all the boxes are processes. Some are just activities while some are processes, and becomes somewhat confusing.

Type 3 is the PIOR Chart. It is just a table listing out the various elements of a process. (**Exhibit 7-3)** The inadequacy of this method is it does not show sequence and interaction clearly.

To bridge the gap for any inadequacy, you should use 2: a) Type 1+Type 2, or b) Type 3+Type 2. Then everything is in place. The choice is a matter of personal preference. I personally prefer a) Type 1+Type 2.

SN7.6. Is it mandatory to designate processes as MP-COP-SP?

No, the prefixes are not necessary. You can use other terms or omit them totally. But there are some advantages in using them to set some priorities. IATF auditors also look for priorities this way. COP are priority areas. COP are important because process owners have direct contact with customer, and there could be undetected risks. In management, a term has been invented "moment of truth" on these contact points. They can either make fans or create enemies for the organization.

MP and SP are support processes. While they are integral part of the QMS, they are often carried out behind the scenes, and therefore less urgent and critical. MP and SP differs in the hierarchical level of implementation. MP have direct top management attention, while SP are managed by HOD and specialists on a routine basis.

SN7.7. What are the criteria to decide MP, COP or SP for processes?

There are 2 ways to classify them: a) any direct contacts with customer?, b) are they getting a lot of customer emphasis? In terms of sequence, we should use the first method first, and then modify the picture using the second.

COP: Customer orientated processes are those with direct contact with customers. They therefore should include RFQ, Order Processing, Product design, manufacturing design, customer complaint, customer satisfaction, invoicing and collection.

MP: Management Processes. There is no customer contact and therefore is a support process, but is a higher form of support process. Additionally, management is directly involved or paying close supervision to them. Business Planning, internal audits, management review, continual improvement, strategic analysis should come into this grouping. I sometimes see but never understood why would an organization consider HR and documentation as MP. These 2 processes are not that high up in the operation hierarchy.

SP. Support Processes are the rest of the processes. The routine type of support activities: HR, documentation, purchasing, maintenance, QAQC services including MSA and SPC, calibration, NC output Handling etc, should come into this group.

When you start to use the second method to modify (customer emphasis), production should be included as COP. Production planning may also be included as COP depending if the planner is in direct contact with customer. QAQC may also be included as COP, if customer emphasises a lot on this capability e.g. customer visits frequently to check on this process. Invoicing and collection can be best downgraded to SP. Although there is direct contact with customers, it is normally of low urgencies and not related with quality or delivery directly.

SN7.8. What is the optimum number of processes to use?

There are no rules on this. We often see 2 common and opposing mistakes:

a) splitting the processes too fine, example a process for IQC, first run IPQC, FQC and OQC.

b) exceptional large processes used. Example, Management process that covers business planning, management review, internal audits, continual improvement, strategic analysis, setting policy and objectives, and corporate responsibility.

The ideal picture is somewhere in between. A better deciding factor is the complexities rather than size. Meaning: how many of commonalities that can fit into a single turtle diagram. In the example of a) above (QC), probably 1 turtle can be used for all the 4 processes, due to similarity in the activities. Whereas in case b) (Management) above, the processes should be broken up into 3-4 processes. Business planning and management review can be the same turtle, internal audit another turtle etc.

A process can have several turtle diagrams to make thing clearer. For example, for purchasing, you can have a turtle diagram for purchasing process, (from PR to PO to tracking to receiving), and another turtle to deal with supplier control. This is a case of 1 process, 2 turtles.

The number of processes should not be a key consideration. But for people to memorize easier, stick close to the departments in existence. 20 processes ± 3 should be optimum, depending on the size of your organization and responsibilities.

4) Exhibits

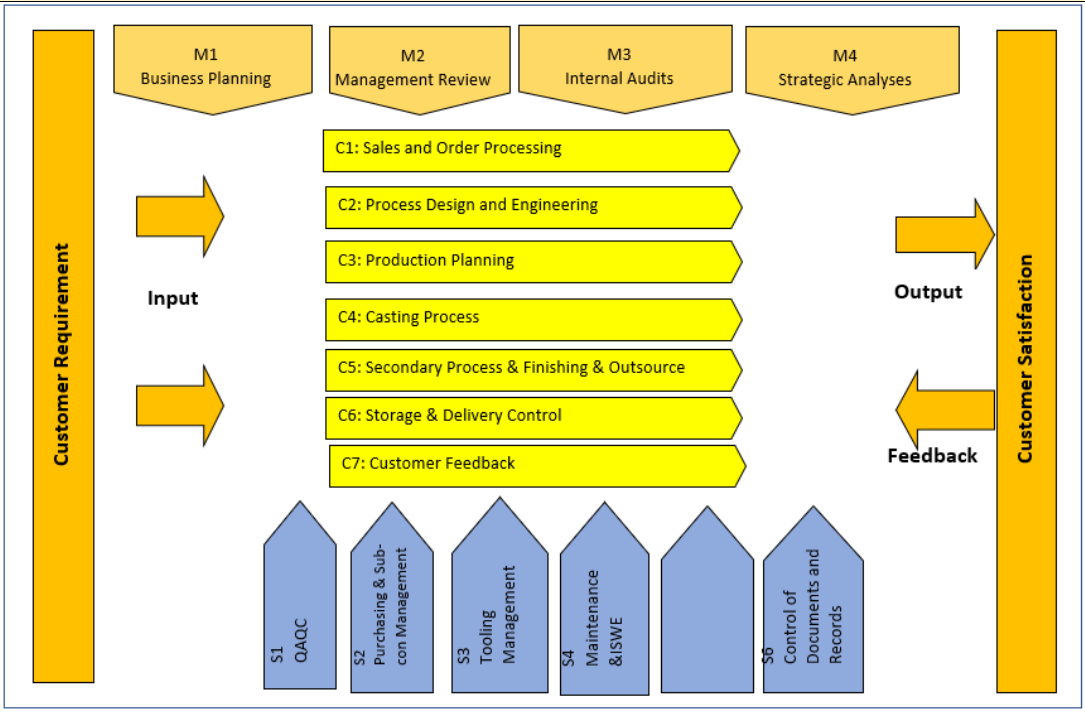
Exhibit 7-1. Forming Processes from Procedures

Procedures	Management Oriented Processes MP
QMR-QSP-06 Business and Resource Planning	MP1.Business Planning
QMR-QSP-01 Management Review	MP2. Management Review
QMR-QSP-03. Internal Audit-System Audit QMR-QSP-04 Manufacturing Process Audit QA-QSP-09 Product Audit, Layout Inspection and Functional testing QA-QSP-02. Internal Quality Audit	MP3.Internal Audits
QA-QSP-03 Corrective action & Preventive Action	MP4.Corrective and Preventive Actions
Procedures	**Customer Oriented Processes COP**
SAL-QSP-01Customer Order Review	COP1: Sales and Order Processing
ENG-QSP-01APQP and Control Plan QA-QSP-05 PPAP ENG-QSP-02 FMEA QA-QSP-06 SPC QA-QSP-07 MSA/GRR ENG-QSP-03 Control of Engineering Change	COP2: Process Design and Engineering
SAL-QSP-01Customer Order Review PDN-QSP-03. Production Planning	COP3: Production Planning Process
Procedures	**Support Oriented Processes SP**
QA-QSP-01 QA Inspection QA-QSP-02 Control of Non-Conforming Product QA-QSP-03 Corrective And Preventive Action QA-QSP-04 Control Of IMT Equipment QA-QSP-08 Internal Laboratory and Control QA-QSP-09 Product Audit, Layout Inspection and Functional Testing	SP1. QAQC
PUR-QSP-01 Purchasing PUR_QSP-02 Management of Suppliers	SP2. Purchasing & Sub-con Management

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

- A procedure is a series of activity implemented to achieve a defined outcome.
- In QMS, a process is generally larger than a procedure, to represent blocks of interrelated activities, which can include many procedures, as shown in the above diagram. A process must have a clear input & output of the activities.
- The purpose of organizing procedures into processes is facilitate process approach.
- The above example showed only 3 processes, due to space constraint

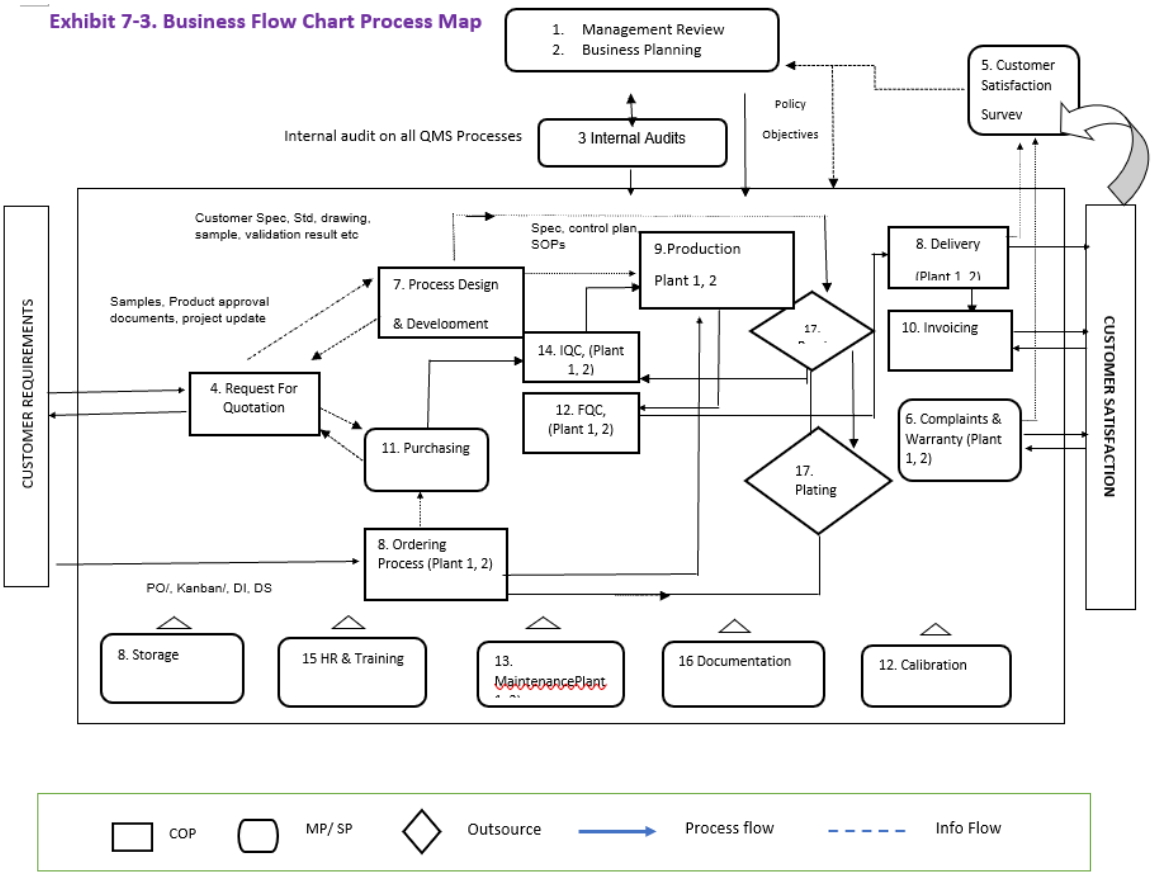
Exhibit 7-2. MP-COP-SP Process Map



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

- This is only one method of showing a process map and the processes are categorized as MP-COP-SP.
- But this is not the only type you can use. In IATF auditor's training, we are exposed to some 10 types
- This map however does not show sequence and interaction well. You normally require a business flow chart to complement this map. See Exhibit 7-3.
- Also note that you may be asked where are the context and interested party analysis. They are shown inside the process map as M4. Strategic Analyses. This method is neater than showing them outside the map and connected by arrows.
- Also note that you may be asked where is outsourcing. They are shown inside the process map, as C5 secondary process and outsource (for this fictitious case)
- Note that the processes shown may not be appropriate for your case. Do modifications as required.

Exhibit 7-3. Business Flow Chart (Box and Line) Process Map



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

- This is one of the best methods of showing sequence of interaction, which the other 2 types of process mapping lack
- For this particular process map, the different types of processes, including outsourcing are indicated by shapes of the box. Processes having companywide responsibilities are placed the bottom. Non-process tasks are shown without the outer boxes.
- The weakness of this map is resources are not shown. Therefore this is best use a supplement with one of the other 2 process maps.
- Unfortunately if you are using this to edit, you need to re0draw this from the beginning, as some part of the chart is not editable, for some unknown reasons

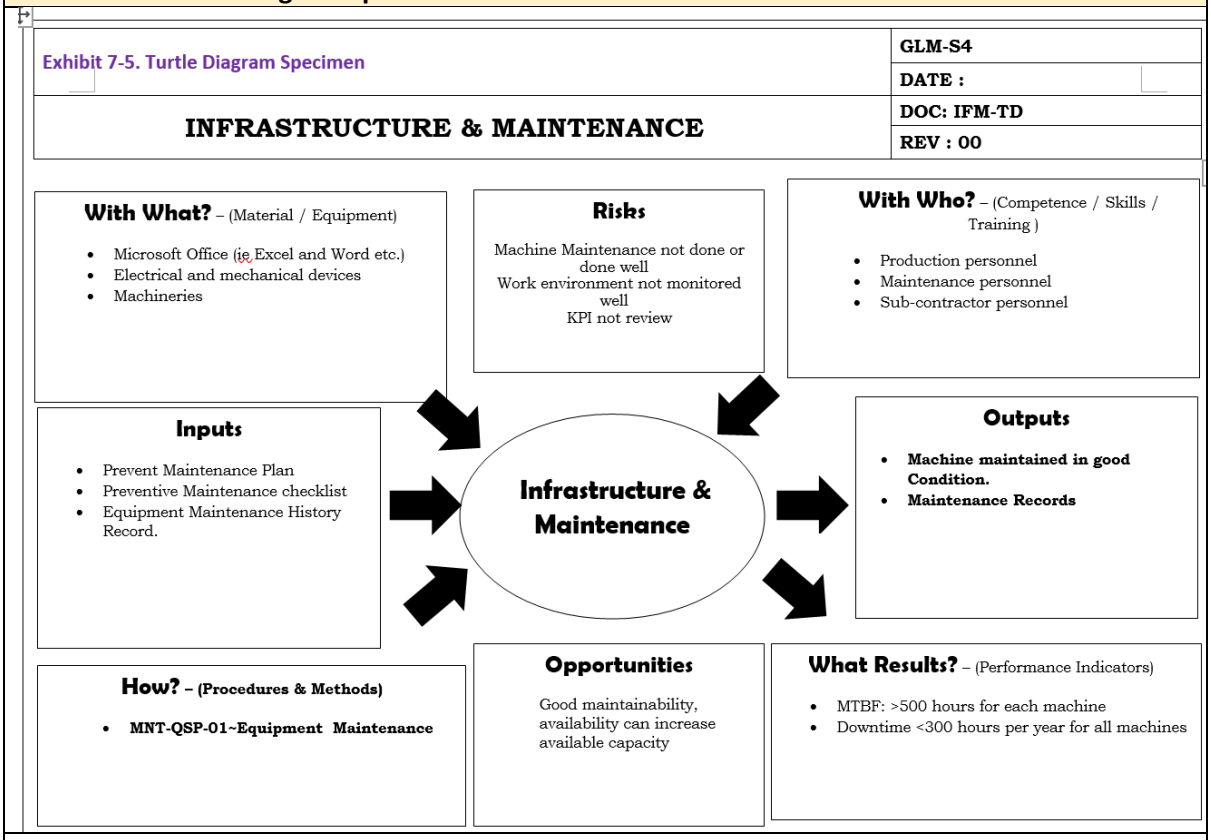
Exhibit 7-4. Process Input-Output, Resocures Chart (PIOR)

No	Process	Input	Output	Resources	KPI	PIC
1	Strategic Analysis	External Context Analysis, Internal Context Analysis, Interested Parties and their needs and expectations. Scope considerations.	• Internal & External Risk and Opportunities analysis reports, Scope Statement, Interested parties analysis report. Action Plans for open issues	Office facilities, external training	Review before internal audits	QMR, HOD GM (as needed)
2	Management Review	Previous Management Reviews, QMS performance results, internal and external audit results, Continual improvement projects & outcome. Business Plan.	• Management Reviews Minutes, • Monthly Performance data and reports	Office facilities, external training	Completed 3 weeks before external audit	MD, QMR
3	Internal Audits	Previous Internal Audits results and external audit results, customer complaints and feedback	• Internal audit program • Internal audit results (3 types) • Corrective actions for CAR	Office facilities, external training, competent internal auditors	Internal audit CAR to reply within 5 working days	QMR
4	HR. Human Resources (Training)	Job Description, Organization Knowledge, TNA input,	• Training schedule, Orientation records, OJT records and Training Evaluations • Annual Training Plan and evaluations	Office facilities, external training, competent internal and external trainers	Min 90% completion of annual training plans	HOD
5	Infrastructure and Work Environment	Infrastructure & Work Environment (ISWE) requirement Master lists of Equipment and Maintenance schedule	• ISWE maintenance activities • Maintenance records • ISWE review results and improvement actions	Maintenance equipment, facilities & relevant skills	MTBF: Min 400 hours	Workshop HOD

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

- Turtle diagram is most famous for showing a process. This is another method of showing processes and their elements
- Each row is actually a turtle diagram. Input-output-resources, KPI and responsibilities are all shown
- The only shortcoming is lack of the sequence and interaction, otherwise it can also be considered as a complete process map
- When used together with a Business Flow Chart Exhibit 7-3, it forms a comprehensive process map.

Exhibit 7-5. Turtle diagram Specimen



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

- This is a turtle diagram, which is commonly used to represent a process graphically.
- It is extremely useful to be used for overview and for audit. IATF auditors often request this document, although it is not mandatory
- Therefore to 'speak' the same language, it is recommended this document be made available
- If you are using the Business Flow Chart (PIOR Exhibit 7-3) for your process map, you just need to transfer the data from there.
- Note that risk and opportunity however is not in PIOR due to space constraint. The information can be obtain from your internal analysis

>> End of Chapter 7 <<

Chapter 8. Eligibility and Conformances

Contents:

0) Introduction

There is only one applicable clause (4.4.1.1) in this chapter. The other two clauses are to provide associated information on what type industries and product lines are eligible for registration/certification under IATF16949:2016. It is hoped that no organization will slog for a year or more in preparation, only to find out at the last minute they are not eligible.

1) 4.4.1.1 Conformance of Products and Processes

(Clause Description-Paraphrase)

The organization shall ensure conformance of all products and processes, including service parts and those that are outsourced, to all applicable customer, statutory, and regulatory requirements.

(Highlights of the clause)

- (Ref to old Standards) This is a totally new clause.
- Service parts are now included for controls. As seen in the field, the performance on service parts control, is somewhat lacking
- Outsourcing needs better control , see d) below
- Conformance is not only to customer requirement but also statutory and regulatory requirements. This is applicable for organization as well as external providers

(Compliance Best Practice)

4.4.1.1 Conformance of Products and Processes

1. *Customer's service parts need equal attention as the production parts, in terms of quality and delivery*
2. *When fulfilling customer requirements, relevant statutory and regulatory requirements are part of the customer requirements*
3. *External providers should be informed on item 2 above (Statutory & Regulatory)*
4. *This is a concept clause, actual implementation involves several fronts. You are just required to understand the intent and ensure compliance. There is generally no need to produce any additional documentation for this clause.*

2) 1.1. Scope-automotive supplement to ISO9001:2015

(Clause Description-Paraphrase)

IATF16949 defines the QMS requirements for design and development, production and, when relevant, assembly, installation, and services automotive related products, including products with embedded software. It is applicable to sites of the organization where manufacturing of customer-

specified production parts, service parts, and/or accessory parts occur. It is appliable throughout the automotive supply chain.

(Highlights of the clause)

- The eligibility of certification under automotive are: design and development, production and, when relevant, assembly, installation, and services automotive related products, including products with embedded software.
- Besides the traditional products and services, there are some addition of items in this new version i.e. accessories which are installed at the OEM.
- The new additions are: floor mats, truck bed liners, wheel covers, sound system enhancements, sunroofs, spoilers, super chargers, warning triangles, safety vests, owner's manuals, fire extinguishers, car jacks. From all indications, the list will grow with time.

Rules 5th ed. 1.0 Eligibility for Certification to IATF16949

Clause Description-Paraphrase)

Automotive: passenger cars, light commercial vehicles, heavy trucks, buses, and motorcycles. Excluded are industrial, agricultural, off-highway (mining, forestry, construction etc), and after markets. Specialty cars are eligible if the uplifting is done by IATF OEM, and the suppliers of parts are certifiable under IATF.

Manufacturing: the process of making or fabricating production materials, production of service parts, assemblies, or heat treating, welding, painting, or other finishing services of automotive-related parts.

(Highlights of the clause)

- types of vehicle eligible to be classified automotive are: passenger cars, light commercial vehicles, heavy trucks, buses, and motorcycles
- The non-eligible ones are: industrial, agricultural, off-highway (mining, forestry, construction etc), and after markets.
- Type of business activities shall be: the process of making or fabricating production materials, production of service parts, assemblies, or heat treating, welding, painting, or other finishing services of automotive-related parts

4) SIs & FAQs

No SIs & FAQs for this Chapter

5) Supplementary Notes

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

Clause	Section	Clarification Subjects
4.4.1.1	CBP	**SN8.1. Why the sudden emphasis on service parts and outsourced parts?**
4.4.1.1	CBP	**SN8.2. How do we cascade statutory, and regulatory requirements, down to the external providers?**
4.4.1.1	CBP	**SN8.3. Can a IATF certified plant produce parts for aftermarket?**
4.4.1.1	CBP	**SN8.4. How do I make sure my internal departments are paying attention on these two areas of service parts and outsourcing?**
1.1, Rules 1.0	HOC	**SN8.5. Are automotive accessories eligible for registration?**
1.1, Rules 1.0	HOC	**SN8.6. What is the purpose of discussing eligibility in this Chapter?**

SN8.1. Why the sudden emphasis on service parts and outsourced parts?

Organizations and OEM tend to pay more attention to production parts. Service parts were not given the same level of attention. Irate car owners will translate their unhappiness as complaints, and splashed over social media, or reported to consumer agencies. Business can be affected eventually. It is understandable that OEMs want put a tighter control on this area.
Outsourcing is common, effective and efficient. However, there is a risk of loss of control, due to the proverbial "out of sight, out of mind" syndrome.
The Standard makes a reminder via this clause to pay attention and keep controls, on these areas. Emphasis are also placed on all applicable requirements, customer, statutory, and regulatory.

SN8.2. How do we cascade statutory, and regulatory requirements, down to the external providers?
Statutory and Regulatory compliance is a harder subject. When you have to pass down the line, it is even harder. In a nutshell, you need to start early, you need to brief the relevant suppliers on what are the requirements and how they should comply. You also need to provide incoming inspection and checks, for verification. And thirdly, you need to visit suppliers' premises to ensure compliance. Chapter 12 has more discussions.

SN8.3. Can a IATF-certified plant produce parts for aftermarket?
Yes, but it cannot be included in the scope. There are some explanations needed:

- the parts must be legal. Counterfeit parts will be an issue
- if the OEM does not have the particular process, the process cannot be included in the scope. For example, a floor mat company supplies rubber mats to aftermarket and not OEM. Rubber mats and the process will not be part of the scope.
- on third party audit, IATF auditors will not audit that process and parts, unless requested to CB, under a separate arrangement. When an OEM product is not in production, a similar part may be audited, aftermarket part if used, is considered a similar part only.

SN8.4. How do I make sure my internal departments are paying attention on these two areas of service parts and outsourcing?
Set KPI on them. Example is: a) for service parts, set delivery KPI; b) for statutory and regulatory compliance of suppliers, set KPI on violation incidents.

SN8.5. Are automotive accessories eligible for registration?
Yes, only if the accessories are installed at the OEM plants. Similar parts sold in aftermarkets are not eligible for registration.

SN 8.6. What is the purpose of discussing eligibility in this Chapter?
This chapter provides some basic rules and requirements on what is eligible for registration, so that organizations will know their eligibility before embarking on the project. It will be most heart-breaking for an organization, to be informed at the last minute their product lines are not eligible for registration. And they could have invested a year or more in time and resources on the project.

6. Exhibits

No Exhibits for this Chapter

>> End of Chapter 8 <<

Chapter 9. Product Safety Related

Contents:

0) Introduction

There is only one applicable clause in this chapter. The reason why a whole chapter is devoted to this is because the Clause is not commonly misunderstood and/or poorly catered for. Many NCs have been written on this clause alone.

1) 4.4.1.2 Product Safety (IATF16949)

Clause Description-Paraphrase)

The organization shall have documented processes for the management of product-safety related products and manufacturing processes, which shall include:

a) identification by the organization of statutory and regulatory product-safety requirements;
b) customer notification of requirements in item a);
c) special approvals for design FMEA;
d) identification of product safety-related characteristics;
e) identification and controls of safety-related characteristics of product and at the point of manufacture;
f) special approval of control plans and process FMEAs;
g) reaction plans (see Section 9.1.1.1);
h) defined responsibilities, definition of escalation process and flow of information, including top management, and customer notification;
i) training identified by the organization or customer for personnel involved in product-safety related products and associated manufacturing processes;
j) changes of product or process shall be approved prior to implementation, including evaluation of potential effects on product safety from process and product changes (see ISO 9001, Section 8.3.6); k) transfer of requirements with regard to product safety throughout the supply chain, including customer-designated sources
l) product traceability

(Highlights of the clause)

- (Ref to old Standards) This is a totally new clause.
- The clause requires documented processes for the management of product-safety related products and manufacturing processes
- The process shall have controls ranging from planning, implementation, checking and corrective/improvement actions.

(Compliance Best Practice)

4.4.1.2 Product Safety

1. *To comply to this clause, a documented process is required.* ***See Exhibit 9-1.***
2. *The documented process must include the necessary controls stated in a) to l) of the Clause description.*

2) SIs & FAQs

SI No	IATF Clause	Description
2	**4.4.1.2 Product safety**	The organization shall have documented processes for the management of product-safety related products and manufacturing processes, which shall include but not be limited to the following, where applicable: a) – m) (…) NOTE: Special approval **of safety related requirements or documents may be required by the customer or the organization's internal processes.** ~~**is an additional approval by the function (typically the customer) that is responsible to approve such documents with safety-related content.**~~ ***Rationale for change:*** *Clarify any confusion related to special approval review for safety related requirements or documents.*

FAQ	IATF Clause	Questions and Answers
4	**4.4.1.2 Product safety**	**QUESTION:** **What is the scope of this clause? Many organizations focus on regulatory/statutory requirements of the product and do not believe they have product safety related manufacturing product or processes.** **ANSWER:** This clause focuses on product and manufacturing process characteristics that affect the safety performance of the final assembly. These characteristics may not be directly addressed in regulatory/statutory requirements, but may be defined by the customer.
13	**4.4.1.2 Product safety**	**QUESTION:** **What are the requirements regarding the levels of training and the particular criteria required to be identified in relation to product safety (4.4.1.2)?** **ANSWER:** As with all personnel competency requirements, the people assigned to specific tasks need to be competent for that task. That competence needs to include the rules and regulations associated with the task. The safety requirements in 4.4.1.2 are very specific as to what is required. The sections include, referring to IATF 16949 section 4.4.1.2: a) suppliers are expected to be aware of all statutory and regulatory requirements associated with the markets for use of the parts, as identified by the customer. The supplier needs to know where to research the regulations for all affected countries or regions. b) Customer specifics will identify any customer notification requirements; therefore, knowledge in customer specifics (which may be taught by an internal designated subject matter expert). c) The special approvals for design FMEAs would be identified in customer specifics, see item b) above. d) and e) The identification of product safety related characteristics and their controls would be defined by the customer in its definition of special characteristics and required controls. The personnel developing PFMEAs and Control Plans would need to be knowledgeable in those areas of their customer(s) documents.

FAQ	IATF Clause	Questions and Answers
13 (cont.)	**4.4.1.2 Product safety**	Each line item f) through m) can also be similarly analyzed to determine the level of training and source of that training for each requirement within the safety requirements. Since many of the requirements depend upon customer specific requirements, there is no single complete industry training on this topic. The organization needs to review the customer and regulatory requirements associated with each of its parts appropriate for the intended country of use and safety-related part characteristics. Some customers may have specific requirements regarding product safety, training, knowledge, and personnel. It is the organization's responsibility to understand their customer's specific requirements related to product safety.

3) Supplementary Notes

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

Clause	Section	Clarification Subjects
4.4.1.2	CBP	**SN9.1. Why is safety repeated in so many places in the Standard?**
4.4.1.2	CBP	**SN9.2. Isn't it repeating, when product safety is already analysed in FMEA, and Special & Critical Characteristics?**
4.4.1.2	CBP	**SN9.3. Is product safety applicable for all organizations?**
4.4.1.2	CBP	**SN9.4. How best can we do for handling safety products?**
4.4.1.2	CBP	**SN9.5. Why bring in training into safety?**
4.4.1.2	CBP	**SN9.6. Looks like Exhibit 9-1 does not have all the points given in the Clause.**

SN9.1. Why is safety repeated in so many places in the Standard?

Safety is a rising concern by governments and customers alike. It is critical requirement, and therefore should be checked thoroughly. Standards writers will naturally hunt down the relevant areas and make reminders.

SN9.2. Isn't it repeating, when product safety is already analysed in FMEA, and Special Characteristics?

For an IATF-certified organization, FMEA, risk and opportunity analyses, special & critical characteristics marking, provide a good start to capture safety-related. But they may not be have identified all. We need to take another look from another angle to exhaust the catch.

SN9.3. Is product safety applicable for all organizations?

No, some organization are not involved in safety-related products and therefore this clause does not apply to them. They can safely declare non-applicability. However, you need to be sure of special situations stated in FAQ-4. Your product may not be safety-related, but being used as a component to a safety-related end-product. Suddenly your product may be classified safety-related.

SN9.4. How best can we do for handling safety products?

If product safety applies in your case, you need to establish a procedure for this requirement. This procedure is best parked under a technical department such as Engineering, Production or QAQC. See **Exhibit 9-1** for a specimen of the Procedure. For training and competency, FAQ-13 should be taken as a guide, and list down the requirement for HR to include in the training program.

After each project that involves product safety is completed, the activities should be checked by the Product Safety Procedure.

SN9.5. Why bring in training into safety?

Any new subjects requires training, all the more critical and safety areas. Some customers may have specific requirements regarding product safety, training, knowledge, and personnel. In this new version, the compliance may include exports. See Chapter 19. It is the organization's responsibility to understand all these and include them into the QMS. HR will play a significant role in this area.

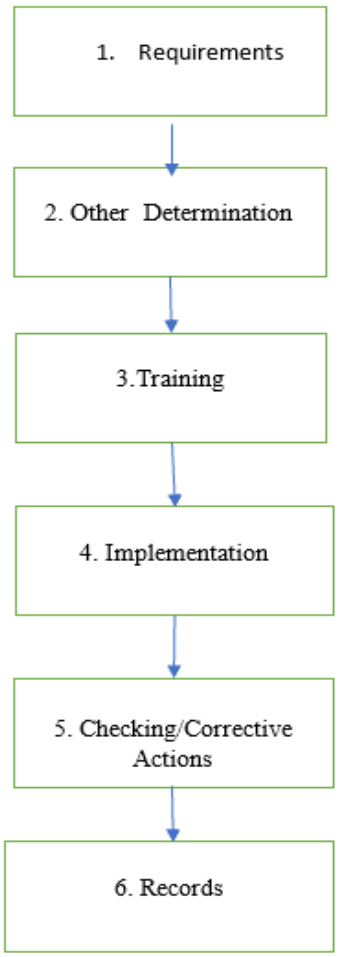
SN9.6. Looks like Exhibit 9-1 does not have all the points given in the Clause.

All points are already taken in, but may have been placed in different location. See the below where the points are found in the steps in **Exhibit 9-1**. Numeral within parenthesis is the step no of the procedure.

a) identification by the organization of statutory and regulatory product-safety requirements; (1)
b) customer notification of requirements in item a); (1)
c) special approvals for design FMEA; (1)
d) identification of product safety-related characteristics; (1)
e) identification and controls of safety-related characteristics of product and at the point of manufacture; (1)
f) special approval of control plans and process FMEAs; (1)
g) reaction plans (see Section 9.1.1.1);
h) defined responsibilities, definition of escalation process and flow of information, including top management, and customer notification; (2)
i) training identified by the organization or customer for personnel involved in product-safety related products and associated manufacturing processes; (2)
j) changes of product or process shall be approved prior to implementation, including evaluation of potential effects on product safety from process and product changes (see ISO 9001, Section 8.3.6); (1)
k) transfer of requirements with regard to product safety throughout the supply chain, including customer-designated sources (3)
l) product traceability (1)

4) Exhibits

Exhibit 9-1. Product Safety Management

PIC	Process Flow	Description
Design /core team Core Team Core team Relevant HOD QAQC Relevant HOD/ DCC		1. Requirements • Statutory and regulatory on the relevant product safety shall be studied & understood • Customer requirements shall be clarified including: o Notification from customer o Product safety related characteristics o Special approvals on DFMEA, PFMEA, Control plans, reaction plan 2. Other determination • Determine responsibility, flow of information • Establish reaction plans and escalation procedures • Determine procedures for changes in product and process of safety-related products including approvals • Determine transfer process throughout the supply chain, on safety related requirement, including customer-designated sources • Product traceability in manufacturing and throughout the supply chain, with manufacturing lot traceability as minimum • Lessons learn process for application to new product introduction • Training needs and training materials required as identified by customer or internal 3. Training • Provide training to internal staff and to relevant external providers 4. Implementation • Implement the purchasing, manufacturing and inspection and stores • Response on problems and resolved 5. Checking • Provide checking during the process as required • The entire project shall be verified using this procedure as the check list • Any lessons learned shall be recorded for reference for new product introduction 6. Records • All relevant records shall be retained as evidence

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

- This procedure is useful to pull all the safety requirements together into a common document for reference/control
- It will also be good to prepare a checklist to verify each product-safety part under development, to ensure all steps above are followed

>>End of Chapter 9 <<

Chapter 10. Leadership Related

Contents:

0) Introduction

There are many interrelated clauses in this chapter, but centering around top management. The responsibility for top management on QMS has been enlarged significantly in this new version. And Top Management needs to be orientated to this new requirements. This chapter helps to provide a useful guideline.

1) 5.1, 5.1.1 Leadership and Commitment (ISO9001)

(Clause Description-Paraphrase) Top management shall demonstrate leadership and commitment with respect to the quality management system by demonstrating accountability, establishing policy and objectives etc. The list of responsibilities are: a) taking accountability for effectiveness of the QMS, b) ensure Quality Policy and Objectives are established, compatible to contents and strategic direction, c) ensure integration of the QMS into the business processes, d) promote process approach, and risk-based thinking, e) provide resources needed for the QMS, f) communicating the importance of conforming to the QMS requirements, g) ensuring QMS achieve its intended results, h) engaging, directing, and supporting others to contribute to the effectiveness of QMS, i) promote improvement, and, j) support other leaders to lead in their respective areas of responsibilities.

(Highlights of the clause)

- (Ref to old Standards) There was a similar clause, 5.1.1 Management Commitment, in the previous version of ISO9001.
- Many of the requirements under this new clause are not new e.g. a) taking accountability of the effectiveness of the QMS, e) providing resources and i) driving continual improvement.
- There are however some new ones: (b, (c), (d) and (g).
- The QMS responsibility of Top Management therefore has increased significantly, with this change.

(Compliance Best Practice)

5.1, 5.1.1 Leadership and Commitment

1. *To help compliance, a procedure should be prepared to guide top management in their new roles and responsibilities. See **Exhibit 10-1.***
2. *Management can also delegate some of these responsibilities and tasks, to a few key assistants, but still holding accountability*
3. *QMR can remain, but the new role should be on advisory, not direct leadership anymore*

4. *Delegation needs to be documented. See **Exhibit 10-2.** And this should be part of attachments to your QM.*

2) 5.1.1.3 Process Owners (IATF16949)

(Clause Description-Paraphrase)

Top management shall identify process owners who are responsible for managing the organization's processes and related outputs. Process owners shall understand their roles and be competent to perform those roles.

(Highlights of the clause)

- (Ref to old Standards). This is a totally new requirement.
- The heads of each process are now required to manage their processes and department/function independently.
- And they need to know their role and be competent at performing those roles.

(Compliance Best Practice)

5.1.1.3 Process Owners

*To comply with this clause, prepare a QMS team chart is required to show all the process owners. This shall be one of the attachments to the QM. See **Exhibit 10-3***

3) 5.3 Organizational Roles, Responsibilities, and Authorities (ISO9001)

Clause Description-Paraphrase)

Top management shall ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization. The primary roles involved are: (a) ensuring that the QMS conforms to the requirements of ISO9001:2015; (b) ensuring that the processes are meeting the objectives, (c) reporting on the process performances and on opportunities for improvement; (d) promoting customer focus throughout the organization; e) ensuring the continued integrity of the QMS when changes take place.

(Highlights of the clause)

- (Ref to old Standards). There has been a similar Clause 5.5, Responsibility, authority and communication, in the old version of ISO9001. In the previous version, the requirement was very simply stated i.e. responsibilities and authorities are defined and communicated.
- New requirement allows to appoint a few key persons to help manage QMS
  - They must ensure the QMS conforms to the requirements of ISO9001:2015
  - ensure that the processes are meeting the objectives
  - reporting on the process performances and on opportunities for improvement
  - ensuring the continued integrity of the QMS when changes take place
- Responsibilities and authorities for these key people are communicated and understood

(Compliance Best Practice)

5.*3 Organizational Roles, Responsibilities, and Authorities*

1. *To comply with this clause, consider QMR and all HOD are the key delegatees*
2. *QMS team chart serves to inform the organization of this delegated responsibilities. This QMS team chart shall be displayed.*

3. *QMR and HOD shall prepare month feedback to Management. It can be a collection of KPI performances. A better method is to submit a simple report, with KPI performance and information on a few other key areas. See **Exhibit 10-4.***

4) 5.3.1 Organizational Roles… supplemental (IATF16949)

(Clause Description-Paraphrase)

Top management shall assign personnel with the responsibility and authority to ensure that customer requirements are met. These assignments shall be documented. This includes selection of special characteristics, setting quality objectives and related training, corrective and preventive actions, product design and development, capacity analysis, logistics information, customer scorecards, and customer portals.

(Highlights of the clause)

- This clause moves down the line, to focus on a few responsibilities that have close connections with customer satisfaction
- Clear assignment of persons-in-charge is required for: selection of special characteristics, setting quality objectives and related training, corrective and preventive actions, product design and development, capacity analysis, logistics information, customer scorecards and customer portals.
- Assignments shall be documented.

(Compliance Best Practice)

5.3.1 Organizational Roles… supplemental

1. *To comply, officially inform and appoint people responsible for those areas mentioned in the clause. See **Exhibit 10-3** for a specimen.*
2. *The document shall be controlled to signify it is a documented information.*
3. *And don't forget to run training for these people, so they can handle the IATF audits*

5) 5.3.2 Responsibility and authority for product requirement and corrective actions (IATF16949)

(Clause Description-Paraphrase)

Top management shall ensure that: (a) persons are authorized to stop shipment and stop production to correct quality problems. (b) personnel with authority and responsibility for corrective action are informed promptly, and nonconforming product is not shipped to the customer, but contained and identified; (c) all production shifts are staffed with personnel in charge of, conformity to product requirements.

(Highlights of the clause)

- (Ref to old Standards). There has been a similar clause. 5.5.1.1 Responsibility for quality, in the old version of ISO/TS16949, It basically stated the same requirements, with clearer elaborations
- Total requirement is given in (a) to (c)
  a) authorise people to stop shipment and production when quality problem occurs
  b) product is cannot be shipped to the customer, but contained and identified
  c) This arrangement is to be for all operating shifts

(Compliance Best Practice)

5.3.2 Responsibility and authority for product requirement and corrective actions

1. *If you are not running shifts, this clause is easy to handle. The full workforce and management is available during normal shifts, to manage quality issues. Just tell Auditor there is no night shifts.*
2. *If you are running shifts, then delegation must be done for the night shifts. The normal arrangement to stop production is delegated to the supervisor or shift leader. And they should be able to explain when asked.*

6) 5.1.2 Customer Focus (ISO9001)

(Clause Description-Paraphrase)

Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that (a) customer and applicable statutory and regulatory requirements are determined, understood and consistently met; (b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed; (c) the focus on enhancing customer satisfaction is maintained.

Author's note: For exact wordings, please refer to standard indicated after the clause title.

(Highlights of the clause)

a) (Ref to old Standards). There had been a similar clause, 5.2 of the same title, in the old version of ISO9001.
b) Like in the older version of IATF, Management shall ensure customer focus. It means focus on the important areas concerning customers
c) There are new items to focus on: a) customer and statutory and regulatory requirements, b) risk and opportunities impacting customers, c) customer satisfaction

.

(Compliance Best Practice)

5.1.2 Customer Focus

1. *This is a concept clause, actual implementation will be carried out all departments and everyone in the company*
2. *You are only required to understand the intent and ensure compliance. There is generally no need to produce any additional documentation as evidence.*

7) 9.1, 9.1.1 Monitoring, measurement, analysis and evaluation (MMAV)

(Clause Description-Paraphrase)

The organization shall determine:

a) what needs to be monitored and measured;

b) the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;

c) when the monitoring and measuring shall be performed;

d) when the results from monitoring and measurement shall be analysed and evaluated. The organization shall evaluate the performance and the effectiveness of the quality management system. The organization shall evaluate the performance and the effectiveness of the quality management system. The organization shall retain appropriate documented information as evidence of the results. (no non-achievement actions)

(Highlights of the clause)

- There are 2 sets of people who needs to make MMAV decisions here, Top Management and QAQC.

- Top Management to set what KPI to monitor the entire processes.
- Process & QAQC decide on what needs to be control for products and process, and at what stages.

(Compliance Best Practice)

9.1, 9.1.1 Monitoring, measurement, analysis and evaluation

1. *Auditors may likely be asking about KPI setting method, be prepared to explain the process of proposing and approving KPI.*
2. *Chapter 25 discusses about setting detail inspection items.*

8. SIs & FAQs

FAQ	IATF Clause	Questions and Answers
5	5.3.1 Organizational roles, responsibilities, and authorities — supplemental	**QUESTION:** **Is the intent that responsibilities be assigned to the function (e.g. Quality), a specific title (e.g. Quality Director) or a named individual (e.g. Bob Smith)?** **ANSWER:** Responsibilities are assigned to the role/position (i.e. specific title, Quality Director) within the organization. Although individuals may have those responsibilities in their roles, the responsibilities remain with the role (e.g. Quality Director). Therefore, top management will assign the responsibility and authority to the role, not to the individuals by name.

9. Supplementary Notes

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

Clause	Section	Clarification Subjects
5.1, 5.11	CBP	**SN-10.1. How do we help Top Management to handle IATF Auditor, on their new QMS roles and responsibilities?**
5.1, 5.11	CBP	**SN-10.2. Will 3P auditor really ask the big boss on QMS details?**
5.1, 5.11	CBP	**SN-10.3. How should Management promote risk based thinking?**
5.1, 5.11	CBP	**SN-10.4. what does integration means and how to achieve this?**
5.1, 5.11	CBP	**SN-10.5. How does Top Management support lower-tiers in leadership?**
5.1, 5.11	CBP	**SN-10.6. Can we still maintain the QMR position, to relief the Top Management of extra burden?**
5.1.1.3	CBP	**SN-10.7. Management can still delegate in the new version. How is this best carried out so that no effectiveness is lost?**
5.3	CBP	**SN-10.8. How should a department QMS report for Management look like?**
5.3	CBP	**SN10.9. When delegating back to a function, is HOD the automatic choice?**

5.3.1	CBP	**SN10.10. Where is the main pitfall in this area 5.3.1?**
5.1.2	CBP	**SN10.11. How do we demonstrate customer focus, since there are no documentation to show as evidence?**
5.3.2	CBP	**SN10.12. What kind of evidence is required to show delegation of quality responsibilities for night shifts.**

.

SN10.1. How do we help Top Management to handle IATF Auditor on their new QMS roles and responsibilities?

Top Management may be asked by IATF Auditor on their new responsibilities on the QMS. To assist them to understand this role, a 1-2 page information/ procedure should be prepared. they can continue to delegate out the real work, but they must be in the know.

SN10.2. Will IATF auditor really ask the big boss on QMS details?

Probably not much, unless the boss shows total ignorance. IATF Auditor's work is very tight, with 1/3 of the time already reserved for production audit. For top management, an auditor tends to enquire on the higher level stuff, e.g. strategic directions, market trends, KPI, target setting and continual improvement. They are less likely to pick on day-to-day operations with top management.

SN10.3. How should Management promote risk-based thinking?

Risk-based thinking is a new subject, that comes with the new version of ISO9001. During transition. training should have been conducted. In Chapter 2, clause 6.1.2.1 also suggested a documented procedure to respond to risks actually encountered, followed by recurrence prevention. Management just have to ensure this kind of response is undertaken, by asking pertinent questions.

SN10.4. What does integration mean, and how to achieve this?

Integration (5.1c) can save time and unify the business operations. It means we should stop thinking QMS being a separate set of management duties from the real business. It should not exist in isolation, but integrated into every sphere of the operations.

SN10.5. How does Top Management support lower-tiers in leadership?

As an operations gets more complex and sophisticated, subordinates need to be self-motivated and self-driven. Leaders should also change their thinking to suit the trend. They need to learn some management soft-skill rather than drilling further down the hard-skill lane. They should become more participative, and less commanding. Top Management is generally more skilful in this area, and can assist the lower-tier leaders to develop this flair.

SN10.6. Can we still maintain the QMR position, to relief the Top Management of extra burden?

The Standard does not say that QMR has to be scrapped. The word 'Management Representative' just disappeared from the document. Yes, you can keep the position. You can even keep the name, but the responsibility must change. Top Management is accountable but can delegate. The easiest way is to delegate responsibilities back to departments concerned. Top Management is finally the person in charge. He or she is no longer totally sheltered from audit by the QMR. He has to demonstrate that he is in the know. QMR can continue to assist the Top Management, but active duties and responsibilities are transferred to each function. QMR should only be in a coordinator or an advisory role. He/she now has a 'staff', rather than 'line' responsibility. **(Exhibit -10-2)**

SN-107. Management can still delegate in the new version. How is this best carried out so that no effectiveness is lost?

Yes, you need to think effectiveness in delegation. Sending an email with a new JD is not good enough. It will not be effective. You need a training to explain to them clearly the new duties and

responsibilities. QMR's role now is only a coordinator or advisor. Finally give the assurance that ongoing support will be given. This support role is what QMR can do very well. Evidence to show in audits are: QMS team chart, samples of their regular reports to management.

SN-10.8. How should a department QMS report for Management look like?

Currently, most organizations are just submitting a KPI status report. Reporting can improve, if some other important headings can be added. such as, resources, safety and environment, changes in the process that can affect QMS and organization, changes in risk and opportunities, opportunity for improvement etc. See **Exhibit 10-4** for a specimen. However, the improved report is not mandatory, A face-to-face reporting is also acceptable.

SN10.9. When delegating back to a function, is HOD the automatic choice?

In most cases yes. But there may be exceptions. An example is production. We will automatically think of the production manager as the chosen one. However, if he/she oversees 3 factories, an operations spanning from injection moulding, to blow-moulding, to secondary processes and the assembly, he is too high up to be an effective process owner. He can remain the overall process owner, but the section-in-charge to each production unit should be identified as the co-process owners. The responsibility to identify the roles and training should be a cross-functional team consisting of the HOD, QMR and HR.

SN10.10. Where is the main pitfall in this area 5.3.1?

If the process owner cannot demonstrate knowledge on this area, or worse he/she doesn't even realise he/she is appointed one, it becomes a finding, if. A case in point was the planner of an organization 'appointed' the process owner for tracking customer portal. She maintained she is not the person, but someone else in HQ was. The audit had to take another direction, in which a remote location has just surfaced, and an onsite audit has to be done on the remote. This is an expensive experience because the HQ is situated in another country.

SN10.11. How do we demonstrate customer focus, since there are no documentation to show as evidence?

IATF Auditors are unlikely going to ask a direct question on this clause, but will pick up on the response and attitude demonstrated on important customer issues such as complaint handling, preventing risks to customers etc, and also matters listed as a) to c) in the clause.

SN10.12. What kind of evidence is required to show delegation of quality responsibilities for night shifts?

If you are running shifts, then the arrangement must be done for the night shifts. The normal arrangement to stop production is delegated to the supervisor or shift leader. Your supervisor/ leader in-charge should explain how do they handle a reject situation. Example, how they will alerting higher-up people, how decisions are made to stop the machine, and activities to contain the lot and identification.

10. Exhibits

Exhibit 10-1. Procedure to Guide Top Management

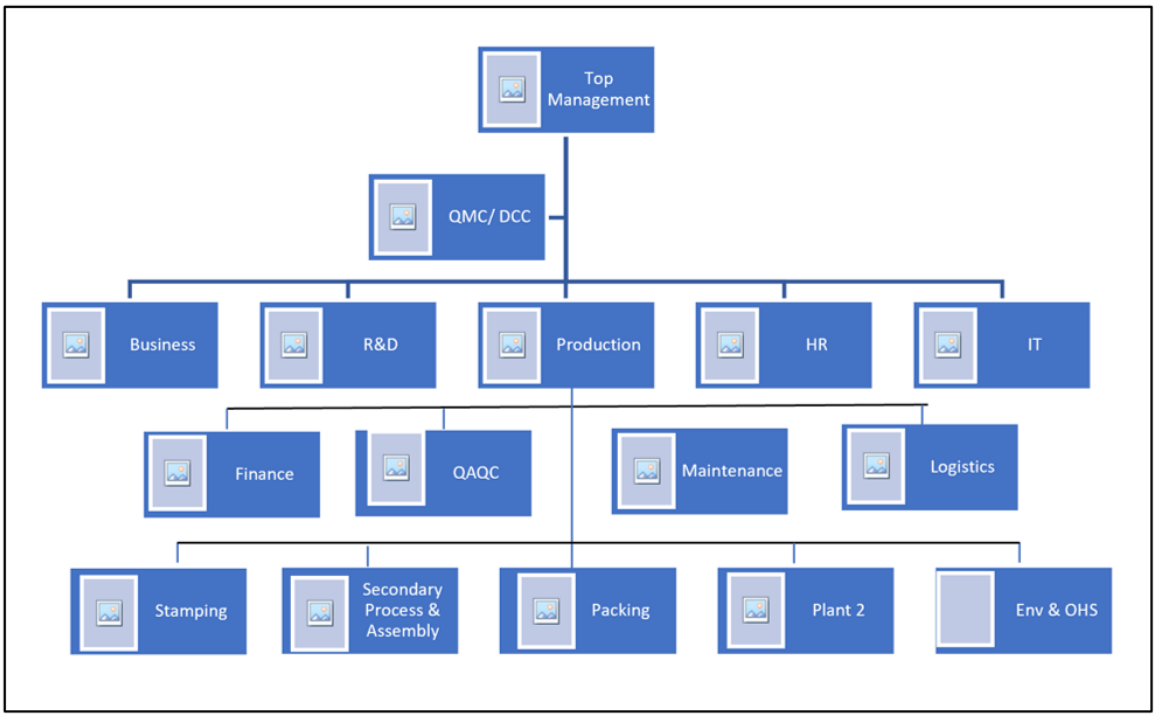
Procedure on Leadership

PIC	Flow Diagram	Key Notes
MD MD/QMR asst MD/QMR Asst MD/QMR Asst MD/QMR Asst MD/QMR Asst	5-02 (1) Assumes Accountability ↓ 5-02 (2) Ensure Quality Policy and Objectives are Established/Reviewed ↓ 5-02 (3) Integrates QMS Requirements into the Business Processes ↓ 5-02 (4) Promotes Process Approach & Risk-Base Thinking ↓ 5-02 (5) Communicates the Importance of Effective Quality Management & Conforming to QMS Requirement ↓ 5-02 (6) Supports Lower-Tier Leaders	5-02 (1) • taking accountability for the effectiveness of the quality management system • where physically not feasible, or due to time constraints, active involvement via assigned process owners needs to be demonstrated • ensuring that the resources needed for the QMS are available; • ensuring that the quality management system achieves its intended results 5-02 (2) • ensuring that the quality policy and quality objectives are established/ reviewed annually • ensuring Policy and Objectives are compatible with the context and strategic direction of the organization; 5-02 (3) • ensuring QMS requirements are integrated into the organization's business processes 5-02 (4) • promoting the use of the process approach and risk-based thinking; 5-02 (5) • communicating the importance of effective quality management and of conforming to the QMS requirements • promoting continual improvement 5-02 (6) • engaging, directing and supporting persons to contribute to the effectiveness of the quality management system; • supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

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

- This procedure is to help Top Management to understand their roles and responsibilities as defined by ISO/IATF
- It is good for QMR to do a briefing for Top Management and retain that as a training record

Exhibit 10-2. Full Delegation Chart



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

- Names of the process owners shall be indicated in the boxes.
- For the last row, names of the co-owners, if applicable, should also be indicated
- This chart should be displayed, to denote communication

Exhibit 10-3. Customer Satisfaction Responsibilities

Customer Satisfaction responsibilities Chart

Rev No	Effective Date	Compiled by	Approved by
01	11 Jun 2019	QMR	MD

No	Customer Satisfaction Activities	Responsibility
1	Selection of Special Characteristics	APAP Team
2	Setting KPI	Various HOD, asst by QMR
3	Setting KPI related training	Various HOD, HR, asst by QMR
4	RFQ handling	Business Development (BD)
5	Customer satisfaction survey	Business Development (BD)
6	Scorecards/ Customer portal	Planner, QA
7	Customer complaints	QA, Asst by BD
8	Product Design and Development	R&D
9	Order Processing/ Production Planning	Planner
10	Capacity analysis	Planner, Production
11	Logistics Information	Planner, storekeeper

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

- For total delegation, a QMS Team chart is used. **See Exhibit 10.2.**
- This list is not the total delegation chart. This is only part of it, as per Clause 5.3.1, the specific areas, which affect customer satisfaction

Exhibit 10-4. QMS Monthly Report

Department	Month	Date	Reported by

A: KPI performance & Achievement

KPI	Target/Expected	Actual	Judgement
Remarks:			

B: Safety & Environment

B: Resources

C: Changes that can affect process, or the organization

D: Risks and Opportunities changes in this area

E: Other Remarks

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

- For reporting of QMS performance, usually only KPI performance is submitted
- This report showing more information than KPI & Graphs, but it is not mandatory
- There are some aspects Management may want to know, e.g. risks, resources, morale, safety etc.
- The above report can be adjusted on subjects to report, according to internal requirement

>> End of Chapter 10 <<

Chapter 11. Policies, Objectives & Action Plans

Contents:

0) Introduction

There are many clauses in this chapter. The subjects concern setting of policies and objectives, implementation, monitoring and taking improvement actions. It is actually a PDCA cycle in illustration. These subjects are in reality part of Chapter 10. However, Chapter 10 is already overcrowded, adding more subjects to it will make it worse.

1) 5.2, .5.2.1 Establishing the Quality Policy (ISO9001)

(Clause Description-Paraphrase)

Top management shall establish, implement and maintain a quality policy that:
(a) is appropriate to the purpose and context of the organization and supports its strategic direction; (b) provides a framework for setting quality objectives; (c) includes a commitment to satisfy applicable requirements; (d) includes a commitment to continual improvement of the quality management system.

(Highlights of the clause)

- (Ref to old Standards).There has been a similar clause 5.3, Quality Policy, in the older version of ISO9001. Essentially the old requirements had been retained in the new Clause.
- A new requirement (d) "includes a commitment to satisfy applicable requirements" is added.

(Compliance Best Practice)

5.2, .5.2.1 Establishing the Quality Policy

1. *To comply with this clause, ensure your Quality Policy has the new element added " commitment to satisfy applicable requirements" or similar wordings. See* ***Exhibit 11-1.***
2. *Before finalizing, you should also ensure the Quality Policy is in harmony with the context and strategic direction, and the objectives set is not in conflict with the Policy. You can do this by consulting the Top Management*

2) 5.2.2 Communicating the Quality Policy (ISO9001)

(Clause Description-Paraphrase)

The quality policy shall: (a) be available and be maintained as documented information; (b) be communicated, understood and applied within the organization; (c) be available to relevant interested parties, as appropriate.

(Highlights of the clause)

- (Ref to old Standards). This requirement has been included in the Clause 5.3 (Quality Policy) in the older version of ISO9001. Now it has become a separate clause, for extra emphasis.
- Basically there is no change in the requirement: a) The Policy shall be documented, and available to the public (now called interested parties), b) it now talks about communicated, understood and applied. "Understood" does not require the employees to memorize the Policy.

(Compliance Best Practice)

5.2.2 Communicating the Quality Policy

1. *On communication of the policy, there are 3 requirements:*
2. *Point (a) is easy to comply by provided a written Policy, and pin it up at strategic locations e.g. main lobby, conference room, entrance to production floor etc*
3. *Point (b) is to include Policy briefing in the induction/orientation materials. For existing employees, a special briefing on the new Policy is needed, evidenced by attendance records.*
4. *Point (c) can be achieved by displaying the Policy on your website. If your do not have a website, keeping a few hardcopies of Policy at the reception or with the QMR will be satisfactory; ready to be distributed to interested parties, on request.*

3) 5.1.1.1 Corporate responsibility (IATF16949)

(Clause Description-Paraphrase)

The organization shall define and implement corporate responsibility policies, including at a minimum an anti-bribery policy, an employee code of conduct, and an ethics escalation policy ("whistle-blowing policy"). Author's note: For exact wordings, please refer to standard indicated after the clause title.

(Highlights of the clause)

- (Ref to old Standards). This is a totally new requirement
- With this requirement, IATF is beginning to touch on corporate social responsibilities, which can a wide subject.
- The Clause states a minimum requirement for the time being is an anti-bribery policy, employee code of conduct and an ethics escalation policy (whistle-blowing policy). This elaboration helps to narrow down the scope.

(Compliance Best Practice)

5.1.1.1 Corporate responsibility

Compliance to Corporate Responsibilities can be achieved as follows:

1. *You can begin with an Anti-bribery policy, and the method of reporting wrongdoings. An assurance from Top Management that the whistle-blowers will not be victimized. This assurance can be printed on the Anti-bribery Policy itself. See* ***Exhibit 11-2.***
2. *For communication, a display of the Anti-bribery Policy is sufficient, although a briefing session is better. Better still if a flow chart can be provided so readers will know how to report a case.*

4) 6.2, 6.2.1 The organization shall establish quality objective (ISO9001)

(Clause Description-Paraphrase)

The organization shall establish quality objectives at relevant functions, levels and processes needed for the quality management system. The quality objectives shall be maintained as documented information. They should be: a) be consistent with the quality policy; b) be measurable; c) take into account applicable requirements; d) be relevant to conformity of products and services and to enhancement of customer satisfaction; e) be monitored; f) be communicated; g) be updated as appropriate.

(Highlights of the clause)

- (Ref to old Standards). There has been a similar clause (5.4.1) of the same title in the old version of ISO9001:2008. The requirement then was simpler: Top management shall ensure that quality objectives, including those needed to meet requirements for product are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy. These are retained in gist in the new Clause.
- Previously, objectives are derived solely from Policy but this thinking has changed, to be like ISO14001 and ISO45001, where open issues may become objectives. But if open issues on risks and opportunities, and interested parties, are dealt with under 6.1, it is acceptable to be left out of the objective setting. For IATF 16949, Objectives shall be set for all the processes.
- There is no need for a documented process. However the Objective lists are required to be retained as documented information.
- For ISO9001, Objectives generally relates to conformity of products and services, and enhancement of customer satisfaction
- Objectives are to be monitored; be communicated, be updated as appropriate

(Compliance Best Practice)

6.2, 6.2.1 The organization shall establish quality objective
See 6.2.2.1 for a combined discussion.

5) 6.2.2 (second part of 6.2 dealing with actions required) (ISO9001)

(Clause Description-Paraphrase)
When planning how to achieve its quality objectives, the organization shall determine: (a) what will be done; (b) what resources will be required; c) who will be responsible; (d) when it will be completed; (e) how the results will be evaluated.

(Highlights of the clause)

- (Ref to old Standards). This is a totally new clause.
- This sub-clause of Clause 6.2 requires the organization to determine what actions to be taken, resources required, persons responsible, due dates and how to evaluate the results.
- In this new version, the organization is expected to be proactive and think through the action plans and controls ahead.
- This is not really applicable for IAT, which follows another method to ensure effectiveness

(Compliance Best Practice)

6.2.2 (Second part of 6.2 dealing with actions required)
See 6.2.2.1 for a combined discussion.

6) 6.2.2.1 Quality Objectives and planning to achieve them-Supplement (IATF16949)
(Clause Description-Paraphrase)
Top management shall ensure that quality objectives to meet customer requirements are defined, established, and maintained for relevant functions, processes, and levels throughout the organization. The results of the organization's review regarding interested parties and their relevant requirements shall be considered when the organization establishes its annual (at a minimum) quality objectives and related performance targets (internal and external).

(Highlights of the clause)

- (Ref to old Standards). This clause is much of a repeat of the old 6.2.2. The extra emphasis is: during setting of quality objectives, the requirements of interested parties shall be considered.

(Compliance Best Practice)

6.2.2.1 Quality Objectives and planning to achieve them-Supplement
Objectives setting:

1. *For IATF's certified organizations, each process shall have an objective or KPI. See **Exhibit 11-3.** See **SN-11.2** for explanations.*
2. *As for open items from Interested Parties Analysis, there is generally no need to include them as objectives. This is because they are already managed under Clause 4.2.*
3. *If you have a separate audit for ISO9001, you should have a set of simpler objectives for it, for practical reasons. **Exhibit 11-4** and **SN-11.3** for explanations.*

7) 9.1.3 Analysis and evaluation
(Clause Description-Paraphrase)
The organization shall analyse and evaluate appropriate data and information arising from monitoring and measurement. The results of analysis shall be used to evaluate:

a) conformity of products and services;
b) the degree of customer satisfaction;
c) the performance and effectiveness of the quality management system;
d) if planning has been implemented effectively;
e) the effectiveness of actions taken to address risks and opportunities;
f) the performance of external providers;
g) the need for improvements to the quality management system.
NOTE Methods to analyse data can include statistical techniques.

(Highlights of the clause)

- (Ref to old Standards) There used to be a similar clause, 8.4. Analysis of Data, in the previous ISO/TS16949. The previous requirement is retained, in different wordings, for better clarification.
- Added to analysis also in the areas of implementation effectiveness, effectiveness of actions to addressing risks and opportunities, need for improvement. See a) to g)
- NOTE mentioned about possibility of using statistical techniques. This is the subtle way IATF encourages the use of SPC.

(Compliance best practice)

9.1.3 Analysis and evaluation

1. *This is a concept clause, actual implementation will be carried out by relevant departments. You are only required to understand the intent and ensure compliance. There is generally no need to produce any additional documentation here.*
2. *However, you should double-check items if a)-g) of Clause Description are indeed monitored*

8) 9.1.3.1 Prioritization (IATF16949)
(Clause Description-Paraphrase)

Trends in quality and operational performance shall be compared with progress toward objectives and lead to action to support prioritization of actions for improving customer satisfaction.

(Highlights of the clause)

- There were some discussion on this area in the old Clause of 5.6.1.1 QMS performance.
- Quality objectives specified in the Business Planning, including Customer satisfaction, shall be achieved.
- Otherwise actions must be taken, and efforts taken shall be by prioritization.

(Compliance Best Practice)

9.1.3.1 Prioritization

1. *The KPI performances must be analysed every month and actions taken when targets are not achieved. Sometimes you may be allowed to observed a little longer, say up to 3 months, to take actions.*
2. *The analysis, comments, corrective actions, results should be noted in the monthly analysis.*

9) 5.1.1.2 Process Effectiveness & Efficiency (IATF16949)

(Clause Description-Paraphrase)

Top management shall review the product realization processes effectiveness and efficiency of the quality management system and support processes to evaluate and improve their effectiveness and efficiency the organization's quality management system. The results of the process review activities shall be included as input to the management review.

(Highlights of the clause)

- (Ref to old Standards).There had been similar clause, 5.1.1 Process Efficiency, in the previous version of ISO/TS16949. It was meant to be a production related KPI. It read: It was a very simple requirement of 1 sentence: Top management shall review the product realization processes and the support processes to assure their effectiveness and efficiency.
- The new version included both effectiveness and efficiency for control.
- Then S1-12 brought in changes, that effectively turned the clause into non-production, but for general QMS. And that is the reason the clause found a place in this Chapter

(Compliance best practice)

5.1.1.2 Process Effectiveness & Efficiency

1. *Set minimum 1 KPI for each of the processes. Critical processes e.g. production, QAQC, customer satisfaction should have more KPIs. Include efficiency type of KPI if appropriate. (Note that efficiency KPI is no longer mandatory by virtue of SI-12)*
2. *The full list of KPI and achievement shall be reported. This can be a list by itself or as part of the process report.* ***Exhibit 11-5, or Exhibit 10-4***

10) SIs & FAQs

No SIs & FAQs for this Chapter

11) Supplementary Notes

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

Clause	Section	Clarification Subjects
5.2	CBP	**SN11.1. How to demonstrate the people understood the Policy?**
Exhibit	EXH 11-1	**SN11.2. The Policy specimen looks so simple. Is it acceptable?**
5.2	CBP	**SN11.3 Are we allowed to have another set of Objectives for ISO9001, different from IATF?**
5.3.1	CBP	**SN11.4. It appears KPI for some processes are quite redundant e.g. Management Review, internal audit, or documentation. Can we skip?**
5.3.1	CBP	**SN11.5. How do we ensure effectiveness of KPI in IATF?**
5.1.1.1	CBP	**SN11.6. Do the IATF auditors really check on corporate responsibilities?**

SN11.1. How to demonstrate that the people understood the Policy?

Auditor may sample an employee to explain a point in quality policy. I see this more likely to happen in ISO than IATF. So long the employee can explain close to the meaning, it should be OK.

SN11.2. The Policy specimen looks so simple. Is it acceptable?

The Policy is straight to the point, a no-nonsense type. It can be used and have been commonly used. Complicated policies can also be used, but sometimes turn out to be counter-productive. A simpler policy is easy to commit to memory. But it is your choice.

SN11.3 Are we allowed to have another set of Objectives for ISO9001, different from IATF?

Yes, there is nothing in the standard that says ISO9001 must follow IATF's KPI. Besides, it is also impractical to do so. IATF's KPI are too many and too tight for ISO9001 organizations. Example, in automotive, customer expectations on on-time delivery is almost 100%. But in non-automotive, customer expectations could be much lower, e.g. 80%.

SN11.4. It appears KPI for some processes are quite redundant e.g. Management Review, or documentation. Can we skip?

Not so. If it is a process, we need to control and improve it. Peter Drucker, a top management expert once said, " If you can't measure it, you can't improve it". For practical reasons, we pick the most important or problematic controls in a process as its KPIs. For Management Review, setting a KPI of conducting the management review '3 weeks ahead of external audit' is a useful one. This is because you are required to submit pre-audit data including the minutes to your CB at least 2 weeks in advance, or you will be slapped with an extra 0.5 day for audit. For documentation, setting a objective of no obsolete document in use, is again useful and practical.

SN11.5. How do we ensure effectiveness of KPI in IATF?

In IATF, the KPI is tracked and reported every month to Management. If a KPI is not met, investigation shall follow, root cause identified, and actions taken. In some exceptional cases, actions may be delayed for 2-3 months, pending on further observations. KPIs are always being monitored and corrective actions ready to kick in. Effectiveness is therefore ensured.

SN11.6. Do the IATF auditors really check on corporate responsibilities?

IATF auditors probably will make sure the Corporate Policy is set and communicated. They probably would not going into the details.

Exhibit 11-1. Updated Quality Policy

XYZ Company

Quality Policy

We are an aluminium casting organization that supports Electrical and Electronics, medical device and automotive industries.

We are committed to:

a) maintain high quality products and services to our customers

b) commitment to satisfy applicable requirement

c) regularly review the suitability of the QMS, the Quality policy and Quality objectives

d) apply the principle of continual improvement

_____

Chief Operating Officer
1 July 2018

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

The key change is the inclusion of applicable requirement, given in red above

Exhibit 11-2. Whistle Blowing Policy

Antibribery & Whistle Blowing Policy

Commitment

1. Employees are expected to conduct themselves with a high standard of professionalism and ethics in the conduct of our business and professional activities
2. All forms of bribery, giving or receiving, are not allowed, except for approved legitimate, above-board business entertainment.
3. Illegal, unethical and questionable, irregular practices and wrongdoings, shall be investigated when reported
4. Identity of persons (whistle-blowers) reporting will remain confidential and protected against any risk of reprisal

Forms of Wrongdoings to be reported:

1. Unlawful action, whether breach in criminal or civil laws
2. Breach of company policy or procedures
3. Fraud, corruption, misappropriation or dishonesty
4. Actions that may cause physical danger/harm to another person, and/or give rise to damage of properties/assets
5. Forgery or alteration of any documents belong to the company, customers, another company or agents of the company
6. Profiteering as a result of insider knowledge
7. Misuse of position or information, and
8. Any other similar or related irregularities

Whistle Blower responsibilities

1. Anyone has the right to whistle blow.
2. The policy is applicable to all employees, suppliers, vendors, associated stakeholders and customers.
3. No absolute proof of wrong doing needed, but you should be reasonably believe the allegation is true, and in good faith that it is not for personal gain or motivated by ill-intention
4. It will also be useful to disclose basis or reasons of your concern

How to report a case

1. Whistle-blowing can be email directly to the Managing Director: XXXX

Outcome of investigation

1. Whistle-blower will be updated on the status of investigation.

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

- For the time being, corporate ethics, whistle blowing, escalation policy are sufficient to satisfy the clause
- In time to come, we should be expecting more and more corporate responsibilities to be included in the IATF Standard

Exhibit 11-3 KPI List

KPI- IATF 2019

Doc No	Rev No/Date	Effective Period	Compiled by	Approved by
IATF-KPI-2019	Rev 00, 1 Jan 19	Jan-Dec 2019	QMR	Managing Director

Process	KPI & Description
MP1: Management Processes	1. Management review on time (Nov)
	2. Business Plan ready by Jan
MP2; Internal Audits	1. Internal NC to reply within 3 days
	2. Zero Repeat NC
MP3. Continual Improvement	1 project a month average
COP1: RFQ Handling	1. To respond within customer specified period, or <5 working days
COP2: Process Design	1. Approved on first submission, and on time
COP3: Order Process	1. To act on the PO within 2 days
	2. Production Plan to be ready within 2 days
COP4: Production	1. Internal rejects <1000 ppm (automotive)
	2. Plant efficiency >80%
COP5: QAQC	1. LAR 100%
	2. Ontime calibration 100%
	3. First piece inspection within 2 hours upon receiving of samples
COP6: Storage & Delivery	1. 100% ontime delivery to customers
	2. No expired materials unidentified
	3. Inventory consistency <5%
COP7. Customer Feedback	1. Customer satisfaction survey >95% (automotive)
	2. Customer complaint <12 cases per year (automotive)
SP1. Purchasing	1. supplier ontime delivery min 90% (automotive)
	2. supplier quality issue zero case (automotive)
	3. 100% ontime supplier audit (automotive)
SP2. HR	1. Min 90% completion of Annual Training Plan
	2. Turnover rate <5%
SP3. Documentation	1. No obsolete document in use. Zero case
SP4. Machine Maintenance	1. Achieve MTRF >400 hours average
	2. Outsource services <RM20000
SP5. Tooling Management	1. Ontime service as per schedule 100%
SP6. Finance	1. No invoicing error. Zero case
SP7. ICT	1. MTTF <4 hours

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

- For IATF, every process must have a KPI. The above is a typical list
- Make sure these KPIs tally with those in the turtle diagrams

Exhibit 11-4. Quality Objectives (non-auto)

For ISO9001 Controls (non-automotive)

Doc No	Rev No/Date	Effective Period	Compiled by	Approved by
OT-2019	Rev 00, 1 Jan 19	Jan-Dec 2019	QMR	Managing Director

A. Objectives, Action Plan and Compilation PIC

No.	Objectives & Targets	Action Plan	Compilation PIC
1	100% ontime delivery to customers	• Ensure FG is ready at 2 days before delivery • Ensure supplier delivery is >90% on time	Planner
2	Customer satisfaction survey >95% (automotive)	• Annual survey • Compile report and analyse and follow up on weaknesses • Take action for cases not meeting the minimum	Sales/QA
3	LAR 100%	• Provide 100% WI to guide inspection • IPQC at 2 hours to maintain • OQC also checks on appearance	QAQC

B. Resources, PIC, Due dates and Result Evaluation

No	Objective & Target	What resources needed	Who will be responsible	Completion Date	How to evaluate the results)
1	100% ontime delivery to customers	Planner to check Shipping to book transfer in time	Planner	Ongoing, review monthly	No of OTD/ total delivery x100
2	Customer satisfaction survey >95% (automotive)	Customer satisfaction survey by March, and improve	Sales	Ongoing, review monthly	Average satisfaction % of all customers
3	LAR 100%	OQC to also double check on appearance	QC	Ongoing, review monthly	Event count.

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

- For non-automotive audit, you are not required to follow the KPIs of IATF, which are too stringent for most situations
- But ISO9001 has its own peculiar requirements on objectives. You need to provide action plans and resources information. See Section B, resources...

Exhibit 11-5 Full KPI Performance Report

Process	KPI	Description	Jan	Feb	Mar	Apr	>>>	Nov	Dec	Ave
MP1: Management Processes	1	Management review on time (Nov)								
	2	Business Plan ready by Jan								
MP2; Internal Audits	1	Internal NC to reply within 3 days								
	2	Zero Repeat NC								
MP3. Continual Improvement	1	1 project a month average								
COP1: RFQ Handling	1	To respond within customer specified period, or <5 working days								
COP2: Process Design	1	Approved on first submission, and on time								
COP3: Order Process	1	To act on the PO within 2 days								
	2	Production Plan to be ready within 2 days								
COP4: Production	1	Internal rejects <1000 ppm								
	2	Plant efficiency >80%								
COP5: QAQC	1	LAR 100%								
	2	Ontime calibration 100%								
	3	First piece inspection within 2 hours upon receiving of samples								
COP6: Storage & Delivery	1	100% ontime delivery to customers								
	2	No expired materials unidentified								
	3	Inventory consistency <5%								
COP7. Customer Feedback	1	Customer satisfaction survey >95% (automotive)								

	2	Customer complaint <12 cases per year (automotive)								
SP1. Purchasing	1	Supplier ontime delivery min 90% (automotive)								
	2	Supplier quality issue zero case (automotive)								
	3	100% ontime supplier audit (automotive)								
SP2. HR	1	Min 90% completion of Annual Training Plan								
	2	Turnover rate <5%								
SP3. Documentation	1	No obsolete document in use. Zero case								
SP4. Machine Maintenance	1	Achieve MTRF >400 hours average								
	2	Outsource services <RM20000								
SP5. Tooling Management	1	Ontime service as per schedule 100%								
SP6. Finance	1	No invoicing error. Zero case								
SP7. ICT	1	MTTF <4 hours								

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

- Some columns are trimmed off because of space constraints. In real case, you have to use a A3 paper to carry this report
- For easy recognition, the under-performed KPI should be highlight, e.g. using red fonts.

>> End of Chapter 11 <<

Chapter 12 . Changes Related

Contents:

0) Introduction

There are 5 applicable clauses in this chapter, but only 3 types of changes. They are lumped together into a chapter to be given some focus attention. Clause 6.3 is totally misunderstood, and seldom seen catered for. This chapter hopes to explain on each type of change, clarify the differences, and suggest some pointers on their management..

1) 6.3. Planning of Changes (ISO9001)

(Clause Description-Paraphrase)

When changes were to take place affecting the quality management system, the changes shall be carried out in a planned manner. The organization shall consider: (a) the purpose of the changes and their potential consequences; (b) the integrity of the quality management system; (c) the availability of resources; (d) the allocation or reallocation of responsibilities and authorities.

(Interpretation & Comments)

- (Ref to old Standards) This is a totally new requirement
- It is not about changes on purchase orders, and it is not about engineering change. It is about other types of changes that may have impact on the QMS and customer satisfaction.
- Management must ensure this is done in a planned manner and considering criteria (a) to (d) of the Clause.
- This has not been a control in the past, but it is now. Control of such changes involve some planning and controls. PDCA will come in handy. Some guidelines given and you can prepare design a form to guide on this requirement. See (a) to (d) of clause description

(Compliance Best Practice)

6.3. Planning of Changes

For Planning of Changes (non-ECN type), there are 2 stages to the requirement.

1. *Stage 1 is an analysis, covering a) to d) of the clause description. Gaps shall be found to plan for change. See* ***Exhibit 12-1.***
2. *Stage 2 is the action plan to take over from Stage 1. The normal quality action plans can be used for planning. For the case in the specimen, only one form is used for both stages*

2) 8.5.6 Control of changes (ISO9001)

(Clause Description-Paraphrase) The organization shall review and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements. The

organization shall retain documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.

(Highlights of the clause)

- (Ref to old Standards). There has been a similar clauses, 7.3.7 in the older ISO9001 standard. Note that it was parked on 'Design' before, but now it is in 'Production'
- The controls is not only about changing drawings requested by customers. It includes changes occurring in your internal departments and by your suppliers.
- Retain documented information, especially on results of the review of changes, the person(s) authorizing the change, and actions arising from reviews

(Compliance Best Practice)

8.5.6 Control of changes
See 8.5.6.1 for a combined discussion.

3) 8.5.6.1 Control of changes-supplemental (IATF16949)

(Clause Description-Paraphrase)

The organization shall have a documented process to control and react to changes that impact product realization. The effects of any change, including those changes caused by the organization, the customer, or any supplier, shall be assessed. The organization shall:

a) define verification and validation activities to ensure compliance with customer requirements;
b) validate changes before implementation;
c) document the evidence of related risk analysis;
d) retain records of verification and validation. Changes, including those made at suppliers, should require a production trial run for verification of changes (such as changes to part design, manufacturing location, or manufacturing process) to validate the impact of any changes on the manufacturing process. When required by the customer, the organization shall:
e) notify the customer of any planned product realization changes after the most recent product approval;
f) obtain documented approval, prior to implementation of the change
g) complete additional verification or identification requirements, such as production trial run and new product validation.

(Highlights of the clause)

- (Ref to old Standards) This is a totally new requirement
- There are a lot of additional requirements added. Some of new requirements are:
  a) define verification and validation activities to comply with customer requirements,
  b) conduct risk analysis on the proposed change and keep records,
  c) Notify customer of intended change and obtain approval before proceeding,
  d) Validation before implementation, e) trial runs and other validation activities as required.

(Compliance Best Practice)

8.5.6.1 Control of changes-supplemental

1. *For ECN type of changes, customer format is normally used*
2. *But you should also have your own format for internal and supplier control. An example is given in* ***Exhibit 12-2.***

3. *You don't need a procedure but records of the ECN shall be retained. As this is a critical area, an ECN procedure is recommended. A specimen is given in* ***Exhibit 12-3.***
4. *For practical purpose, both 8.5.6 and 8.5.6.1 should be incorporated in the same ECN procedure.*

(4) 8.5.6.1.1 Temporary Change of Process Controls

(Clause Description-Paraphrase)

The organization shall identify, document, and maintain a list of the process controls, including inspection, measuring, test, and error-proofing devices. ~~that includes the primary process control and the approved back-up or alternate methods~~. (phrase removed by SI-11)

The requirements are:

a) The organization shall document the process that manages the use of alternate control methods. The organization shall include in this process, based on risk analysis (such as FMEA), severity, and the internal approvals to be obtained prior to production implementation of the alternate control method.

b) Before shipping product that was inspected or tested using the alternate method, if required, the organization shall obtain approval from the customer(s).

c) The organization shall maintain and periodically review a list of approved alternate process control methods that are referenced in the control plan.

d) Standardised work instructions shall be available for each alternate process control method. The organization shall review the operation of alternate process controls on a daily basis, at a minimum, to verify implementation of standard work with the goal to return to the standard process as defined by the control plan as soon as possible.

e) Example methods include but are not limited to the following:

i) daily quality focused audits (e.g., layered process audits, as applicable);

ii) daily leadership meetings. Restart verification is documented for a defined period based on severity and confirmation that all features of the error-proofing device or process are effectively reinstated.

f) The organization shall implement traceability of all product produced while any alternate process control devices or processes are being used (e.g., verification and retention of first piece and last piece from every shift).

(Highlights of the clause)

- This is a totally new requirement
- Through SI-11, IATF remove a clause (requirement for both primary and secondary methods for all controls). This waiver can save a lot of wasted hours and misery
- This clause is about temporary use alternative inspection, testing and error-proofing methods, which can impact conformity to requirement.
- Detail requirements are given in a) to f) in the clause

(Compliance Best Practice)

8.5.6.1.1 Temporary Change of Process Controls

1. *This change is about changes of process controls to some temporary or alternative measures, due to failure of primary method*
2. *Requirements for alternative or temporary process controls should best be decided and pre-approved by customer at the development stages, or during subsequent reviews.*
3. *With the temporary method pre-approved, it can kick in to replace the failure system, without delays.*

4. *Therefore, during development stage, risks on the primary monitoring and measuring methods should be studied. If any of them are problem-prone, it should be given backup, or alternative methods.*
5. *Once finalized, the backup/alternative method shall be included inside the PFC, FMEA and Control Plan.* ***Exhibit 12-5.*** *Acceptance by customers on your FMEA and Control Plan may not be sufficient. You should alert them on the temporary or alternative measures within, and request their approval.*
6. *Ad-hoc application for approval needs a lot of documentation, including risk analysis, validation data etc. It is suggested that a procedure be established, to handle such a complicated task. See* ***Exhibit 12-4..***

5) 8.2.4 Changes to requirements for products and services (ISO9001)

(Clause Description-Paraphrase)

The organization shall ensure that when the requirements for products and services are changed, the relevant documented information is amended, and that relevant persons are made aware of the changed requirements.

(Highlights of the clause)

- (Ref to old Standards) This used to be Part of Clause 7.2.2 of previous version. Now taken out as a Clause by itself
- Basically the message is the same: Changes required documented information amendments and relevant people informed of the changes

(Compliance Best Practice)

8.2.4 Changes to requirements for products and services

1. *This type of changes concerns customer purchase order changes*
2. *Make sure customers issue P/O or equivalent for purchase of your products*
3. *If there is a request for changes, it should be studied before approval. Once approved, a new P/O, or supplementary P/O shall be issued by customer*
4. *New or modified P/O shall then be taken into the system, either as hardcopy or e-copy. Inform all relevant people as soon as possible, if not immediately*
5. *Do not rely email notifications alone, you should consider to add verbal reminders, or conduct a meeting*
6. *Planner should go round checking to make sure the modification has been effected*

6) SIs & FAQs

SI Nbr	IATF Clause	Description
11	8.5.6.1.1 Temporary change of process controls	The organization shall identify, document, and maintain a list of the process controls, including inspection, measuring, test, and error-proofing devices~~, that includes the primary process control and the approved back-up or alternate methods.~~ The list of process controls shall include the primary process controls and the approved back-up or alternate methods, if back-up or alternate methods exist. ***Rationale for change:*** *Clarified that not every primary process control has a back-up or alternate method. Clarified that if a back-up or alternate method exists, that those back-up or alternate methods are included on a list maintained by the organization. It is not a requirement to have an alternative process control for every primary control.*

FAQ	IATF Clause	Questions and Answers
17	8.5.6.1.1 Temporary change of process controls	**QUESTION:** **Does there have to be an alternative process control for each primary control specified in the control plan?** **ANSWER:** No, it is not a requirement to have an alternative process control for every primary control. When introducing new products, an organization should consider the risk of the primary control potentially failing and, based on risk and severity of failure mode, decide where alternative process controls are needed. When back-up or alternate process controls are needed, then both the primary and alternative process controls should be defined in the process flow, PFMEA, control plan, and the standardized work available. For existing processes, where there is a failure in the primary process control, and no alternative process control is defined, the organization should consider risk, (e.g. FMEA) and if approved, develop standardized work for an alternative process control, implement the controls, verify effectiveness through daily management, and then revalidate when the primary control is restored. Periodically, the organization shall review instances of where alternative process controls have been used and consider this as an input to update the process flow, FMEA, and control plan. **(See SI 11)**

7) Supplementary Notes

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

Clause	Section	Clarification Subjects
6.3	CBP	**SN12.1, For 6.3 type of changes, can give some examples and how they affect QMS?**
8.5.6, 8.5.6.1	CBP	**SN12.2. Where are the pitfalls for ECN control? Can give an example?**
8.5.6.1.1	CBP	**SN12.3. Temporary Change of Process Controls. Does it really happen? Can give an example?**

8.2.4	CBP	**SN12.4. Changes to P/O. Can give example how it can go wrong?**

SN-12.1, For 6.3 type of changes, can give some examples and how they affect QMS?

Example 1:

Organization A decides to close down a 3rd Party warehouse and bring all the inventory back to the plant for warehousing and delivery. There was not much planning and management intend to 'play by ear' to deal with any issue. A host of problems cropped up, ranging from wrong delivery, late delivery, invoicing problem, stock out situation. Endless customer complaints and business losses were the results.

Example 2:

Organization B was working closely with 2 new customers for the launch of 2 range of new products. A very thorough planning was done, including provision of new production lines, machinery and facilities, re-designing of plant layout to support the new operations, and training for new technology. Sales doubled within 12 months, and yet there was very little hiccup and stress to the workforce. Good planning for changes can pay off handsomely.

SN-12.2. Where are the pitfalls for ECN control? Can give an example?

Usually the area for noncompliance is with the internal departments, ECN are not initiated for changes, and not noticed, until problem blows up. An example: new production manager was trying improve on a process to increase output. Many rounds of changes took place without proper ECN control. Output increased but rejects/returns were coming back steadily. As there is no records and no traceability, no improvement is possible. Customer complaints could not be replied. A major customer was lost as a result.

SN-12.3. Temporary Change of Process Controls. Does it really happen? Can give an example?

Yes, it happens but not so often. Example: An organization was using a customer-designed assembly station with a built in torque wrench. At the time of audit, the built-in torque wrench was out of order, and a backup manual wrench was used. This alternative method was not on the control plan. No application to customer for approval was evident. Worse, the torque wrench was not calibrated. A major NC was raised.

SN-12.4. Changes to P/O. Can give example how it can go wrong?

This is rare due to the practice is mostly in place. It can still go wrong in rare cases. Example: an organization had an order for 5 containers of a product. Before it goes into production, a new drawing came from the customer requesting to make a dimensional change. There was a communication breakdown and production went ahead without changes. QC also passed the lot because the old drawing was used for inspection. All 5 containers were return by the customer.

Exhibit 12-1. Planning for Changes

Department	Proposed Change	Reasons for Chane	Proposed by	Approved by
Delivery	Discontinue with 3P Warehouse, and bring the products back to Plant	Better control, as many complaints of late delivery, wrong delivery		

Resources needed	Actual	Impact	Action Options	Action Summary
Space	Space not enough to accommodate	Same mess like 3P warehousing now. Problem to customer	Use the empty wing we have, re-organize. Build racks	• Project shall be ready by 31 Aug 2019 • do a project plan with budget for approval by 31 Jan 2019 • Project Leader is XX • QMS shall be study and upgraded when project completed. Temp procedure to be documented.
Manpower/Competency	No one is competent in inventory management	Can totally stall the operations	Immediately start recruiting. Project Head go to Thailand to study their system	
Delivery facilities	No trucks available and driver to deliver	Cannot deliver to customers unless use outsourced contractors	Can buy truck, also can continue using the 3P warehouse's transport service. Need to study	
MRP system	MRP can handle with some upgrading	Cannot print out D/O and adjust inventories. Affect our inventory control	Upgrading as required	

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

- This change is not about ECN and it is not about customer order changes.
- It is about anything else that can affect QMS, e.g. combining of QA and QC departments

Exhibit 12-2. ECN Form Specimen

ENGINEERING CHANGE NOTICE

Requesting Subcon/Internal Dept	Request Reference	Date

Type of Change

☐ raw materials ☐ packaging materials ☐ manufacturing process	☐ equipment ☐ place of manufacture/Subcon change ☐ measuring method

Characteristics

Before	After

(Attach evidence of verification and validation, if available)

Duration

☐Temporary, From to	☐Permanent

Reason for change

Approval

Requester sign	Decision	Approver sign	Remarks
	☐Approved ☐ Not approved		

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

- This is just a specimen, not prescribed by ISO or IATF.
- In general, approval must be obtained before proceeding.
- For application to customer for approval, follow customer procedure and use customer specified forms.

Exhibit 12-3. ECN Procedure Specimen

PIC	Flow Diagram	Key Points
Requester Engineering Engineering Engineering Leads PIC Planner DCC/PIC	9-04 (1) Engineering Change Proposal ↓ 9-04 (2) Conduct Risk Analysis ↓ 9-04 (3) Apply Documented Approval from Customer ↓ 9-04 (4) Implement change ↓ 9-04 (5) Production Trial ↓ 9-04 (6) Retain Verification & Validation Records ↓ 9-04 (7) Notification before shipment ↓ 9-04 (8) Update and standardize relevant documentation	9-04 (1) • Engineering changes refer to changes on materials, manpower, machines, processing method etc, that may impact product quality • Request for engineering changes may come from the customer, internal departments or from subcon • Internal departments and subcons change request shall via ECN, F-XXX. Customer request differs from simple email to full request with drawings 9-04 (2) • All request shall be evaluated on potential risk on product or process, using FMEA form. Validation shall be conducted. • If the change is expected to lead to a problem (s), a solution must be provided and validated before implementing. • Otherwise the request shall be rejected 9-04 (3) • Internal and subcon proposed changes shall be sent for pre-approval 9-04 (4) • If the impact study is satisfactory and approval obtained, implementation may proceed 9-04 (5) • Where requested by customer, production trial may be needed 9-04 (6) • All production trial, verification and validation record shall be retained 9-04 (7) • Notification before shipment is required • Comply to all identification and traceability requirement 9-04 (8) • Update and standardize relevant documentation, which may be process flow chart, FMEA, Control Plan, Work Instructions, Inspection Sheets etc

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

- This procedure is more complicated than usual because it covers requirements of both 8.5.6 and 8.5.6.1
- The perforated brackets may not be required, depending on situation

Exhibit 12-4 Alternative method in PFMEA

PROCESS FMEA

Process Functions / Requirements	Potential Failure Mode	Potential Effect(s) of Failure	S	C	Potential Cause(s) / Mechanism(s) of Failure	O	Current Process Control Prevention	Current Process Control Detection	D	RPN	Recommended Action(s)	Responsibility & Target Completion Date	Action Results: Actions Taken	S	O	D	RPN
Trimming (Primary)	Wrong dimension	Rejects by customer	7		Wrong die used	3	Setter check before set up	Checked by first piece and FQC results	4	48							
	Cut at edges not clean	Touch up needed	7		Die not service or sharp	5	Service every 6 months	Visual First-off checking/ FQC checking	7	245	Step up to every 3 months	Toolroom	May-18	7	3	7	144
		Touch up needed. Slow down cycle time and output	7		Die not service or sharp	5	Training of operators.	Visual First-off checking/ FQC checking	7	245	Install grinder to deburring	Production	May-18	7	3	7	144
Manual Triming (Alternative) Use only if triming machine spoil	Cut at edges not clean	Touch up needed. Slow down cycle time and output	7		Manual Process-speed limited per person	5	Training of operators.	Visual First-off checking/ FQC checking	7	245	Increase manpower temporarily	Production	May-18	7	3	7	144

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

- The full PFMEA is not shown, to allow the relevant areas to be seen clearer
- This is only for PFMEA. You need to include the alternative method also in process flow chart, control plan and generate a new WI.

Exhibit 12-5. Listing the alternative method on PFMEA

PIC	Flow Chart	Description
Process owner	1. Request to use temporary verification method	Step 1 ▪ Request is normally due to the primary verification method fails, and the temporary facilities is proposed to be used
Process owner	2. Risk Analysis	Step 2 ▪ A risk analysis shall be carried out on FMEA
QA	3. customer approval	Step 3 ▪ Customer approval shall be applied with support evidences e.g. comparison results etc
Process Engineering	4. Prepare WI	Step 4 ▪ Prepare work instructions and provide training to relevant PIC
Process owners	5. Implement	Step 5 ▪ Implement the use of the temporary ▪ Implement traceability e.g. verification and retention of first and last piece from every shift
Process owner	6. Tight controls	Step 6 ▪ Provide tight surveillance throughout the period, including daily checking on the results, performance of the equipment ▪ In some cases, layered process audit may be required ▪ Reporting to top management daily on the performance ▪ Objective is still to return to the primary method as soon as possible
Process owner	7. Reinstatement	Step 7. ▪ When reinstating the primary method, verification is needed as defined in control plan Results shall be documented.
DCC	8. Update records	Step 8 ▪ Update records and standardize relevant documentation ▪ The temporary method should be included in the control plan for future application
Process Engineering	9. Periodic Review	Step 9 ▪ Set a time every year to review temporary and alternative methods on the control plans

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

- This is an example of a procedure on temporary or alternative method
- Good Management should consider to prepare requirements early e.g. during development stage or during subsequent reviews.

>> End of Chapter 12 <<

Chapter 13. HR, Training & Competency

Contents:

0) Introduction

There are many applicable clauses in this chapter. Organization Knowledge is a new, rather confusing addition to this broad area. There are also other new subtle additions. For practical purpose, internal auditor competencies are discussed in Chapter 33, where second party auditor competencies are discussed under Chapter 25, Purchasing.

1) 7.1.1 (Resource) General. (ISO9001)

(Clause Description-Paraphrase)

The organization shall determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system. The organization shall consider: (a) the capabilities of, and constraints on, existing internal resources; (b) what needs to be obtained from external providers.

(Highlights of the clause)

- (Ref to old Standards)There has been a similar clause, 6.0 Resource Management, 6.1 Provision of Resources, in the older version of ISO9001.
- Basically, resources consist of infrastructure, equipment and people. The Clause explains that these resources are for the purpose of establishing, implementing, maintaining and continually improving the QMS, and to achieve customer satisfaction.
- What is new is that the Organization shall assess if there are constraints and lack of capabilities internally, and what needs to be procured externally
- Severe lack of resources, including manpower, and doing nothing to improve is a nonconformance.

(Compliance Best Practice)

7.1.1 (Resource) General.

- *This is a concept clause, actual provision is by management and implementation by relevant departments and functions.*

- *There is generally no need to produce any additional documentation here, as evidence.*
- *However, if there are obvious lacking of resources, some analysis should be done and actions taken. External procurement to fill gaps is allowed.*

2) 7.1.2 People (ISO9001)

(Clause Description-Paraphrase) The organization shall determine and provide the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes.

(Highlights of the Clause)

- (Ref to old Standards). This is something new and probably came about that many organizations are controlling on headcount too tightly, to the point of quality being affected
- Auditors can now raise NC on lack of manpower, which is rather new. Therefore organization should be more realistic with manpower provision.

(Compliance Best Practice)

7.1.2 People

- *See 7.1.1 above.*

3) 7.2 Competency (ISO9001)

(Clause Description-Paraphrase)

The organization shall: (a) determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system; (b) ensure that these persons are competent on the basis of appropriate education, training, or experience; (c) where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken; (d) retain appropriate documented information as evidence of competence.
NOTE: Applicable actions can include, for example, the provision of training to, the mentoring of, or the reassignment of currently employed persons; or the hiring or contracting of competent persons.

(Highlights of the Clause)

- (Ref to old Standards).There was a similar clause, 6.2.2 Competence, training and awareness, in the previous version of ISO9001
- The previous requirements are all retained in the new Clause.
- There are two subtle changes (a) persons under its control are also included. In other words, the onsite suppliers are included; (c) training is removed as the only means to acquire competence. It can still be used but no longer specified as the only means of acquiring competency.
- Other forms of actions can be provided in place of training e.g. mentoring, re-assigning of currently employed persons, or hiring or contracting of competent persons (see NOTE)
- Whatever actions taken, evaluation of the effectiveness of the actions taken is required

(Compliance Best Practice)

7.2 Competency

1. *Competency is in relations to the job expectations. To judge competencies, a basis is required. Job Description (JD) is one convenient tool for this purpose. See* ***Exhibit 13-1.***

2. *You need to periodically update the JD to include changes either: a) on the job, b) ISO changes, c) customer requirement changes, c) new management directives etc. Incorrect JD leads to wrong preparation of skill sets*
3. *OJT should have been developed from the JD. See **Exhibit 13-2.***
4. *As a general concept, training should be based on JD, whether OJT or annual. You should do the gap analysis to guide your training plan, for the immediate year. Do not attempt too far ahead, to avoid getting overloaded (**Exhibit 13-3).** Gap for OJT is based on the recruitment interview, and annual training based on TNA (**Exhibit 13.5**), and Organization Knowledge gap (**Exhibit 13-9**).*
5. *Gaps identified from Organizations knowledge analysis should be included, either as standard training, or ad-hoc training **(Exhibit 13-9)***
6. *Training evaluations must be done after training. Evaluations can be carried out on any appropriate formats as defined by the organization. There should be 2 evaluations, one immediately after the training, and another 1-6 months after the training See **SN-13.9** for explanation. See **Exhibit 13-4** (internal) and **Exhibit 13-6** (External).*
7. *TNA shall be conducted to detect weaknesses for improvement efforts. See **Exhibit 13-5.***
8. *TNA results shall help to decide on training for each employee for the coming year. TNA may be a survey, based on appraisal, etc**.***
9. *Despite of all efforts to be accurate, some areas may still be overlooked, especially due to changes. To respond to such possibilities, the Annual Training Plan (AMP) should be allowed to change. For isolated or individual situations, a Training Application Form may be used for supplementary budget approval. See **Exhibit 13-6.***

4) 7.2.1 Competency-supplemental (IATF16949)

(Clause Description-Paraphrase)

A documented procedures is needed for identifying training needs, including awareness and achieving competence of all personnel performing activities affecting conformity to product and process requirements. Personnel performing specific assigned tasks shall be qualified, as required, with particular attention to the satisfaction of customer requirements.

(Highlights of the Clause)

- (Ref to old Standards) This Clause was known as 6.2.2.2 Training, in the older ISO/TS 16949 Standard.
- The new requirement is almost word-for-word reproduction of the old clause, except process is added besides products. The 2 NOTES of the older version have been removed.
- A documented procedure is needed, to cover awareness, and competency building
- All persons whose work affect quality shall be trained, qualified, with particular attention to the satisfaction of customer requirements.

(Compliance Best Practice)

7.2.1 Competency-supplemental

(Additional to Clause 7.2)

1. *Competency needs a documented information. Therefore a documented process is required. This should be already available in all organizations, as it had been a mandatory procedure in the previous version of IATF. .*
2. *All persons doing work that impact quality shall be qualified as per JD*
3. *Customer specified training shall be complied**. SN-13.8***

5) 7.2.2 Competency-on-the-job training (IATF16949)

(Clause Description-Paraphrase)
The organization shall provide on-the-job training (which shall include customer requirement training) for personnel whose work can affect for personnel in any new or modified job affecting conformity to quality requirements, internal requirements, regulatory or legislative requirements; and this shall include contract or agency personnel.
The level of detail required shall be commensurate with the education level and also the complexities of the job. Persons whose work can affect quality shall be informed about the consequences of nonconformity to customer requirements.

(Highlights of the Clause)

- (Ref to old Standards). There was a similar clause, 6.2.2.3, Training on the job, in the previous standard. Contents are quite similar, except customer and regulatory requirements are now added.
- Customer requirement training shall be included for a) personnel whose work can affect quality, and b) for personnel in any new or modified job affecting conformity to quality requirements, internal requirements, regulatory or legislative requirements;
- Contract or agency personnel shall be included in the training program
- The level of detail required shall be commensurate with the education level and also the complexities of the job.

(Compliance Best Practice)

7.2.2 Competency-on-the-job training
(Additional to Clause 7.2 & 7.2.2)

1. *Contract or agency personnel shall be included for training. Records shall be kept as evidence.*
2. *For this type of personnel, WI training is the minimum to be provided.*

6) 7.3 Awareness

(Clause Description-Paraphrase)
The organization shall maintain documented information that demonstrates that all employees are aware of their impact on product quality and the importance of their activities in achieving, maintaining, and improving quality, including customer requirements and the risks involved for the customer with non-conforming product.

(Highlights of the Clause)

- This requirement was also found in the older standard under Clause 6.2.2. The awareness part has been taken out to become a clause by itself.
- For awareness, the organization shall ensure persons doing work under organization's control are aware of
- The quality policy, b) Relevant quality objectives, c) Their contribution to the effectiveness of the QMS, including the benefits of improved performance, d) The implications of not conforming with the QMS requirement

(Compliance Best Practice)

7.3 Awareness

- *Awareness is generally understood as gaining early knowledge on the organization, its product & services, its mode operandi, its culture, its welfare and rules etc. It does not*

include job specifics yet. In most countries, there is the initial training or briefing conducted on day 1, or thereof, and referred to as Induction or Orientation. This reference manual will use the term of Orientation.

- *Orientation is best conducted when a new recruit reports to work, via a guided program.* ***Exhibit 13-7***
- *To comply, the induction materials should cover policy, and point c) and point d**)** of the Clause Description**.** See **Exhibit 13-7**. From field observation, item c) and d) are almost never done in any organization.*
- *Quality Objectives are better covered by the department head or department seniors. This can be done during orientation, or slightly later, during the subsequent OJT*

7) 7.3.1 Awareness-supplemental (IATF16949)

(Clause Description-Paraphrase)

The organization shall maintain documented information that employees are aware of their impact on product quality and the important of their activities in achieving, maintaining and improving quality, including customer requirements and the risks involved for the customer with non-conforming product.

(Highlights of the Clause)

- This is totally new, but content is about the same as 7.3 above, except it emphasises on customer requirements and the risk to customers with non-conforming product.
- And documented info (records) are needed as evidence.

(Compliance Best Practice)

7.3.1 Awareness-supplemental

(Additional to 7.3 Awareness)

1. *To comply with this clause, employees shall be trained to maintain and improve quality, and records shall be retained. This is a repeat of 7.3.*
2. *No special effort is necessary here, if 7.3 has been catered for.*

8) 7.1.6 Organization Knowledge (ISO9001)

(Clause Description-Paraphrase) The organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services. This knowledge shall be maintained and be made available to the extent necessary. When addressing changing needs and trends, the organization shall consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates. There are 2 NOTES provided to clarify organization knowledge.

NOTE 1 Organizational knowledge is knowledge specific to the organization

NOTE 2 Organizational knowledge can be gained via many sources e.g. (a) internal sources (e.g. intellectual property; experience; lessons learned; undocumented knowledge and experience; improvements); (b) external sources (e.g. standards; academia; conferences; knowledge and experiences from customers or external providers).

(Highlights of the Clause)

- This is a totally new requirement. In the past, HR and training are assumed to handle this requirement.

- The Clause requires the organization to determine knowledge needed for the operations of its processes and to achieve conformity of products and services.
- The knowledge shall be maintained and be made available to employees to the extend necessary.
- When addressing changing needs and trends, the organization shall consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates.
- This is similar to the Knowledge Management popular in the 80s and 90s. It is about compiling, updating, improving, sharing and retaining knowledge and to build up new knowledge

(Compliance Best Practice)

7.1.6 Organization Knowledge
This is a totally new subject, and it is a little confusing in some parts of the clause. The following method is proposed.

1. *First determine the knowledge necessary for the operation of the processes and to achieve conformity of products and services. Use the processes to help to decide the knowledge required.*
2. *A word of caution on point 1) above, is to focus on the a few key tasks, activities and the relevant knowledge.* ***Exhibit 13-8*** *is an example of key knowledge.*
3. *After the initial knowledge determination, each process/department shall then be assessed for competency.*
4. *Use a 'team perspective' to determine competency.* ***See Exhibit 13-9****. Weaknesses and gaps detected can be bridged, by acquiring the additional knowledge. You can pursue the training route or other means. The clause allows augmentation by external resources, including assistance from suppliers and customers.*
5. *The list is re-evaluated every year due to changes and turnover of staff. This list is also useful to assess if it is adequate to deal with changes and trends.*
6. *Sharing of information although is listed in NOTES, has important benefits, particularly in sharing of lessons learned and suggestions. A public folder can be used for this dissemination and exchange. See* ***Exhibit 13-10***
7. *The NOTES of this clause are causing a lot of confusion. This Chapter hopes to throw some light on this confusion.* ***SN-13.12.***

9) 7.3.2 Employee Motivation and Empowerment (IATF16949)
(Clause Description-Paraphrase)
The organization shall maintain a documented process to motivate employees to achieve quality objectives, to make continual improvements, and to create an environment to promote innovation. The process shall include the promotion of quality and technological awareness throughout the whole organization.
Author's note: For exact wordings, please refer to standard indicated after the clause title.

(Highlights of the clause)

- There had been a similar clause, 6.2.2.4 of the same title in the previous version of TS16949. In fact, They are almost a word-for-word equivalents.
- Most organizations interpret this clause as a welfare clause, providing more incentives, perks etc. There are many organization focussing on welfare and good work environment, with annual employee satisfaction survey. This is incorrect.

- The emphasis is to motivate employees toward productivity, quality and innovation, achieving targets etc. Incentives and reward program in this direction is then correct. IATF is not against improving on welfare, but that's is not the intent clause.

(Compliance best practice)

7.3.2 Employee Motivation and Empowerment

- *To comply, there should be evidence of promoting the achievement of quality objectives, continual improvement, innovation, and quality and technological awareness.*
- *This can be achieved via programs of Employee Suggestion Scheme, regular meetings, Small Group Activities, improvement project activities, attendance incentives etc.*
- *What is commonly misunderstood by organizations is that IATF is asking for improvement on welfare and incentives, and employee satisfaction. This is not the intent, although a good deed.*

10) SIs & FAQs

No SIs & FAQs for this Chapter

11) Supplementary Notes

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

Clause	Section	Clarification Subjects
7.1.1, 7.1.2	CBP	**SN13.1. How would an auditor know we are short of manpower?**
7.1.2	CBP	**SN13.2. Are we allowed multi-tasking to save manpower?**
7.1.6	CBP	**SN13.3. How best we measure Organization knowledge?**
7.2	CBP	**SN13.4. How do we decide on training subjects, when there are far too many request? Can training plan be changed once set?**
7.2	CBP	**SN13.5. Where would a HOD get his/her suggestions for training for a particular employee?**
	CBP	**SN13.6. Is it OK to used Standard list for annual training, instead of the hassles of running a TNA survey?**
7.3	CBP	**SN13.7 OJT only for technical departments? Do we have to do for non-technical. What are the training materials to use for non-technical departments?**
7.2.2	CBP	**SN13.8. Can give examples of customer-specified training?**
7.2.2	CBP	**SN13.9 Why should we have a stages of evaluation on training effectiveness?**
7.3.2	CBP	**SN13.10 How to prove motivation?**
7.2.2	CBP	**SN13.11. A lot transferring of data e.g. for training. Anyway to solve this problem?**
7.1.6	CBP	**SN13-12. Organization knowledge described about intellectual properties, patents etc. Do we have to aim for those things to be really in compliance?**

SN13.1. How would an auditor know we are short of manpower?

IATF auditor will not deliberately check on this point. There are a few indications that may lead him/her to this point. First, for every audit, he or she will ask for your manpower data. A rubber product plant with assembly reporting only 15 employees is a big tell-tale sign. Another indication is the same person seems to be in charge everywhere. The third indicator is documentation work not updated, or slip shot work performed. With the above indications, an IATF auditor will look into manpower issues.

SN13.2. Are we allowed multi-tasking to save manpower?

Definitely so. First you have to make sure the person is competent for all the assignments. Second, there is a limit as to how far you can stretch a person. When you cross the point, fatigue sets in and work quality deteriorates. That's where ISO/IATF will intervene.

SN13.3 How best we measure Organization knowledge?

There is no right or wrong, when the standards do not prescribe a method. Prioritizing the assessment areas is Pareto is not only preferred, and encouraged by ISO/IATF. The main focus of this clause is retention of knowledge. Retention is by either document or via personal learning and retention. We set a standard what is needed for each department and then evaluate actual situations against these standards. To ensure integrity, the evaluation is repeated every year, or when there are major changes.

SN13.4. How do we decide on training subjects, when there are far too many request? Can training plan be changed once set?

In a good TNA exercise, the feedback should be a lot and naturally you cannot afford to adopt all, due to budget and time constraints. You should go through a process of elimination by filtering through 3 criteria: a) relevance, b) urgency, and c) budget. Once decided, the list is then sent for Management approval, where some more axing may happen. Yes, you can change training plans as needed. However, reasons must be given and the replacements, if applicable, are pre-approved.

SN13.5. Where would a HOD get inputs for training for a particular employee?

2 main area: Job description and annual appraisals. Job description is the most useful document, as it is the reason why a job existed in the first place. In order the person can continue to exist in an organization, the job holder must perform the required tasks and responsibilities competently. By referring to this document during TNA, gaps can be easily detected. An important point to note is the Job Description must be updated.

Annual appraisals are scorecards of the employee's performance, where strength and weaknesses are analysed and determined. However, some appraisal forms used are not useful. They have standard criteria for all categories of employees, And the assessment criteria are mainly on attributes, rather than skill or performance.

SN13.6. Is it OK to use Standard, repeating list for annual training, instead of the hassles of running a TNA survey?

A good 20-30% of the organizations I have audited used this method. The same subjects are carried out year after year. Yes, it saves a lot of time, but that is not the intent of ISO/IATF. Training is for the purpose of supporting the operations. To be effective it should aim at filling needs on knowledge and skill. In other words, training should be targeted. Going by a standard list is not a targeted approach, and is not TNA. The previous lists can very well be used as a reference, TNA cannot be omitted as it is a requirement.

SN13.7. OJT is commonly carried out for technical departments? Do we need OJT for non-technical staff? What are the training materials to use for non-technical departments?

OJT for technical employees such as operators and QC insepctors make good sense, as these people are involved directly on product quality. Nowadays, when we talk quality in ISO/IATF etc, we refer to total quality or TQM. Both direct and indirect quality are to be taken care of.
Non-technical staff are indirect quality contributors and OJT should be provided, although not spelt out clearly in the standard. Training materials for these categories of employees are more flexible as the tasks are more forgiving. Therefore different methods can be used. Flowcharts can be develop for internal use. The quality procedure for the department shall be part of the OJT, to fit into the companywide QMS.

SN-13.8. Can give examples of customer-specified training?

A car plant in Malaysia dictates a 6-month frequency for refresher training for operators on work instructions. Another car plant in Malaysia requires a metal fabrication plant to run refresher training with evaluations on new parts, for 6 months. A Japanese owned, tier-one organization in China, requires its suppliers to conduct annual refresher training on critical areas.

SN13.9 Why should we have 2 stages of evaluation on training effectiveness?

The first evaluation is immediately after the training. The trainer may conduct quiz, interview or observation comprehension during the course of the training, to gauge understanding. The second evaluation is normally done 1-6 months after the training. This second evaluation is on how well the training has been adopted by the trainee or on the job, as required. The results can be very different.

SN-13.10 How to prove motivation?

First, the notion that motivation is about incentives and employee satisfaction, need to be corrected. These things while being encouraged are not the motivation intended in clause 7.3.2. The motivation is only the means, the intended outcome is improvement in meeting targets, quality, innovation etc. Your means should be able to link to the intended outcome. They may be: incentives for full attendance, incentives for hitting targets, sharing forums on innovation, QCC/SGA to promote quality, improvement projects for continual improvement, visits to trade fairs etc to broaden thinking horizons.

SN-13.11. A lot of transferring of data e.g. for training records. Anyway to solve this problem?

Unfortunately this is the evidence needed to prove training activities. There are some annoying transfer and repeat of recordings. There are application software available in the market, but you really need to study if it fits your circumstances. Or you can attempt to write one for yourself. I have seen in the Middle East, where the HR manager wrote a program that her staff only need to enter some fields once, and the data is automatically posted to the relevant files.

SN-13-12. Organization knowledge described about intellectual properties, patents etc. Do we have to aim for those things to be really in compliance?

No. There is not the intent of ISO/IATF. These are only examples, but can be misleading**:**

- Note 1 tends to take some organization astray to look for some earth-shaking specific knowledge. This is not the intent. The knowledge is just the knowledge and skills required to do the job and they may be very basic.
- Note 2 contains big words of intellectual property, standards, academia etc. All these are nice to have, but most likely unavailable for the common organizations.

How organization knowledge comes about could be very simple. Example, the founder or the pioneer management could have started with a set of knowledge and skill. They consists of tested procedures and knowledge learnt from others or own experiences. They are improved gradually based on further experiences, complaints, field failures, and interactions with customers, suppliers and other training and exposure. This is perfectly acceptable and no drastic changes are required.

12) Exhibits

Exhibit 13-1. Job Description

Job Title: Purchaser	**Reporting to: Director**

Minimum Qualification:

- SPM or Diploma in any field

Experience Required:

- Minimum 3 years in purchasing experience.

Special Expertise / Requirements:

- Strong negotiation skill.
- Strong interpersonal skills with written and verbal communication skill.

Scope of Duties:

a. Oversee Purchasing and function.

b. Review Purchasing and processes and ensure effectively.

c. Provide resources for implementing & maintaining the quality management system.

d. Inventory Control.

e. Update Purchase Order information.

f. Update the Approved Vendor List for timely basic.

g. Supplier selection / re-evaluation processes.

On-the-job competencies:

a. Quality Policy & Objectives

b. Purchasing Procedures.

c. Vendor Evaluation Procedure

d. Vendor Pre-qualification Procedure

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

- This is quite a typical Job Description .
- It is good for recruitment but seldom linked to training.
- There is always a OJT and also annual training needs analysis, but their linkage to JD is seldom seen
- The method suggested in my model will bridge this gap

Exhibit 13-2. On-job Training

On-the-Job Training Subjects

Job Category	On Job Knowledge and Skill
Incoming QC Inspector	1. Materials and methods of checking , WI 2. Evaluating Accompanying document e.g. Mil spec, COA etc 3. Use of relevant measuring equipment 4. Recording forms usage 5. QC Pass labelling
Final QC Inspector	1. Products and methods of checking , WI 2. Use of relevant measuring equipment 3. Recording forms usage 4. Reading Drawings 5. QC Pass labelling 6. preservation: FIFO, shelf-life and re-inspection

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

- On-job training means the basic training provided to a new recruit, generally inhouse, so he/she can start to operate independently quickly. The above are 2 examples given.
- It may be given based on written instructions, demonstration, practical work etc
- OJT training are normally provided by department seniors, although some organizations use dedicated internal trainers for this job
- The OJT training plan should be reviewed regularly to ensure they cater for the current requirements of the job
- OJT subjects may be adjusted based on: a) Job Description, b) Corporate plans, c) Existing OJT training plan, d) Organization knowledge, e) Appraisals etc

Exhibit 13-3. JD-based Training

JD-based Training

(2019)

Job Category	Knowledge & Skill Requirement Stated in JD/ or other document	Training for 2019	Reason	Training Type
Incoming Quality Control Inspector (IQC)	1. Materials and methods of checking , WI	Yes	IQC on raw part from customer XYZ Reason: new requirement to check	By customer
	2. Evaluating Accompanying document e.g. Mil spec, COA etc	No	Competent	NA
	3. Use of relevant measuring equipment	No	Competent	NA
	4. Recording forms usage	No	Competent	NA
	5. QC Pass labelling	No	Competent	NA

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

- The above knowledge of skill is the most important things for training. You can also add another section for soft skill, leadership etc.
- The skill is not only important for OJT, but the ensuing years. Annual TNA should assess employees' competency based on this top priority knowledge and skill. Refresher training can be arranged for weak cases.

Exhibit 13-4. Personal Training Records

Personal Training Record

Name	Employee No	Position/Dept	Joined Date
Yasmin	10078	QC	15 Jul 2018

No.	Training Subjects	Training Dates	Trainer's Name	Trainee's Initial	Trainer's Evaluation	Supervisor's Evaluation		
					Pass/Fail	Pass /Fail	Initial/	Date
1	Materials and methods of checking , WI	16-17 Jul 2018	Joanne	JoL	P	P	LCN	16/10/18
2	Evaluating Accompanying document e.g. Millspec, COA etc	18 Jul 2018	Joanne	JoL	P	P	LCN	16/10/18
3	Use of relevant measuring equipment	19-23 Jul 2018	Swazi	SZM	P	P	LCN	16/10/18
4	Recording forms usage	23 Jul 2018	Swazi	SZM	P	P	LCN	16/10/18
5	QC Pass labelling	24 Jul 2018	Swazi	SZM	P	P	LCN	16/10/18

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

- The recording form will begin with OJT. Some organizations will record from Orientation
- Recording will go on until the person leaves the organization, to form a continuous record for training
- Unfortunately, there are quite some recording and transferring of data required.

Exhibit 13-5. TNA

Type 1: TNA on Department

Department	Training Year	Submitted by	Date
QAQC	2018	Netto QA Manager	

	/Subject/ Employee	Mr A	Ms B	Mr C	Mr D	Mr E	Ms F	Ms G	Remarks
1	5S				x	x	x	x	
2	SOP-QA01. QAQC Procedure			x	x	x	x	x	
2	IATF internal audit course	x	x		x				For roles as internal auditors
3	Leadership	x							As QA Senior Supervisor
4									
5									

Type 2: TNA to improve Skill Matrix

No	Critical Knowledge and Skill	Model 113	Model 238	Model 239	Model 420	5S	Start-up checking	Others
1	Ahmad Current score	100	75	75	75	75	75	Int Audit 75%
	Improve target	NA	NA	NA	NA	NA	NA	
2	Bahadur Current score	75%	75%	50	50	50	50	
	Improve target	NA	NA	75	NA	NA	NA	
3	Ngu Yin Current score	75%	50	50	25	25	25	
	Improve target	NA	75	NA	NA	NA	NA	

Type 3: TNA by individual

Year	Name	Key Dept/Position	Other responsibilities	Date Compile
2017	Janet Lewis	IQC Inspector	Dept trainer, internal auditor (QMS), second party auditor, EMS roles	21 Jan 2017

Competence Rating: 1 = Low, Appreciation Level only, 2=Medium, Competent, 3=High, Can Teach. Gap of ≥2 needs action

Activity	Critical knowledge and Skill	Competence				Notes on high gap	Improvement Action	Int/Ext	Approval
		Target	Actual	Gap	Action?				
Job	Use of all measuring equipment in IQC	3	1	2	Yes	Need to learn use of hardness meter	QC supervisor to train	INT	
Job	QC procedure for IQC	3	3	0	No	NA			
QMS	QMS system auditor	3	2	1	No	NA			
SQE	2nd Party Auditor	3	1	2	Yes	Need process of knowledge of alum. casting	QA Engineer to provide training	INT	
EMS	Aspect-Impact	3	1	2	Yes	General weak in this area	EMR to provide training	INT	

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

- Type 1 is most common and most HR officers know how to use this to compile a companywide training program. The survey should include assessment findings from Exhibit 13-9.
- Type 2 is more for skill matrix improvement. It is getting important because head count is tight nowadays, and employees are needed to be multi-skilled. This analysis is generally not required to take into the annual training plan, but managed by department HOD
- Type 3 is a little ahead of time for most companies. It is based on individual where the various roles are considered for improvement. This is actually the best method, where a person's total competency is assessed against a target level.

Exhibit 13-6 Supplementary Training Request.

Applicant	Department	Date
Training Course/Topic		Training Provider (preferred) Period Preferred:
Training Cost	☐ Master Training Plan	☐ Ad-hoc

Purpose
☐ Basic Job Requirement ☐ New Job Requirement ☐ Info/Tech Updating ☐ For Improvement

Evaluation I -by Trainee (Circle)

Suitable to Purpose	Training Material	Trainer competence	F&B	Recommended
Yes/Borderline/No	Good/Fair/Poor	Good/Fair/Poor	Good/Fair/Poor	Yes/OK/No

Evaluation II- by Immediate Supervisor (direct report)

S/No.	Area of review	Score
1	Is the training relevant to the employee's job scope?	
2	Is the employee able to apply what is learnt from the training attended effectively?	
3	Is there a difference in work performance after the training?	
4	Is the cost of the training worth the improvement in the work performance?	
5	Would there be opportunity for the employee to regularly apply the knowledge learnt?	
6	Would this training be recommended to other employees?	
	Score: 5-Excellent 4-Good 3-Average 2-Fair 1-Poor **Total score %**	

Application and Approval Record

Applicant Signature	HOD Support	Top Management Approval

HR Records

Date Attended	Course:	Training Provider
Cost if Applicable	Trainee Evaluation of Program Excellent/Good/Fair/Poor/Bad Sign/Date	General Evaluation by HOD Excellent/Good/Fair/Poor/Bad Sign/Date

Remarks given here explain on the exhibit. Do not include them as part of the form

- This Exhibit is shown here for 3 purposes: a) it is used for ad-hoc training request, b) the evaluation of external training effectiveness, c) evaluation of the external training program
- (a) sometimes a new training is required, in addition to the TNA exercise. The form can be used to apply for additional training and budget
- (b) Evaluation II is by supervisor after 1-3 months. A additional evaluation by HOD can be done at 'HR Records". It does not need to be elaborated because the supervisor has done earlier. Sometimes I still public trainers are requested to evaluate the trainee, besides the certificates. For goodwill they obliged, but the effectiveness is serious doubtful.
- (c) this part is seldom done on external training, except those conducted inhouse. The only way to do it meaningfully is by the trainee, using the space in 'Evaluation I'.

Exhibit 13-7 Orientation Program

Orientation Program

Name	Position	Department	Date Joined

No.	Training Subjects	Training Materials	Actual Training Dates	Trainer's Name	Trainee's Initial	Pass/ Repeat
1	Company introduction	Company Profile				
2	Products/Services	Samples, pictures, brochures, catalogue etc				
3	Organization chart & Direct Superior	Organization Chart				
4	Basic Responsibilities or Job Specifications (if available)	Job Description				
5	Work /time, Lunch, Tea-time, Overtime System	Company Rules, Regulations and Code of Conduct				
6	Other Rules and Regulations	Company Rules, Regulations and Code of Conduct				
7	Safety	Company Rules				
8	QMS-Basic Briefing	ISO 9001:2015 M&P, Policy and Objectives				
9	How to contribute to the effectiveness of the department and the QMS, and what benefits will there be to the company	PowerPoints Picture				
10	Implication of not conforming with the QMS and consequences to the company Slide Show/ Briefing	PowerPoints Picture				

Normally neglected topics

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

- Orientation program's primary purpose is to provide background information to a new recruit. It is really not a training. Evaluating is not necessary. Judging the person's general understanding, however, is still needed. Written information should be given, or readily accessible to the new employee
- Different trainers may be used. For example, QMS part is best done a by QMS team member. Objectives are generally a departmental affair, and best conducted by a department senior or HOD

Exhibit 13-8. Critical Knowledge by Process

Process: Business Planning

No	Knowledge/ Skill Needed
a	Understand the economy especially the automotive market outlook
b	Understand Strategic Planning & business management
c	Knowledge to prepare business plan as corporate requirment
d	Knowledge to approve KPI proposals

Process: Management Review

No	Knowledge/ Skill Needed
a	Fully understand the Management Review agenda and the intent of each item
b	Meeting chairing skill
c	Skill in preparing Review minutes
d	Coordination skill to ensure action items are bing followed up to completion

Process: Internal Management

No	Knowledge/ Skill Needed
a	Internal auditing skill and knowledge
b	Skill in weakness and noncompliance identification
c	Problem solving skill
d	Project managment skill to ensure action items are implemented effectively

Template 4: Continual Improvement

No	Knowledge/ Skill Needed
a	Project identification and management skill
b	Project managment skill to ensure action items are implemented effectively
c	

Template 5: RFQ Handling

No	Knowledge/ Skill Needed
a	Skill in quotation preparation
b	Coordination skill to get information and data for feasibility study
c	Quotation preparation knowledge

Template 8: Order Processing

No	Knowledge/ Skill Needed
a	Understand how to access customer order from customer server
b	Understand the flow /process to execute the orders
c	Kowledge to resolve with customer if there are issues on the order

Template 9: Production Planning

No	Knowledge/ Skill Needed
a	Knowledge to translate customer orders into organization's parts equivalent
b	Knowledge to plan production in relations to capacity utilization
c	Skill to coordinate with relevant departments to ensure Ontime Delivery

Template 6: Customer Feedback & Complaints

No	Knowledge/ Skill Needed
a	Knowledge to conduct customer satisfaction and skill to encourage participation
b	Knowledge to interpret feeback and skill to get internal cooperation to handle points of dissatisfaction.
c	Skill to interact with customers and inform remedial actions taken
d	Skill to interface with customer to resolve the complaints or warranty
e	Understand customer's requirement e.g. response time, reporting formats,

Template 10: Purchasing

No	Knowledge/ Skill Needed
a	Understand the IATF requirement on Purchasing
b	Knowledge for selection of new suppliers
c	Management skill on supplier to ensure top performance
d	Knowledge on establishing second party audit

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

- Organizational knowledge concerns with the core knowledge. To enable a process to operate to keep pace with the rest even under unforeseen interruptions
- It is not meant to record every little bit of knowledge and skill, otherwise we are repeating what the training dept is doing. That will be redundant.
- The method used here is to focus on 3-5 critical knowledge per process initially, but make sure the function/process is able to maintain a high operational standard. You can built up the list gradually.
- Note that the list only show some processes due to space constraints

Exhibit 13-9. Organization Knowledge Evaluation

Organization Knowledge Analysis

2018

(Process: Internal Audit)

No	Knowledge/ Skill Needed	Knowledge Retention Strategy	Actual	Judgement
1	Internal auditing skill and knowledge	• Doc Info • Min2 trained auditors for QMS, 1 for MPA, 1 for PDA	QP4-1 Internal Audit Procedure Training materials from external trainer. QMS auditor (5), MPA Auditor (2), PDA Auditor (2). Training certs available	OK
2	Skill in detection of weakness and noncompliances.	• Training materials from external training • Min 2 trained auditors for QMS, 1 for MPA, 1 for PDA	Training material from Apex Skill. A copy maintained by HR QMS auditor (5), MPA Auditor (2), PDA Auditor (2). Training certs available	OK
3	Problem solving skill (NC closing method)	• Training materials from external training • Min 2 trained auditors for QMS, 1 for MPA, 1 for PDA	Training material from Apex Skill. A copy maintained by HR QMS auditor (5), MPA Auditor (2), PDA Auditor (2). Training certs available	OK
4	Project managment skill to ensure action items are implemented effectively	• Training materials from external training • Min 2 auditors competent	Training material from Apex Skill. A copy maintained by HR Only 1 auditor trained with cert. 2 others learned from experience	OFI

(Process : HR & Training)

No	Knowledge/ Skill Needed	Knowledge Retention Strategy	Actual	Judgement
1	Knowledge of Training process and evaluation, and where records are kept	• Doc Info • Min 2 trained persons	QP6-1. HR Officer with Internal training evidence Back up by Adm Director, with Internal training evidence	OK
2	Knowledge to initiate TNA and use the output to prepare Annual Training Plan	• Doc Info • Min 2 trained persons	QP6-1. HR Officer with Internal training evidence Back up by Adm Director, with Internal training evidence	OK
3	Internal trainers must also be competent	• 3 years experience in the subject • Min 1 person	1 trainer, Johan only for production 5 years experience, TTT cert	OK

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

- Organization Knowledge recommended here are for a few important knowledge. You can include as many as you wish.
- Organization knowledge is about how to retain critical operations knowledge and skills. The techniques generally include documenting the knowledge and skill and protect them. For knowledge and skills that are difficult to document, retention by people/training will be relied on. A minimum no of trained people shall be defined, usually 2 is the minimum.
- This analysis should be conducted once a year, or during a significant change e.g. massive lost of people, or organization embarking onto some new technology
- Note that the responsibility mentioned here should preferably be evidenced from JD, and subject to verfication by auditor
- As this is just an illustration, all processes evaluated were satisfactory, If properly evaluated, there should be a lot of weaknesses detected
- Weaknesses can be bridged by training, procurement of professional services, augmentation assistance from customer or external providers, so long it can be proven and effective.
- Note that only 2 process evaluation are shown here due to space constraint. There are another 20 or so in the full list.

Public Folder Sharing Specimen

Date	Proprietary Knowledge gained	Source/ Type	Suggestion for Other Application	Contributor	File & Location
11.5.17	Use of spraybooth to capture dust in the sandblasting area. Very effective (Usually dust collector system is used and dust collected by air filters)	Innovation	Deburring section can consider this concept	Lee CM (Production)	SGA Project 1 Drawing at Maintenance
18.6.17	Supplied incoming part XX to be measured by USB calliper and automatically feed to computer. Save time, error free, and prevent 'short-cut' by errand inspectors	NCR by Customer	Can extend concept to FQC	Shah Amin (IQC)	QA Files

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

- This is not a requirement as it appears in a NOTE. However, I think it is a good practice to improve the strength of the organization to adopt this. I have seen many auditors asking this question, making it more advisable to do so
- This kind of sharing via public folder is quite easy to do. There are also companies that organized networking sessions to share such information
- A public folder is better, as it is documented and available at any time of the day

Chapter 14. Infrastructure and Work Environment

Contents:

0) Introduction

There are a few applicable clauses in this chapter. The focus is on infrastructure and work environment needed to support the operations. This chapter is only on provisions of infrastructure and work environment, and some conceptual changes. Details on their maintenance are in Chapter 27.

1) 7.1.3 Infrastructure (ISO9001)

(Clause Description-Paraphrase)

The organization shall determine, provide and maintain the infrastructure necessary for the operation of its processes and to achieve conformity of products and services. Infrastructure is explained in the note as: a) buildings and associated utilities; b) equipment, including hardware and software; c) transportation resources; d) information and communication technology.

(Highlights of the clause)

- (Ref to old Standards) There has been a similar clause 6.3, of the same title in the older version of ISO9001
- The previous requirements were all taken into the new Clause. And there is no additional requirements.
- The requirement is there shall be adequate infrastructure to support the production and quality obligations.
- The infrastructure shall be sufficient to, (a) to meet new requirement, (b) maintaining the required operation state.

(Compliance Best Practice)

7.1.3 Infrastructure

1. *When considering an RFQ, infrastructure will be reviewed for feasibility study. This is one way to assess adequacy of infrastructure. But it has some shortcomings.*
2. *Infrastructure are normally big-ticket items and involve high investments, and need be budgeted. Many RFQ has to be foregone due to lack of infrastructure. Infrastructure investment should be continuously provided so it would not be totally off limit to a new opportunity*
3. *One way is to conduct a review of infrastructure & environment once a year, e.g. during the internal audit. See **Exhibit 14-1** for a specimen. This was a requirement in the previous version of IATF.*

4. *The review is qualitative in nature and done on section to section basis, for the entire plant. This is sufficient as a first effort to assess adequacy. At least the general auxiliary improvement can be provided, so that any future RFQ investment will be lightened.*
5. *Plant, machinery and facilities need to be maintained. The emphasis is on preventive and predictive, and not on breakdown maintenance. See Chapter 27 more discussion.*

2) 7.1.3.1 Plant, facility, and equipment planning (IATF16949)

(Clause Description-Paraphrase)

The organization shall use a multidisciplinary approach for developing and improving plant, facility, and equipment plans. Organization shall also ensure good plant layout to achieve, a) optimize material flow, material handling, synchronous material flow and value-added use of floor space.
Manufacturing feasibility for new product or new operations shall be conducted. Capacity, proposed changes to existing operations, periodic re-evaluation relative to risk shall also be studied.
Author's note: For exact wordings, please refer to standard indicated after the clause title.

(Highlights of the clause)

- (Ref to old Standards).There has been a similar clause, 6.3.1, Plant, facility and equipment planning, in the old version of ISO/TS16949.
- This new Clause continues to emphasize the use of multidisciplinary approach for developing and improving plant facilities and equipment plans.
- The previous requirement on designing plant layout remained.
- There is a new focus is on new product, changes to existing operations, and capacity study. Risk evaluation, risk mitigation from changes also need to be studied and adopted.

(Compliance best practice)

7.1.3.1 Plant, facility, and equipment planning

1. *There are many requirements within this Clause. The first portion is about shop floor and equipment planning. IATF Auditor usually probe by asking if there had been any improvement study conducted on the shop floor. If so, the reports will be studied to assess the planning effectiveness and also any follow-up actions. Refer to Point 3 & 4 below.*
2. *The second portion of the clause deals conducting feasibility study on new product or changes to exiting products or operations. This is normally done during APQP and PPAP activities. If there has been any APQP/PPAP activities for the past year, they are your evidences of compliance.*
3. *The third portion of the clause is about maintaining existing process effectiveness. Processes need to be re-evaluated depending on risk analysis, and should show the incorporation of any changes made during process approval, control plan review, maintenance review; and verification of job set-ups etc. Note that SI-13 requires reporting of process studies, which is related this Clause. See* ***Chapter 23*** *for more information on process study.*
4. *For general plant and facilities, there are also some expectations for improvement:*
   a) Material flow study and time study can be achieved by means of value-stream analysis. The method available in the internet and not discussed here.
   b) Plant layout improvement. This will be based on the findings of multidisciplinary team. Take note that some customers require to be informed in the event of changes done to production lines and facilities.

3) 7.1.4 Environment for Operation of Processes (ISO9001)

(Clause Description-Paraphrase)

The organization shall determine, provide and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services. Two (2) Notes say that social, psychological, physical considerations can be included; and for personnel safety, registration to ISO45001 is considered complying.

(Highlights of the clause)

- (Ref to old Standards). There has been a similar clause, 6.4 Work Environment, in the older version of ISO9001. The wordings differ somewhat but the content remained.
- From the NOTE, the scope now may include the 'comfort' part for work environment such as social, psychological and physical. Human and Physical factors are: (a) social (e.g. non-discriminatory, calm, non-confrontational); (b) psychological (e.g. stress-reducing, burnout prevention, emotionally protective); (c) physical (e.g. temperature, heat, humidity, light, airflow, hygiene, noise.
- The former Clause 6.4.1 (Personnel safety to achieve conformity to product requirement) under the old ISO/TS16949, has been removed.
- A NOTE now appeared stating that if there is a OHS (occupation health safety) program in force, safety and environment may be left out of the audit.

(Compliance best practice)

7.1.4 Environment for Operation of Processes

1. *IATF Auditor will check on this area during the production line audit, where he or she can understand what kind of work environment is needed and how it is provided and maintained.*
2. *There is no special evidence required, except for the availability of controls and maintenance of the required environment. For OHS, even if you have an ISO45001 certification, personnel safety is still subject to audit. IATF auditors however will not purposely look for non-compliances in OHS, such as picking on operators wearing safety-shoes or ear plugs. But processes that have potential impact on the operators will be looked into.*
3. *On the question of whether the comfort part should be provided is entirely at the discretion of the organization, as it is mentioned only as a "NOTE".*

4) 7.1.4.2 Environment for the operation of processes- supplemental (IATF16949)

(Clause Description-Paraphrase)

The organization shall maintain its premises in a state of order, cleanliness, and repair that is consistent with the product and manufacturing process needs.

(Highlights of the clause)

- (Ref to old Standards). There has been a similar clause, 6.4.2. Cleanliness of premise, in ISO/TS16949.
- There is no change and it appears in the same wordings. Therefore lack of 5S can be a finding in automotive QMS.

(Compliance best practice)

7.1.4.2 Env for the operation of processes- supplemental

1. *Good housekeeping is a requirement for IATF16949, not for ISO9001*
2. *You don't need a full-scale 5S program, but keeping the place neat and tidy is required*
3. *Like in the case of safety, IATF auditor will not purposely look into compliance of this clause, but will pick up non-compliance while doing his/round rounds.*

5) SIs & FAQs

SI Nbr	IATF	Clause Description
18	7.1.3.1 Plant, facility, and equipment planning	The organization shall use a multidisciplinary approach including risk identification and risk mitigation methods for developing and improving plant, facility, and equipment plans. In designing plant layouts, the organization shall: a) optimize material flow, material handling, and value-added use of floor space including control of nonconforming product; ~~and~~ b) facilitate synchronous material flow, as applicable; and c) implement cyber protection of equipment and systems supporting manufacturing. ***Rationale for change:*** *Cybersecurity is not limited to the support functions and office areas using computers. Manufacturing also uses computerized controls and equipment which would be at risk to cyber-attack. This addition drives the implementation of necessary protections to ensure continued operation and production to meet customer requirements.*

6) Supplementary Notes

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

Clause	Section	Clarification Subjects
7.1.3	CBP	**SN14-1. Do we need to conduct a periodic review on adequacy of infrastructure, equipment?**
7.1.3.1	CBP	**SN14-2. Why does the standard keep emphasizing multi-disciplinary appropriate for plant design, review and planning?**
7.1.4	CBP	**SN14-3. Does the clause 7.1.4 requires us to improve on the comfort part to all employees?**
7.1.4.1	CBP	**SN14-4. Do we need a formalized 5S program for compliance?**
7.1.4.1	CBP	**SN14-5. If I also have ISO45001, can I totally ignore the OHS clauses.**

SN14-1. Do we need to conduct a periodic review on adequacy of infrastructure, equipment?

It used to be so, in the last version of IATF. But it is no longer required. It is still done, not as a fixed event, but most likely during RFQ. Review of risk and opportunity is another possibility that the infrastructure and working environment will be reviewed. But you can always carry out a review, as suggested earlier in the Best Practice, and the findings are submitted for management decisions. See **Exhibit 14-1.**

SN14-2. Why does the standard keep emphasizing multi-disciplinary team for plant design, review and planning?

In SME, it is common for the boss to make all the decisions, including equipment purchase, often without consulting. Operating experience and market feedback are also not considered much. When

a wrong decision is made, the organization has to live with the mistake for a long time. Therefore IATF encourages to go team work, consult and based on informed opinions before acting.

SN14-3. Does the clause 7.1.4 requires us to improve on the comfort part to all employees?
No. the part of comfort is just a NOTE. It is not mandatory. But you can, you are encouraged to do so, as it attracts people to stay with you longer.

SN14-4. Do we need a formalized 5S program for compliance?
5S is required but not a formalized program. Auditor will base perception on what he/she see. It will not be a full scale 5S audit. Some posters will be good, but also not mandatory. Just keep the place neat and tidy.

SN14-5. If I also have ISO45001, can I totally ignore the OHS clauses?
No. Auditor still has the responsibility to ensure safety. The perception will be on what he/she see. Just keep the place safe and free of significant hazards. IATF auditors will be more concerned with work steps that can cause injury or health hazard to operators, not so much the general environment. Your WI must show safety caution as it is a requirement.

7) Exhibits

Exhibit 14-1. ISWE Review

ISWE Review

Facilities/Department Reviewed	Team Leader	Members	Date
Cutting			

	Check Items	Audit Notes	NA	OK	Obs	NC
A.	**Infrastructure** 1. Is there enough adequate space to perform work?	Space is very tight			x	
	2. Are there sufficient filing cabinets and shelves?	No space but not required		x		
	3. Are there sufficient equipment and are these equipment up to date?	Machine and forklifts-sufficient		x		
	4. Can the equipment cope with an increased business of, say, 30%? (For forward planning purpose)	Doubtful. Forward planning needed now			x	
	5. Are there sufficient storage areas and facilities for materials, WIP and tools?	Currently kept where space can be found, including walkways and machine areas. Trimming waste is also stack everywhere				x
	6. Is the building and fixtures properly maintained?	Upkeep lacking				x
B	**Working Environment** 1. Is the temperature/lightings, humidity etc optimum to maintain product quality or perform testing?	Acceptable		x		
	2. Are there problematic elements that may affect product quality or perform testing e.g. noise, odour, presence of insects?	Lighting is poor. Temperature is hot but more from OHS and productivity effect perspective		x		
	3. Is the factory layout to minimize unnecessary movements and handling? Is there minimum criss-crossing of material flow to avoid cross-contamination (where applicable)?	Flow from cutting to packing is not logical. Redesigning may be needed			x	
	4. Is the place clean and orderly (5S)?	Drastic improvement needed.				x
Signatures of ISWE Team Members						

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

- This is not a mandatory activity, but one with good merits. It is good for renewal of strength. Infrastructure ages and losing efficiency with time, even with good maintenance program.
- Best to do this annually, and the findings can be considered for budgets for the coming year.
- Relying solely for RFQ to analyze infrastructure may be inadequate, as some of these are big-ticket items that need a longer time-frame to plan. They may also need time to acquire, even with the funding available

>> End of Chapter 14 <<

Chapter 15. Monitoring and Measurement Resources Related

Contents:

0) Introduction

There are several applicable clauses in this chapter. The focus is on monitoring and measuring, measurement equipment, and laboratory controls. Some new requirements e.g. calibration labs, need explanation to understand IATF's intent. There have been many NCs written on this area.

1) 7.1.5 , 7.1.5.1 Monitoring and measuring resources (ISO9001)

(Clause Description-Paraphrase)

The organization shall determine and provide reliable monitoring and measuring resources to ensure products and services conforms to requirements. The organization shall ensure that the resources provided: (a) are suitable for the specific type of monitoring and measurement activities being undertaken; (b) are maintained to ensure their continuing fitness for their purpose. Appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources shall be retained

(Highlights of the clause)

- (Ref to old Standards) There has been a similar clause 7.6. Control of monitoring and measuring equipment, in the old version of ISO9001, which was lengthy and complicated.
- The new clause only takes the first portion of the older clause. Additionally, it is also simplified. It states the organization shall provide resources (a) suitable for the specific type of monitoring and measurement activities being undertaken; (b) maintain the resources to ensure continued fitness for their purpose.
- The requirement becomes more readable. One subtle change is from 'equipment' to 'resource', but there is no real significance in terms of controls. You can continue to use the word 'equipment' without penalty.
- There is another Clause 7.1.5.2 Measurement Traceability, that deals with the traceability matter (2nd portion of the old clause). And there is also a third related clause 7.1.5.2.1 that deals with Calibration/Verification records.
- Documented information shall be retained as evidence.

(Compliance Best Practice)

7.1.5 , 7.1.5.1 Monitoring and measuring resources

1. *To ensure suitable equipment has been selected, an organization should be able to explain how equipment are decided. For example, why a calliper is used instead of a height gauge.*
2. *There is generally no need for documented evidence, but convincing answers should be ready.*
3. *IATF Auditor will certainly ask to see a master list of Monitoring and Measurement equipment, and you should have this ready. The list shall include all measuring equipment: lab and field equipment, measuring jigs and fixtures. See* ***Exhibit 15-1.***

2) 7.1.5.2 Measurement Traceability (ISO9001)

(Clause Description-Paraphrase)

When measurement traceability is a requirement, or is considered by the organization to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be: (a) calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification shall be retained as documented information; (b) identified in order to determine their status; (c) safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

The organization shall determine if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and shall take appropriate action as necessary

NOTE A number or another identifier traceable to the device calibration record meets the intent of the requirements in ISO 9001 :2015.

(Highlights of the clause)

- This is the second part of the Clause 7.6 of the previous ISO9001:2008 standard. Essentially nothing has changed but wordings are not the same. It becomes more readable.
- Measurement traceability is not mandatory for ISO9001. Its provision shall be based on customer or internal requirement. However, for IATF, traceability is required.
- Refer to clause content a) to c). Actions shall be taken if an equipment is found to be unfit for use.

(Compliance best practice)

7.1.5.2 Measurement Traceability

- *Measurement traceability means traceable to international standards, or the national equivalent. In practice, this means accreditation to ISO/IEC 17025, or to the national equivalent.*
- *Accreditation certificate of the calibration lab shall be ready for verification*

3) 7.1.5.2.1 Calibration/Verification records (IATF16949)

(Clause Description-Paraphrase)

A documented process is needed to manage calibration/verification records. Records of the calibration/verification activity for all gauges and measuring and test equipment (including employee-owned equipment relevant for measuring, customer-owned equipment, or on-site supplier-owned equipment) needed to provide evidence of conformity to internal, legal, and customer requirements shall be retained. Calibration/verification activities and records shall include the following details: (a)

revisions due to engineering changes; (b) incidents of out-of-calibration readings; (c) assessment of the risk caused by the out-of-calibration condition; (d), records previous measurement results obtained with this piece of test equipment, last calibration date and the next due dates; (e) notification to the customer if suspect product or material has been shipped; (f) statements of conformity to specification after calibration/verification; (g) verification that the software version used for product and process control is as specified; (h) records of the calibration and maintenance activities for all gauging); (i) production-related software verification used for product and process control

(Interpretation & Comments)

- (Ref to old Standards). There had been a similar Clause, 7.6.2 of the same title, in the previous ISO/TS 16949. The content has been much expanded.
- A documented process is now needed for managing records and calibration/verification activities and records.
- All employee-owned, customer-owned, and onsite-supplier owned equipment are subjected to this control, as before.
- .Records shall include information of (a) to (i) of the requirements.
- A few new things being added as requirement: software versions used for product and process control required for calibration; and notification records to customer in the event that product conformities are affected by out of specs equipment.

(Compliance best practice)

7.1.5.2.1 Calibration/Verification records

- *An organization shall have an master list of monitoring and measuring equipment, showing all the equipment, equipment reference code, type of calibration, frequency of calibration, calibration date and next due date. See **Exhibit 15-1** for a specimen. Note that the listing shall also include software for product and process control.*
- *The master list is further cascaded down to individual equipment. See **Exhibit 15-2.***
- *And when an equipment fails between calibrations, there is a great risk of non-conforming parts flowing out to customers. You need to respond and check on many things in mitigation: notifications to customers, actions taken for out-of-calibration are recorded and reported. This is best recorded in another form,* as *evidence for compliance. See **Exhibit 15-3.***
- *Calibration certificate of an equipment must have the accreditation body's logo and Lab's membership number (normally the national accreditation body's) on the certificate. If there is no logo printed on the certificate, it means the lab is not accredited for the particular test. It is not wrong use of stationery as the labs might claim.*
- *Also note that calibration and verification reports shall be approved by a responsible authority internally and indicated on the reports. A phrase "approved for use" and signed, or affix a personalized stamp is sufficient to satisfy item (g) of the requirement.*

4) 7.1.5.3.1 Internal laboratory (IATF16949)

(Clause Description-Paraphrase)

An organization's internal laboratory facility shall have a defined scope that includes its capability to perform the required inspection, test, or calibration services. This laboratory scope shall be included in the quality management system documentation. The laboratory shall specify and implement, as a minimum, requirements for: (a) adequacy of the laboratory technical procedures; (b) competency of the laboratory personnel; (c) testing of the product; (d) capability to perform these services correctly, traceable to the relevant process standard; when no national or international standard(s) is available,

a methodology shall be defined to verify measurement system capability; (e) customer requirements, if any; (f) review of the related records.
NOTE says accreditation to ISO17025 is not necessary.

.

(Highlights of the clause)

- (Ref to old Standards). There had been a similar clauses, 7.6.3.2.1 of the same title, in the old version of ISO/TS16949. It is almost a word-for-word reproduction of the old clause.
- The only exception is point (e), customer requirement is now a point of consideration.
- Should spell out the capability relevant info (a) to (f)

(Compliance best practice)

7.1.5.3.1 Internal laboratory

- *Compliance of this clause requires the organization to list down all the testing capabilities (can be by category e.g. dimension, force, mass etc.). See **Exhibit 15-4** for a specimen.*
- *Next, you can infer competency by listing down the tests, test methods/work instructions, customer requirement, competency requirement, technicians/operators etc. See **Exhibit 15-4.***
- *IATF Auditor may sample from the list for competency. Example: if you indicate technician competency is trained on calibration by an external lab, then certificates should be available as evidence.*

5) 7.1.5.3.2 External laboratory (IATF16949)

(Clause Description-Paraphrase)

External/commercial/independent laboratory facilities used for inspection, test or calibration services by the organization shall have a defined laboratory scope that includes the capability to perform the required inspection, test or calibration, either (a) accredited to ISO/IEC 17025 or national equivalent (e.g., CNAS-CL01 in China, see SI-10), (b) evidence that the external laboratory is acceptable to the customer

NOTE 1 gives allows second party audit using customer-approved method

NOTE 2 Calibration by the equipment manufacturer is still allowed, but organization should ensure that the lab meets the requirements listed in 7.1.5.3.1

(Highlights of the clause)

- (Ref to old Standards). There had been a similar clauses, 7.6.3.2 of the same title. There had been no change from the previous requirement.
- The external lab performing calibration will be checked on their accreditation as well as their scope of services.
- When calibration services are performed by equipment manufacturers, it is still allowed with conditions. In the past, this was generally taken lightly, but now it is under control.
- Second party audit of calibration, lab is also allowed, but customer approved needed and method shall be used is approved by customer.

(Compliance best practice)

7.1.5.3.2 External laboratory

- *The calibration lab used must provide evidence of accreditation and the scope authorized.*
- *For using labs not accredited to ISO/IEC17025, organization needs to obtain waiver from relevant customers.*
- *Some equipment can only be calibrated by the OEM. They are still permitted to do so, with conditions., as below:*
  - *obtain customer waiver for their use. This can be just a letter from all customers affected. This is the best option.*
  - *provide evidence of the OEM's compliance to 7.1.5.3.1. See* ***Exhibit 15-5.***
  - *2nd Party audit of the calibration lab is also allowed with customer approval.*
- *2nd Party audit of the calibration lab is not preferred as the lab auditing is a specialized skill that needs special training*

6) SIs & FAQs

SI Nbr	IATF Clause	Description
10 ***revised***	**7.1.5.3.2. External laboratory**	External/commercial/independent laboratory facilities used for inspection, test, or calibration services by the organization shall have a defined laboratory scope that includes the capability to perform the required inspection, test, or calibration, and either: — the laboratory shall be accredited to ISO/IEC 17025 **or its national equivalent (e.g., CNAS-CL01 in China) by an accreditation body (Signatory) of the ILAC MRA (International Laboratory Accreditation Forum Mutual Recognition Arrangement –** www.ilac.org) ~~or national equivalent~~ and include the relevant inspection, test, or calibration service in the scope of the accreditation (certificate); the certificate of calibration or test report shall include the mark of a national accreditation body; or — there shall be evidence that the external laboratory is acceptable to the customer. ***Rationale for change:*** *Some organizations found the lab accreditation requirements for external/commercial/independent laboratory facilities used for inspection, test, or calibration services confusing and needed clarification. Clarified lab accreditation requirements and expectations.*

FAQ I	ATF Clause	Questions and Answers
7	**7.1.5.3.2 External laboratory**	**QUESTION 1:** **When can the equipment manufacturer be used to calibrate inspection and test equipment?** **If an accredited laboratory exists but is very remote and/or expensive and the inspection or test equipment manufacturer is nearby and available can they be used (even if they are not accredited to ISO/IEC 17025)?** **ANSWER 1:** The inspection or test equipment manufacturer developed the methodology to maintain and adjust the equipment to meet calibration requirements as part of the design and manufacture of the inspection or test equipment. Therefore, the original equipment manufacturer of the inspection and test equipment is qualified to calibrate the equipment they designed and manufactured. The organization shall obtain customer approval before using any original equipment manufacturer for calibration services. **QUESTION 2:** **If the organization has inspection, measuring and test equipment in the final assembly and test area, is it considered an internal laboratory?** **ANSWER 2:** No. In-line measurement and test equipment used in any part of the manufacturing process or assembly process is not considered to be an internal laboratory.

14	**7.1.5.3.2 External laboratory**	**QUESTION:** **Is it required that the calibration certificate or (test) report of an external laboratory bears the mark (or logo or symbol) of the relevant national accreditation body that accredited the laboratory to ISO/IEC 17025?** **ANSWER:** Yes, only certificates of calibration or test reports including the mark of a national accreditation body are acceptable. The accreditation mark (often also called "accreditation logo" or "accreditation symbol") of a national accreditation body provides documented evidence that the provided inspection, test, or calibration services were performed according to the accreditation scope and that they comply with the requirements of ISO/IEC 17025, and are subject to supervision of a national accreditation body.

7) Supplementary Notes

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

Clause	Section	Clarification Subjects
7.1.5, 7.1.5.1	CBP	**SN15-1. On basis of choice for measurement equipment, where can we get some guidelines?**
7.1.5, 7.1.5.1	CBP	**SN15-2. Will IATF auditor really check on equipment suitability stated in the above question?**
7.1.5.3.2	CBP	**SN15-3. Why do we ask for the accreditation certification of calibration lab? Isn't a company number given by the national standard adequate?**
7.1.5.3.2	CBP	**SN15-4. What are the common equipment that needs equipment manufacturers to calibrate.**
71521	CBP	**SN15-5. What is software for product and process control? How is this calibrated?**

SN15-1. On basis of choice for measurement equipment, where can we get some guidelines?
This is a section in AIAG MSA reference manual, discussing on this subject. Please refer.

SN15-2. Will IATF auditor really check on equipment suitability stated in the above question?
An auditor may only ask this kind of questions when an equipment chosen seems inappropriate. Example, the control plan says a dimension is to be measured by callipers, but a height gauge is used in the production line. The IATF auditor will naturally ask which is the correct method, and what is the basis of the decision.

SN15-3. Why do we ask for the accreditation certification of calibration lab? Isn't a company number given by the national standard adequate?
Although the membership is given by the accredited lab, the scope does matter. The scope is stated on the certificate or attached as an addendum. Not all members are accredited to do all sorts of tests and permitted to calibrate all kinds of measuring equipment. Additionally, there is also an expiry date of the accreditation cert. An expired accreditation certificate is not an admissible evidence of validity.

SN15-4. What are the common equipment that needs equipment manufacturers to calibrate.
Common equipment are CMM, torque wrench, machine operating software, colour meter, some process control software etc.

SN15-5. What is software for product and process control? How is this calibrated?
Software for operations control generally has the capability to judge, calculate etc, and controlled by the settings. These settings may deviate with usage and time, and calibration is needed. Examples are

robotic welders, automatic load cells for chemical mixing etc. In the lab, there are also measurement software on plating or paint thickness. They are either calibrated with another software or another method for comparison. If the outcome is not obtained, the software is out of order and need adjustments.

8) Exhibits

Exhibit 15-1. Equipment Master List

Measuring Equipment Master List

Description		Model/Serial No.		Acceptance Criteria		Equipment No.	

Date	Type/ Serial No	Internal/External , Frequency	Passed-Cert No/Report	Failed-Disposition	Location	Next Due Date

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

- This master list is common. It is either a printed sheet, or stays on the computer. Recently I have also seen special software for controlling measurement equipment and calibration, which is interesting
- Both externally calibrated and internally verified equipment shall be on the list, irrespective if it owned by the organization, employee, or onsite supplier.
- Besides lab equipment, but measuring equipment fixed on shop floor, work stations, and measuring jigs shall also be included

Individual Measuring Equipment Calibration Record

Description	Equipment No	Model/Serial No.	Type: Internal/External	Frequency

Date	Type Int/Ext	Date First Use	Pass/Fail	Cert No/Report	Disposition (if fail)	Calib master (int Veri)	Next Due Date

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

- This is a recording sheet for individual equipment, but getting less popular. The master list (Exhibit 15-1.) if well designed, will make this form redundant.
- However, this may be necessary for internally verified equipment to provide a running history, especially those with verifications more than once a year

Exhibit 15-3. Calibration Incident Records

Calibration Incident Record
(Equipment Out-of-Specs)

Date Failure	Equipment	Failure Description	Product Lots Affected	Flow out?	Customer Notification	Disposition

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

- This recording is not mandatory. So this form is also not mandatory
- However IATF and customer auditors do ask around this area, to ensure calibration incident is well responded to
- If you have records, it should be easier to handle such queries. Such recording also create better awareness of the risk of calibration incidents

Exhibit 15-4 Internal lab capability

Internal lab capabilities

Type of Testing Capabilities

A. **Dimensions.** A1.Callipers, A2.Micrometers, A3.Feeler gauge, A4. Height gauge, A5. Smart scope, A6. Pin gauge, A7.Block gauge, A8. CMM
B. **Weight.** B1.Digital balance
C. **Force:** C1. Torque meter, C2.Torque wrench
D. **Temperature:** D1. Thermometer, D2. IR thermometer, D3.Thermal couple
E. **Visual:** E1. cracks, E2. Burr, E3.Wrinkles, E4. Waving

Competency

No	Name	Competent at	Testing	Verification	Int/Ext Trained
1	Zambri Ismail	A1, A2, A3, A4, A5, A6, A7, A8	x		Internal
		A1, A2, A3, A4, A5, A7		x	External
2	Zarith	A1, A2, A3, A4, A5, A6, A7	x		Internal
		A1, A2, A3, A4, A5, A7		x	External

Test Methods:

No	Test Method	Standard
1	Callipers	??
2	Weighing machines	??

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

- There are many organizations just ignoring this clause and hoping that the auditors do not asked. If they ever, do, they will use their convincing talent to prove they are competent. Sometimes they are not so lucky.
- This requirement is here to stay. If auditors have not asked before, it does not mean they won't in the next round. You should start to prepare the evidence.
- This is a very simple way to show internal lab capabilities and no reasons why it cannot be done

Exhibit 15-5. Evidence by non-ISO17025 OEM-page 1

Common Document to Prove Conformance to 7.1.5.3.1 Internal Laboratory
By Equipment Manufacturers without ISO/IEC17025

1. Self Declaration as Equipment Manufacturer Evidence. Registration, patent, brochure etc.

2. If the calibration is performed by a agent, appointment letter to certify the appointment, as below:

HEXAGON

CERTIFICATE OF CONFORMITY

This is to certify that

DigiGate Technology (Thailand) Co., Ltd.
Portable Measuring Arms Service Center
72/50-51 Moo 3 Tambol Bangtalad
Ampur Pakkrad, Nonthaburi 11120
Thailand

has been assessed by the Factory;
conforms to requirements and
demonstrates competence in the area(s) of

Service of CIMCORE Absolute Arms (Level 3)
Calibration of CIMCORE Absolute Arms

ASC-DGTTHNTB-2018	2018-02-28 to 2019-02-28
Certificate	Validity
2018-03-28	
Issued	Certification Authority

3. Competency of Technician, attach evidence:

DigiGate

Ref No. 17/080

CERTIFICATE OF TRAINING

Hereby Awards this Certificate of Accomplishment to

[redacted]

Digigate (Thailand) Co., Ltd.

In Recognition for attendance of Training in

"Calibration and Service Training"

On 26-28 July 2017

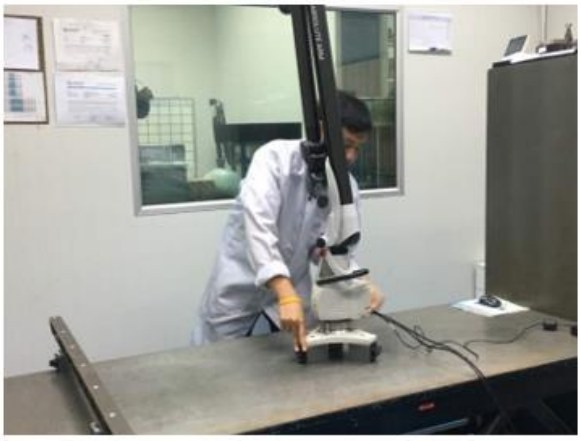
Yunood Salamad
DigiGate Technology (Thailand) Co., Ltd.

Chaiyod Kampradam
DigiGate Technology (Thailand) Co., Ltd.

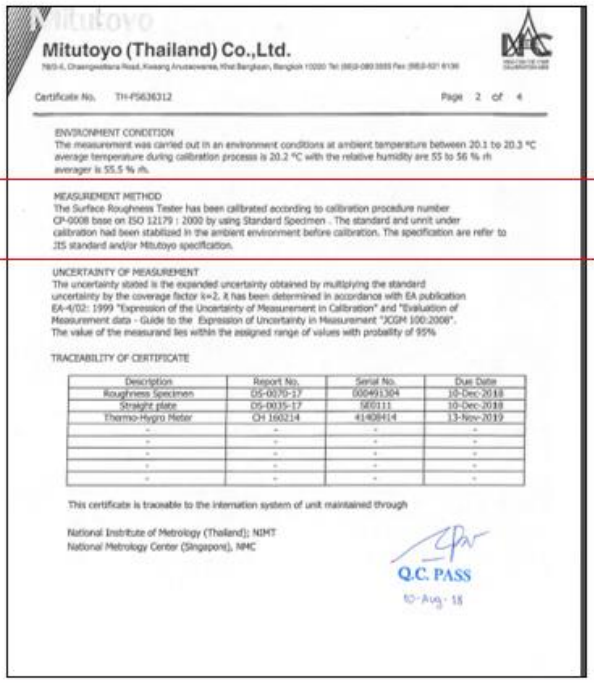
Please call + 66 0875981331 and ask for Technical Support if you have any questions.

Exhibit 15-5. Evidence by non-ISO17025 OEM-page 2

4. Lab Facilities: photo, calibration certs of equipment used for calibration. This can be exempted if calibration is done onsite, by calibration certs of equipment used are required.



5. Test Method (on the certificate of calibration



Mitutoyo (Thailand) Co.,Ltd.

Certificate No. TH-F5636312 Page 2 of 4

ENVIRONMENT CONDITION
The measurement was carried out in an environment conditions at ambient temperature between 20.1 to 20.3 °C average temperature during calibration process is 20.2 °C with the relative humidity are 55 to 56 % rh averager is 55.5 % rh.

MEASUREMENT METHOD
The Surface Roughness Tester has been calibrated according to calibration procedure number CP-0008 base on ISO 12179 : 2000 by using Standard Specimen . The standard and unrit under calibration had been stabilized in the ambient environment before calibration. The specification are refer to JIS standard and/or Mitutoyo specification.

UNCERTAINTY OF MEASUREMENT
The uncertainty stated is the expanded uncertainty obtained by multiplying the standard uncertainty by the coverage factor k=2, it has been determined in accordance with EA publication EA-4/02: 1999 "Expression of the Uncertainty of Measurement in Calibration" and "Evaluation of Measurement data - Guide to the Expression of Uncertainty in Measurement "JCGM 100:2008". The value of the measurand lies within the assigned range of values with probality of 95%

TRACEABILITY OF CERTIFICATE

Description	Report No.	Serial No.	Due Date
Roughness Specimen	05-0070-17	0004913304	10-Dec-2018
Straight plate	05-0035-17	520111	10-Dec-2018
Thermo-Hygro Meter	CH 160214	41408414	13-Nov-2019
-	-	-	-
-	-	-	-
-	-	-	-
-	-	-	-
-	-	-	-

This certificate is traceable to the internation system of unit maintained through

National Institute of Metrology (Thailand); NIMT
National Metrology Center (Singapore), NMC

Q.C. PASS
10-Aug-18

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

- If you are using equipment maker to calibrate your equipment , who is not certified to I7025, you should first try customer waiver
- If for some reasons, you cannot get the waiver, you can provide evidence of internal lab capability of the equipment maker. This is generally accepted as alternative compliance.

>> End of Chapter 15 <<

Chapter 16. Communications

Contents:

0) Introduction

There are a few applicable clauses in this chapter. The focus of this chapter is on communications, which include internal, external and customer communications. Customer communication and internal communication had always been controlled. External communication is new.

1) 7.4 Communications (ISO9001)

(Clause Description-Paraphrase)
Organization shall determine the internal and external communications relevant to the quality management system, including: (a) on what it will communicate,(b) when to communicate, (c) with whom to communicate, (d) how to communicate, (e) who communicates.

(Highlights of the clause)

- (Ref to old Standards) There had been a similar clause, 5.5.3 Internal Communications, in the previous version of ISO9001.
- It is now expanded to cover external communications as well. It also emphasizes on the need of planning for communications. However, it did not say whether you need to plan how far ahead.

(Compliance best practice)

7.4 Communications

1. *For internal communications, prepare a schedule on those subjects you need to communicate regularly. See **Exhibit 16-1**. Any other ad-hoc items can be added to the list, as and when*
2. *For external (interested parties) communications, it should be formal as communication of this nature could have legal ramifications. You should plan well, as given in a) to e) of the Clause Description. The nature is ad-hoc, and there is no requirement for a regular program. Records keeping, however, is important**.** See **Exhibit 16-3.***
3. *External communication is a 2-way communication. Sometimes you inform and notify, sometimes you received input and complaints etc. A procedure is useful to guide internal staff how to handle this. See **Exhibit 16-2***

2) 8.2 Requirement for products and services

8.2.1 Customer communication

(Clause Description-Paraphrase)

Communication with customers shall include:

a) providing information relating to products and services;

b) handling enquiries, contracts or orders, including changes;

c) obtaining customer feedback relating to products and services, including customer complaints;

d) handling or controlling customer property;

e) establishing specific requirements for contingency actions, when relevant.

(Highlights of the clause)

- (Ref to old Standards). There was a similar clause, 7.2.3. Customer Communication. in the previous version of ISO9001.
- It was much shorter then and represented by (a)-(c) above. Requirements (d) and (e) are new additions.

(Compliance best practice)

8.2.1 Customer communication

1. *Consider to have a webpage for your organization, if you do not have one currently. The webpage should describe your products and services and contact details, as the minimum.*
2. *You should also have a list of contacts for the convenience of regular customers. Your telephonist and reception should have this list.*

3) 8.2.1.1 Customer communication-supplemental

(Clause Description-Paraphrase)

Written or verbal communication shall be in the language agreed with the customer. The organization shall have the ability to communicate necessary information, including data in a customer-specified computer language and format (e.g., computer-aided design data, electronic data interchange).

(Highlights of the clause)

- (Ref to old Standards). There had been a similar clause, 7.2.3.1 Customer communication-supplemental) in the old version ISO/TS16949.
- Basically there is no change but reworded to clarify the meaning of the requirement. Notably the word 'agreed with' rather than 'specified' allows some room for negotiation.
- Customer-specified language, (Computer language and format etc. EDI, design software etc) continues to be a requirement

(Compliance best practice)

8.2.1.1 Customer communication-supplemental

1. *On language to be used, it will be as agreed with the customer. I have even seen this specified in the business contract. However, there is generally no need to produce any evidence other than your disclosure.*
2. *Customer communications involving customer language, formats, EDI, design software etc, These are things you have to comply and use for the operations. Example, if a customer only releases P/O via its portal, and you need an EDI software to extract it. You*

either have the facility to complete the transaction or you don't get involved. Customer will not get out of the way send you a P/O by email etc.

4) 8.5.5.1 Feedback of Info from Service (IATF16949)

(Clause Description-Paraphrase)

The organization shall ensure that a process for communication of information on service concerns to manufacturing, material handling, logistics, engineering, and design activities is established, implemented, and maintained.

NOTE 1 The intent of the addition of "service concerns" to this sub-clause is to ensure that the organization is aware of nonconforming product(s) and material(s) that may be identified at the customer location

or in the field.

NOTE 2 "Service concerns" should include the results of field failure test analysis (see Section 10.2.6) where applicable

Author's note: For exact wordings, please refer to standard indicated after the clause title.

(Highlights of the clause)

- (Ref to old Standards). There was a similar clause, 7.5.1.7 of same title, in the previous version of ISO/TS16949. Only minor changes occurred.
- New clause added logistics, material handling. Instead of outside the organization, it is specific to customer location.

(Compliance best practice)

8.5.5.1 Feedback of Information from Service

1. *This kind of feedback will come from 3 sources, Sales department, planner and QAQC.*
2. *IATF auditor may ask how such issues are fed back to the organization, and how actions are taken to resolve issues with customers.*
3. *You need to have a process, not necessarily documented, so that the relevant departments know what need to be done*

5) SIs & FAQs

No SIs & FAQs for this Chapter

6) Supplementary Notes

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

Clause	Section	Clarification Subjects
7.4	CBP	**SN16-1. Should I have a program with schedule for external communications?**
7.4	CBP	**SN16-2 How do we actually communicate internally, with the schedule given in Exhibit 16-1?**
7.4	CBP	**SN16-3. How to communicate externally? Can provide some examples?**
8.2.1	CBP	**SN16-4. Must I have a website to customer communication?**

SN16-1. Should I have a program with schedule for external communications?

Although not stated very clearly, external here means interested parties. External communication should be ad-hoc, it should stay ad-hoc. Only when there is something important to communicate, then communicate. No one has time to hear your stories unless they are critical and urgent to them

SN16-2 How do we actually communicate internally, with the schedule given in Exhibit 16-1?

For internal communication, there is generally 2 categories. Category 1: Routinely matters e.g. order changes, rejects, customer spec changes, policy and object and risk changes. Non-quality maters such as risks, safety. environment and legal matters can also be included. Routine can be summarized in a table (**Exhibit 16-1**) as evidence. Most IATF companies have daily meeting, mostly morning. It is a good forum to disseminate such information. Communications can also go by email notification, but that can happen if everyone is into IT. Category 2 is ad-hoc, things that happen once in a while without warnings. This is probably done through a townhall meeting. Record shall be retained, such as attendance, minutes, reports etc.

SN16-3. How to communicate externally? Can provide some examples?

Having a procedure/process is useful, like **Exhibit 16-3** given. First thing when an event especially a negative one happen, Risk-Base Thinking has to be practiced, to foresee who are impacted and how, and decide if who need to be informed. The method to handle the fallout and response should be figured out. A good case in point is when the airbags of Takata was found to be defective, the affected OEMs notify the public and car owners of a pending recall program and implemented it. The recall program was tedious and there are car owners not responding. With legal implications, the OEM must still complete the recall, or face a legal risk later. Other situations may be less critical, unlike the above, planning is still needed, although simpler. Keep a record on the communications taken place.

SN16-4. Must I have a website to customer communication?

Website is a hardworking marketing tool. Besides existing customers, potential and new customer can also visit your site to see what you are offering. The website works for you 24 hours a day, 7 days a week. Having a website for business is no longer a novelty idea. Plus it is very inexpensive these day, there should be no reason not to get one.

Exhibit 16-1 Internal Communications

Regular Internal Communications

No	What to communicate	To Whom	When	How	Responsibility
1	Quality Policy	Internal-all employees	• First introduced • Orientation • And when revised	Email, briefing Display	QMR/HOD/HR
2		Relevant external interested parties	• First introduced • And revised	Website change Targeted email	QMR/IT
3	Quality Objectives/KPI	By department	• First introduced • And when revised	Email, briefing	QMR/HOD
4	Product Line changes	Internal Depts-all employees	• When changed	Email, briefing	QMR/HOD/HR
5	Special processes that may affect some employees	Affected dept & onsite subcons	• First introduced • During revised	Briefing	QMR/HOD/HR
6	Statutory and regulatory changes	Internal-all employees	• First introduced: • And when revised	Email, briefing Display	QMR/EHS Leader/ HOD
7	Customer requirement changes	Internal-all employees	• First introduced: Orientation • And when revised	Email, briefing Display	QMR/EHS Leader/HOD

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

- This chart is not complete. There are also daily communications in the form of management meetings, daily production meetings, problem-solving and improvement project meetings
- The subjects shown are primarily for internal communication. There is one item (#2)also extending to external parties, as a matter of convenience; instead of creating another document.

Exhibit 16-2.External Communications Procedure

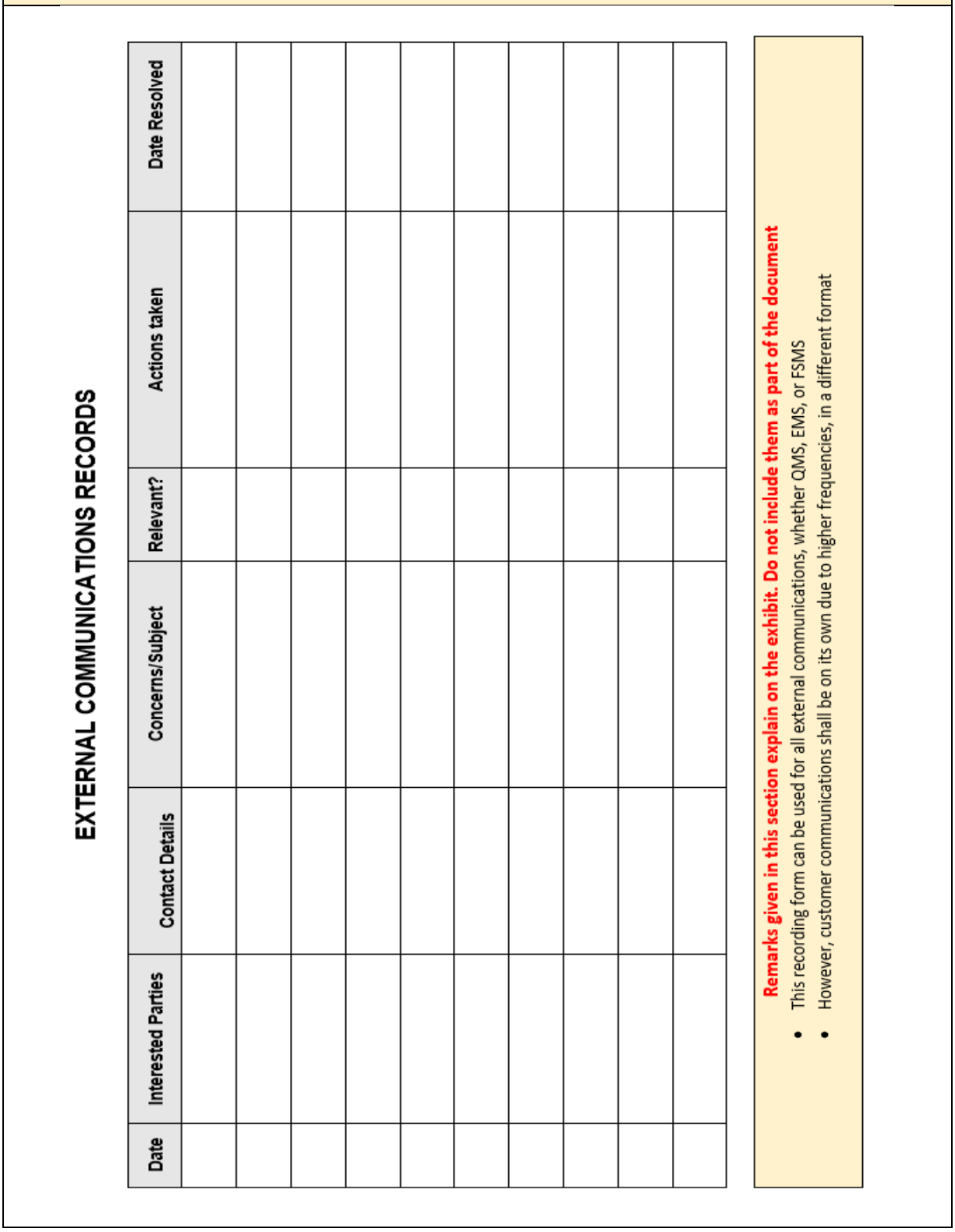
External Communications Procedure

PIC	Flow Diagram	Description
Management Assigned Person Assigned Person	*(A. Outbound Communications)* A1. Issues to Notify External Interested Parties ↓ A2. Decide Method of Communications ↓ A3. Implement the Plan ↓ A4. Handle and deal with Response	Step A1 • Issues arises that external interested parties could be changes env hazards, activities that will cause inconveniences to external parties. Step A2. • Decide Method of communications and prepare for it, 5W1H (What, why, where, when, who and how) Step A3. • Implement the plan actually Step A4, • Handle and deal with response, that could be an acknowledge or hostility or disagreement
Interested party Responsible person Doc Control	*(B. Inbound Communications)* B1. Feedback from External, including Complaints ↓ B2. Investigate & Take Containment Actions ↓ B3. Problem Solving ↓ B4. Maintain Communications till resolution ↓ B5. Update Records	Step B1. • Feedback from external may be product related or on other aspects e.g. environmental • If feedback is complimentary. Thank the party and share with internal departments if appropriate • If complaint or negative issues, pass message to responsible person to handle e.g. EMR Step B2 • Investigate and take containment actions • If valid, the case will be further investigated and permanent actions taken • Promise to keep communication channels open Step B3 • Take corrective actions Step B4 • Maintain communications and provide feedback until resolve Step B5 • Update records

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

- External communications is no longer about waiting for incoming messages. It is also about, probably more so, outgoing communications
- The above provides guidelines on how to conduct internal and external communications

Exhibit 16.3. External Communication Records



EXTERNAL COMMUNICATIONS RECORDS

Date	Interested Parties	Contact Details	Concerns/Subject	Relevant?	Actions taken	Date Resolved

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

- This recording form can be used for all external communications, whether QMS, EMS, or FSMS
- However, customer communications shall be on its own due to higher frequencies, in a different format

>> End of Chapter 16 <<

Chapter 17. Documentation

Content:

0) Introduction

There are several applicable clauses in this chapter. The focus of this chapter is on documentation. It picks up from where we left in Chapter 1. Two other areas are also discussed in this Chapter: a) automotive record retention time, and b) response to customer request on changes to engineering specifications.

1) 7.5.1.1 QMS Documentation (IATF16949))

This is already covered in Chapter 1. Please refer

2) 7.5.2 Creating and Updating (ISO9001)

(Clause Description-Paraphrase)

When creating and updating documented information, the org shall ensure appropriate:

a) Identification and description (title, date, author, or reference no)
b) Format (language, software version, graphics) media (e.g. paper, electronics)
c) Review and approval for suitability and adequacy

(Highlights of the clause)

- (Ref to old Standards) There had been a similar clause 4.2.1. in the previous version.
- In this new version. ISO decides that documentation control can be relaxed.
- You decide what is necessary subject to individual requirements and logic. A) to C) needs a little considerations

(Compliance best practice)

7.5.2 Creating and Updating

1. *ISO9001 now allows for a lot of freedom on documentation. But IATF does not fully subscribe to this relaxation.*
2. *My recommendation is you stick to the old method and provide full documentations. The reasons is you cannot be sure what is acceptable to a customer auditor, sometimes even an IATF auditor.*

3) 7.5.3, 7.5.3.1. Control of Documented Information (ISO9001)

(Clause Description-Paraphrase)

Documented information (Document & Records) required by the QMS and by this international standard shall be controlled to ensure (a) it is available and suitable for use, where and when it is needed, (b) it is adequately protected (from loss of confidentiality, improper use, or loss of integrity).

(Highlights of the clause)

- (Ref to old Standards). There had been a similar clauses, 4.2.3 control of document, in the older version of ISO9001.
- The requirements have been abridge. If a document is required. The requirements (a) and (b) in the clause content.

(Compliance best practice)

7.5.3, 7.5.3.1. Control of Documented Information

1. *So long you have a document created, document creation or revision control shall be applicable.*
2. *IATF Auditor will still examine compliance in this area.*

4) 7.5.3.2 (on record control) (ISO9001)

(Clause Description-Paraphrase)

Control of Documented Information requires to observed the following:

a) distribution, access, retrieval and use
b) storage and preservation, including preservation of legibility
c) control of changes (e.g version control)
d) retention and disposition

Doc info of external origin also needs to be identified and controlled

Doc info retained as evidence conformity will be protected from unintended alterations

(Highlights of the clause)

- (Ref to old Standards). There had been a similar clauses, 4.2.4 control of records, in the older version of ISO9001.
- There are some new elements e.g. 'retain for evidence of conformity need to be protected from unintended alterations'
- The full requirement is a) to d).

(Compliance best practice)

7.5.3.2 (on record control)

1. *So long you have a record, record control shall be applicable.*
2. *Records must be able to retrieve quickly. Some CB give 15 minutes' allowance to find a record; or it is a finding*
3. *IATF auditors tend to check documents and records, the new ones more so. There is no change in this practice and you should not neglect this area*

5) 7.5.3.2.1 Record Retention (IATF16949)

(Clause Description-Paraphrase)
The organization shall define, document and implement a record retention policy. The control of records shall satisfy statutory, regulatory organizational and customer requirements. Production part approvals, tooling records (including maintenance and ownership), product and process design records, Purchase Orders (if applicable), or contracts and amendment shall be retained for length of periods specified by customer. If none, that active years + 1 calendar year shall be followed.

(Highlights of the clause)

- (Ref to old Standards). There is a similar clause, 4.2.4.1 of same title, in the old version of IATF16949.
- The record retention back then was to satisfy statutory, regulatory and customer requirements. Now it expanded to include statutory, regulatory, organizational and customer requirements.
- Automotive record retention in most cases are being practiced but not stated in the ISO9001 or TS16949 standards previously. Now it is stated clearly in 4.2.4.1. It shall be according to customer requirement. Where there is no customer requirement, the formula active years + 1 calendar year shall be used

(Compliance best practice)

7.5.3.2.1 Record Retention

1. *The retention time is generally prepared in a list. See **Exhibit 17-1**.*
2. *However for automotive, customer requirements can be very different, from one to another. So a general list applicable for all, is not possible*
3. *You should provide a supplementary list to the main list**.** See **Exhibit 17-2.***
4. *You can also use the CSR summary as evidence instead of an extra list.*

6) 7.5.3.2.2 Engineering Specifications (IATF16949)

(Clause Description-Paraphrase)
The organization shall have a documented process describing the review, distribution and implementation of all customer engineering standards/specifications and related revisions based on customer-required schedule, as required.

When an engineering standard/specification change results in a product design change, refer to the requirement in iSO9001 clause 8.3.6. If the change affect production, refer to 8.5.6.1. Organization shall retain a record of the date implemented in production. Implementation shall include updated documents.

Review should be completed within 10 working days of receipt of notification of engineering standards/specification changes.

NOTE. A change in these standards/specifications may require an updated record of customer production part approval when these specifications are referenced on the design record or if they affect documents of production part approval process, such as control plan, risk analysis (such as FMEAs) etc.

(Highlights of the clause)

- There was a similar clause (4.2.3.1) in the older version of IATF16949. The only real change is from 2 weeks to 10 working days.
- So basically it means the same, but more precise. You get 1 extra day if a public holiday falls in between.
- This clause also appears under Product and Process Design, as it is very relevant in the act areas.

(Compliance best practice)

7.5.3.2.2 Engineering Specifications

1. *For compliance of this clause, you need to have a documented process on management of customer engineering standards/specifications.*
2. *The documented process can be anything suitable for your system. It may be a standalone flowchart, or park inside QM, Compliance Matrix, Doc Control, APQP Procedure, PPAP Procedure, ECN Procedure, or the Design and Development Procedure etc.*

7) SIs & FAQs

No SIs & FAQs for this Chapter

8) 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	**SN17.1. Why the sudden relaxation on documentation?**
7.5.1.1	CBP	**SN17.2. What are the hierarchy now. with R&O, IPNE, process map and turtle diagram?**
7.5.1.1	CBP	**SN17.3.Why can't we use the new method of very few documents?**
7.5.2	CBP	**SN17.4. What are the common problem with document creation?**
7.5.3.2	CBP	**SN17.5. Can we really dispose the records, after the period retention period?**
7.5.3.2.2	CBP	**SN17.6. What is the different of 14 days previously and 10 working days now?**
7.5.3.2.2	CBP	**SN17.7. On the above question, does it mean we have to complete the engineering specs change within 10 working days?**

SN17.1. Why the sudden relaxation on documentation?

I read an ISO 9001 book that says with computerization, the difference between document and records are blurring. And often it is 2 in 1 application, when you input some data to a form and it becomes a record. There is also good filing systems in computer programs, with search capabilities. The classification of document and record is getting meaningless I personally think that after 30 years of ISO indoctrination on documentation control, practitioners have master this area, and controls can be relaxed.

SN17.2. What should be the documentation hierarchy now, with the introduction of R&O, IPNE, process maps and turtle diagrams etc.?

I had always thought that Policy should come before everything else. It should sit right on top. And I was pleased to note that ISO22163 Railway QMS share the same thought. Policy and Objectives can be Level 1, R&O and IPNE should be at Level 2, QM (and Compliance Matrix if available) at Level 3, Procedures, Process Maps and Turtle Diagrams at Level 4, WI at level 5, and Standardized Forms and Formats, Records at Level 6. But this is just a personal opinion. There is no right and no wrong here. You can decide the levels you want.

SN17.3.Why can't we use the new method of very few documents?

You will end up with a lot of argument with your customers, and sometimes IATF auditors. Some of them prefer written information to serve as good starting points for discussion. They kind of lose the handle with just a few document here and there, and need to work much harder and longer to complete the audit.

SN17.4. What are the common problem with document creation?

a) Request for document change not obtained before implementation. This is done in a hurry, documentation is forgotten after that

b) approval by the wrong authority. QM is normally to be approved by Top Management, but often QMR is found to approve it

c) HOD amends procedures without regards to interface, and can affect the integrity of the QMS. This is caused by no mandatory review by the QMR before approval by Management.

SN17.5. Can we really dispose the records, after the period retention period?

Not advisable. Customers sometimes still come back to request for service parts, even after the retention period is over. And they expect suppliers to assist. And they still have new business to award.

SN17.6. What is the different of 14 days previously and 10 working days now, for engineering specifications response?

I think it was meant to be the same. If Saturday and Sundays are taken off, 14 days is 10 working days. However, it there are public holidays within the period, 10 working days work out to be longer in terms of calendar days. But it does not make an significant differences in reality.

SN17.7. On the above question, does it mean we have to complete the engineering specs change within 10 working days?

No. It means you need to study the request and clarify what is required and get ready to implement. Implementation duration depends on the nature of the request and hard to generalize.

9) Exhibits

Exhibit 17-1. Record Retention

A: General List on Record Retention

No.	Document/Records	Period to Keep, Min	Filing Station
1	Quality Manual	Current + 1 back copy	Doc Controller
2	Quality Procedures	Current + 1 back copy	Doc Controller
3	Work Instructions	Current + 1 back copy	• One copy with Doc Control • Control copies near each relevant work station
4	Quality Forms Masters	Current + 1 back copy	QMS Master Form File
5	Quality Policy	Current + 1 back copy	• Posted up in strategic locations in company • One copy with Doc Control
6	Quality Objectives	Current + 3 back copy	• Posted up in strategic locations in company • One copy Doc Control
7	Document Change Request	1 year	Doc Controller
8	Document Change History	1 Year	Doc Controller
9	Record Disposal Forms	1 Year	Doc Controller
10	NCR Records	1 Year	Doc Controller
11	NCR Log	1 Year	Doc Controller
12	Internal Audit Schedule	1 Year	Doc Controller
13	Internal Audit Reports with Checklists and IA-CAR	3 Years	Doc Controller
14	Management Review, Notice and reports and CAR	5 Years	Doc Controller
16	Vendor Information	5 Years	Purchasing Department
17	Vendor Evaluation Form	5 Years	Purchasing Department
18	Approved Vendor List	Current + 1 back copy	Purchasing Department
19	Measuring Equipment Master List	5 Years	QC Department
20	Calibration Records	5 Years	QC Department
21	Orientation Briefing	Employment Period	HR Department
22	Performance Appraisal Forms	Employment Period	HR Department
23	Personal Training Record	Employment Period	HR Department
24	Training Attendance	5 Years	HR Department
25	QMS Monthly Reports,	5 Years	Doc Control
26	Maintenance Schedule	6 months	Maintenance
27	Maintenance Records	6 Months	Maintenance
28	Tooling records	Until tooling replaced	Tooling
29	Customer complaint records	1 Year	QA
30	Customer Satisfaction Survey, with summary	3 Years	Business Development
31	Drawings	Through Active years	R&D
32	Other process and product control records	3 years	Production Department

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

- This list applies commonly to all types of records, except where stated otherwise as CSR
- CSR of automotive customers are normally given in another list. See exhibit 17-2.

Exhibit 17-2. Record Retention - Automotive supplement

QMS Records Retention Periods
Automotive Supplemental

Important:

- Retention period is per customer requirement
- If not specified, it follows the automotive general requirement of (Active years + 1 year)
- Applicable documents usually include PPAP type documents, tooling records, maintenance, design records, contracts and amendments

Customer A. (Automotive)

No	Record Type	Retention Period
1	PPAP package, Tooling buy off records	Active + 1 calendar year
2	Tooling maintenance records	Entire tooling life

Customer B. (Automotive)

No	Record Type	Retention Period
1	PPAP, tooling records, product…	30 years

Customer C. (Automotive)

No	Record Type	Retention Period
1	Normal QC records	3 years
2	PPAP related	8 years

Customer D. (Automotive)

No	Record Type	Retention Period
1	PPAP records	Active + 6 years
2	Other quality records	3 years

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

- This list shows the CSR on record retention of automotive customers. It is given as a separate list, because if it combines with the general list, it will be very confusing
- If you have done a CSR summary for each customer, and the record retention time is given there, this list is not necessary.

>> End of Chapter 17 <<

Chapter 18. RFQ Handling, Order Processing, Production Planning and Scheduling

Contents:

0) Introduction

There are several closely-related clauses in this chapter. It concerns activities of planning for a customer P/O, arrangements for production, and ensuring delivery on time. There are some new requirements on planning; and some parts of order review need re-visiting to avoid problem.

1) 8.2.3, 8.2.3.1 Review the requirement of products and services (ISO9001)

(Clause Description-Paraphrase)

The organization shall ensure that it has the ability to meet the requirements for products and services to be offered to customers. The organization shall conduct a review before committing to supply products and services to a customer, to include: (a) requirements specified by the customer, (b) requirements not stated by the customer, but necessary for the specified or intended use, (c) requirements specified by the organization; (d) statutory and regulatory requirements, (e) contract or order requirements differing from those previously expressed.

Contract or order requirements when differ from those previously defined must be resolved. When customer does not provide a documented statement of their requirements, the contract shall still be confirmed.

NOTE. In situations, such as internet sales, a formal review is impractical for each order, an alternative method e.g checking against catalogues can be used.

(Highlights of the clause)

- (Ref to old Standards) There was a similar clause 7.2.2 Review of requirements related to the product, in the previous version. The requirement is expanded somewhat in the new version.
- A very important point to retain records for the review seems to be omitted in the new version, but not true. It is now mentioned as a new clause 8.2.3.2.
- A general rule is an order needs to be confirmed by organization before acceptance.
- In ISO9001 context, sometimes not possible to use another method when it is not feasible, e.g. in note the internet's sales case. This unique situation does not exist in automotive and therefore would not be discussed here
- A disappointing point is it did not specifically mention considerations of technical and capacity and costing in the review. These are only found in clauses 8.2.3.1.3 and 8.3.3.2, which may give the impression that they are only needed only when the bid is won.

(Compliance Best Practice)

8.2.3, 8.2.3.1 Review the requirement of products and services

1. *There are 2 occasions for contract review: a) when invited to bid or submit quotations, b) when processing repeat orders.*
   RFQ:
2. *For RFQ situations, It means you have to comb through the RFQ & input from the potential customer e.g. drawings, technical specs and their fine prints and 'note items', quantiies, standards to follow, materials and nominated suppliers, packaging, delivery method etc.*
3. *There will be problem if you miss out on some crucial points. Bear in mind, that in some countries, submitting a quotation is a commitment to supply, at the terms specified. And there are legal implications for default.*
4. *Submission on requested date is also important, as it is a customer requirement on its own. IATF auditor will check on this point too.*
   Repeat Orders:
5. *In most repeat order cases seen, there is generally very little emphasis on contract review. Compliance is claimed that orders are checked, but no record. A note, initial or a stamp by PIC on regular orders would be better, than relying on inference or logic.*
   Feasibility Study Format
6. *For RFQ, a simplified feasibility can be used to save time. See* ***Exhibit 18.1.*** *But you can also use the AIAG Team Feasibility Commitment form. See* ***Exhibit 22-1.***
7. *Capacity study is now a mandatory item and another document may be required See* ***Exhibit 22-2.***
8. *Costing is generally done on the format of the organization. You can use standard costing method, or real-time costing based on current prices. This is confidential and IATF auditor should respect if you only show the format and not the actual data.*
9. *If there is a target price given by customer, IATF auditors would want to see how this has been taken into account, during the costing.*

2) 8.2.3.1.1 Review of the requirements for products and services – supplemental (IATF16949)

(Clause Description-Paraphrase)

If contract review is not done for IATF, documented evidence of waiver from customer is required.

(Highlights of the clause)

- There was a clause 7.2.2.1. Review of the requirements for products– supplemental, in the previous ISO/TS16949.
- There is some re-phrasing of the requirement, but essentially there is no change in the content
- Waiver of review needs documented evidence, or it will be a finding.

(Compliance best practice)

8.2.3.1.1 Review of the requirements for products and services – supplemental

1. *If you are not going to conduct a Contract Review in a RFQ situation, you need a written waiver from the customer, otherwise it is a finding*
2. *Same thing about contract review on repeat orders, review is needed.*

(**3) 8.5.1.7 Production Scheduling (IATF16949)**

(Clause Description-Paraphrase) The organization shall ensure that production is scheduled in order to meet customer orders/ demands such as Just-In-Time (JIT) and is supported by an information system

that permits access to production information at key stages of the process and is order driven. The organization shall include relevant planning information during production scheduling, e.g., customer orders, supplier on-time delivery performance, capacity, shared loading (multi-part station), lead time, inventory level, preventive maintenance, and calibration.

(Highlights of the clause)

- (Ref to old Standards). There had been a similar clauses, 7.5.1.6 Production Scheduling, in the previous version of ISO/TS16949. There are a lot more requirements added.
- Planning now must show the basis of planning with a lot data, and not only a copy of the customer P/O from sales or order desk
- Such information are: customer orders, supplier on-time delivery performance, capacity, shared loading (multi-part station), lead time, inventory level, preventive maintenance, and calibration.

(Highlights of the clause)

8.5.1.7 Production Scheduling

1. *The new version requires extra data and information to be available within reach of the planner. Some may be available in the ERP system, but not all.*
2. *You need to make some arrangement for the data/info are verifiable within reach of the planner. Example: inventory can be from a public folder, and tooling information from real-time confirmation from the toolroom. It will be even better if you can include a verification record of these data, in hardcopy or e-copy..*

4) 8.2.4 Changes to requirements for products and services (ISO9001)

This has been addressed in Chapter 12. Please Refer.

5) SIs & FAQs

No SIs & FAQs for this Chapter

6) Supplementary Notes

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

Clause	Section	Clarification Subjects
8.2.3, 8.2.3.1 8.2.3.1. 1	CBP	**SN18.1. If the submission date is not given by customer, or stated as ASAP, what target should I use?**
8.2.3, 8.2.3.1	CBP	**SN18.2. Must costing be exact or an estimate?**
8.2.3, 8.2.3.1	CBP	**SN18.3. Must the target price given by customer be complied?**
8.2.3, 8.2.3.1	CBP	**SN-18.4. When the enquiries are a lot, and average success rate is low (say only 20%), it is not worth running detail capacity studies for all enquiries. Is it OK we selectively conduct capacity studies?**
8.2.3, 8.2.3.1	CBP	**SN18.5. If I use organizational manufacturing feasibility for quotation purpose, does it mean I don't have to repeat it during PPAP preparation?**
8.5.1.7	CBP	**SN18.6. Can production planner and order processer be the same person?**

8.5.1.7	CBP	**SN18.7. Is there a better way to have to ensure tooling availability on time?**

SN18.1. If the submission date is not given by customer, or stated as ASAP, what target date should I use?

You should follow your own internal standard, such as 1 week. And you strive to meet that date.

SN18.2. Must costing be exact or an estimate?

Costing must be real, not an estimate. You can use standard costing to save time. Standard costing is a set of costing the organization adopts for quotation purposes, which normally has a safe margin included. Or you may use real-time costing basing on latest prices.

SN18.3. Must the target price given by customer be complied?

No, that's why it is called a target price. If you can meet, the chances of winning the bid is higher. However, the real costing is also important to set prices. There is no point in winning a business, when you are not making a profit, or worse, incurring losses.

SN18.4. When the enquiries are a lot, and average success rate is low (say only 20%), it is not worth running detail capacity studies for all enquiries. Is it OK we selectively conduct capacity studies?

Organizations dealing with near-commodity parts do have this tendency. To be practical, you should be allowed to conduct capacity studies selectively. For major clients, with substantial quantities for the RFQ, capacity study is required. For small enquiries, or where enquiries are for budgeting exercise, or for quotation shoppers, detail capacity calculation is really not worthwhile. Monthly reports on available capacity should still be used to make rough decisions.

SN18.5. If I use organizational manufacturing feasibility for quotation purpose, does it mean I don't have to repeat it during PPAP preparation?

No, the two have slightly different purpose. During RFQ, the feasibility study can be less exact because the order is not confirmed yet. Sometimes the product specs are also subject to change. That's why you need not be so exact. For feasibility study during PPAP, you already have the order in hand, and you need to be very firm on what is and what is not. Moreover, the feasibility study during RFQ and PPAP stages can be 2-3 years apart, and changes would have occurred. You should re-do the feasibility study even if not asked, for risk management.

SN18.6. Can production planner and order processer be the same person?

This is quite a common practice. One person handles the entire process from order arrival to shipment. It is in fact preferred, as hand-changings are omitted. Hand-changing is a point where miscommunication can occur, and things can go wrong.

SN18.7. Is there a better way to have to ensure tooling availability on time?

It is common to share the production plan well ahead with the toolroom, say a month ahead. Maintenance head can then plan the maintenance in step with the demand. In most situation, maintenance is short-handed. This kind of forward planning can be very useful to ensure tooling availability, on time and cost-efficiently.

7) Exhibits

Exhibit 18-1. Simple Contract Review

Contract Review for RFQ

(Only the circled functions need to comment)

No	Function	Representative Name	Position	Recommendation			Remarks	Signature
				OK	OK-some caution	Not Recommended		
1	Marketing							
2	Engineering/ R&D							
3.	Purchasing							
4	QA							
5	Production							

Recommendation to Top Management:
Proceed/ Hold & Resolve Issues/ Decline

Review Leader

Top Management Decision
Proceed/ Hold & Resolve Issues/ Decline

Management Sign/Date)

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

- This is a simpler type of review for RFQ. Organization can elect to use the Team Feasibility Commitment form from AIAG
- This type of review is simpler, faster and particularly suitable for some type of business, where enquiries are a lot, but chances of turning into orders are low. This simpler review will relieve some strain on resources

>> End of Chapter 18 <<

Chapter 19. Product, Service, Statutory & Regulatory Requirements

Contents:

0) Introduction

There are several applicable clauses in this chapter. The chapter focuses on customer requirements, which also include statutory and regulatory requirements. Three clauses (8.1.2, 8.5.5, 8.5.5.2) that had received low attention are now added to this chapter for discussion. This area has many FAQ and SI and therefore some emphasis is due.

1) 8.2.2 Determining the requirement of products and services (ISO9001)

(Clause Description-Paraphrase)

When determining the requirements for the products and services to be offered to customers, the organization shall ensure that:

a) the requirements for the products and services are defined, including:
   1) any applicable statutory and regulatory requirements;
   2) those considered necessary by the organization;

b) the organization can meet the claims for the products and services it offers.

(Highlights of the clause)

- (Ref to old Standards). There had been a similar clause, 7.2.1 Determining the requirement related to the products, in the old version of ISO9018.
- Previous requirement for post-delivery activities are covered by Clause 8.5.5 of the new standard, and not exempted.
- Apart from that, there is no change to the requirement.
- Full requirement is given in a) to b) of clause description.

(Compliance best practice)

8.2.2 Determining the requirement of products and services

1. *In the ISO9001 context, products may not be made to a particular customer's specifications, but for general market offering. Hence this clause has a special significance, as the organization must decide what will appeal to the customers out there.*
2. *The requirements are identified by many ways, e.g. by assumption, by market survey, by R&D etc.*

3. *The output of this determination becomes the input or starting point for design and development.*
4. *In IATF' cases, customers are known and specs are generally provided or agreed on. Relevant functions are represented in the Core Team to manage the product and manufacturing process design. The requirements are then summarized in the form of Design Objectives or PPAP list. See Chapter 22, design & development, for details.*

2) 8.2.2.1 Determining the requirements for products and services – supplemental (IATF16949)

(Clause Description-Paraphrase)

These requirements shall include recycling, environmental impact, and characteristics identified as a result of the organization's knowledge of the product and manufacturing processes. Compliance to ISO 9001, Section 8.2.2 item (a)1, shall include but not be limited to the following: all applicable government, safety, and environmental regulations related to acquisition, storage, handling, recycling, elimination, or disposal of material.

(Highlights of the clause)

- (Ref to old Standards). There is a new clause, formed from the NOTES of the old 7.2.1.
- Compliance include all applicable government, safety, and environmental regulations related to acquisition, storage, handling, recycling, elimination, or disposal of material.

(Compliance best practice)

8.2.2.1 Determining the requirements for products and services – supplemental

1. *After the design, organization shall ensure other requirements stated above i.e. legal requirements on recycling, environmental impact, and characteristics determined by the organization have been included, where applicable.*
2. *Double-check before handling over the requirement list to Design department, as an error can result in a lot of inconveniences later.*

3) 8.4.2.2 Statutory and regulatory requirements (IATF16949)

(Clause Description-Paraphrase)

The organization shall document their process to ensure that purchased products, processes, and services conform to the current applicable statutory and regulatory requirements in the country of receipt, the country of shipment, and the customer-identified country of destination, if provided. If the customer defines special controls for certain products with statutory and regulatory requirements, the organization shall ensure they are implemented and maintained as defined, including at suppliers' place.

(Highlights of the clause)

- (Ref to old Standards) There used to be a clause, 7.4.1.1 Statutory and regulatory conformity in the older version of ISO/TS16949. The old requirements are retained, with some addition.
- Now the clause included the statutory and regulatory requirement of country of receipt, country of shipment, and country of shipment.
- If customer specify special controls for statutory and regulatory requirements, they shall be complied

(Compliance best practice)

8.4.2.2 Statutory and regulatory requirements

1. *On the last paragraph of the clause description, statutory and regulatory controls on products must be complied, and ensured the requirements are cascaded down the supply chain. More information on how to achieve this is given in Chapter 24.*
2. *The part on statutory and regulatory controls in other countries need some discussions, as it is new. First the definitions of the various types of countries:*
    a. *country of receipt: is the country of manufacturing site, where your organization is located*
    b. *country of shipment: the country of receiving*
    c. *country of destination: where the product are finally sold or used*

    (Author: definitions of a. and b. above seem to be mixed up)
4. *To each of the countries above, you need to understand the statutory and regulatory requirements. concerning the products, application, logistics etc. This kind of information is normally provided by the customers. Your first action should be to request for them*
5. *For country of destination, it is only required if specified by the customer, and provided by the customer. If they don't, you are exempted. See FAQ-24*
6. *Irrespective of the sources (either from customer or by organization), the information shall be recorded as evidence. See* ***Exhibit 19-1***

4) 4.3.2 Customer-specific requirement (IATF16949)

This has been covered in Chapter 6, CSR and will not be repeated here.

5) 8.1.2 Confidentiality (IATF16949)

(Clause Description-Paraphrase)

The organization shall ensure the confidentiality of customer-contracted products and projects under development, including related product information.

(Highlights of the clause)

- (Ref to old Standards).There was a similar clause 7.1.4 Confidentiality in the previous ISO/TS16949 version:
- It is largely a word-for-word reproduction. Hence no change in requirement.
- Full requirement please refer to the clause description

(Compliance best practice)

8.1.2 Confidentiality

1. *You are just required to understand the intent and comply. There is generally no need to produce any documentation.*
2. *IATF Auditors will have an impression how you control confidentiality the moment they enter your premises. It is best not to skip the procedure for registering them as visitors. Issued a gate-pass or visitor tag for wearing, if this is the norm.*
3. *Another point they may ask is the control of visitation to the production, inspection and design areas. Displaying a sign of entry restriction will be helpful, although not mandatory.*
4. *Next and more importantly is the control of customer information such as drawing and technical specs. You need to show how this confidential information are being protected against unauthorized leakage. Data access by password for authorized personnel and*

levels are expected. Limiting file size so that drawings cannot be sent out, and control usage of USB copying of files are good practice.

5. *You may need to negotiate with customers on the extend you are prepared to abide. Some evidences of approval from customer are required if IATF auditor feels the controls seem to be inadequate.*

6) 8.5.5 Post-delivery activities (ISO9001)

(Requirement-paraphrase)

The organization shall meet requirements for post-delivery activities associated with the products and services. In determining the extent of post-delivery activities that are required, the organization shall consider:

a) statutory and regulatory requirements;
b) the potential undesired consequences associated with its products and services;
c) the nature, use and intended lifetime of its products and services;
d) customer requirements;
e) customer feedback.

NOTE Post-delivery activities can include actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.

(Highlights of the clause)

- (Ref to old Standards). No specific clause in the previous ISO9001. But mentioned in 7.2.1, 7.5.1
- To determine requirements for post-delivery, a list is given as guide, see a) to e) of the clause description. Examples of post-delivery services are given in the NOTE

(Compliance best practice)

8.5.5 Post-delivery activities

1. *There is a tendency for organization to declare there is no requirement on this, because it saves the hassles to prove compliance. But IATF auditors roughly would know what product lines or operations will have post-delivery activities, and you may be asked to justify.*
2. *There is the list given by Clause Description, a) to e) for you to check. It may be a good idea to design a form to record your evidences, based on this list. See* ***Exhibit 19-2.***

7) 8.5.5.2 Service Agreement with Customer (IATF16949)

(Clause Description-Paraphrase)

When there is a service agreement with the customer, the organization shall:
a) verify that the relevant service centres comply with applicable requirements;
b) verify the effectiveness of any special purpose tools or measurement equipment;
c) ensure that all service personnel are trained in applicable requirements.

(Highlights of the clause)

- (Ref to old Standards). There used to be a clause 7.5.1.8 of the same title in the old version of ISO/TS16949.
- There is no change in content, but reworded for clarify only

- This area concerns requirements on service centers. This is applicable only if a service agreement exist.
- The full requirements are given in the clause description.

(Compliance best practice)

8.5.5.2 Service Agreement with Customer

1. *In most cases, this is not applicable. Applicable situations may be: a) service contract signed between an OEM with a fleet owner, b) certain proprietary supplies that needs onsite support, that an onsite service centre is needed.*
2. *As the external provider, you need to ensure the service centres are well equipped for the role. Internal and IATF auditors will audit these centres as remote locations.*
3. *Procedures are recommended to define practices, controls and monitoring. Internal audits can also use the procedure to check for compliances*

8) 8.6.5.Statutory and regulatory conformity

This is discussed in detail at Chapter 30. Please refer.

9) SIs & FAQs

SI No	IATF Clause	Description
1	**3.1 Terms and definitions for the automotive industry**	**customer requirements** all requirements specified by the customer (e.g., technical, commercial, product and manufacturing process-related requirements, general terms and conditions, customer-specific requirements, etc.) **Where the audited organization is a vehicle manufacturer, vehicle manufacturer subsidiary, or joint venture with a vehicle manufacturer, the relevant customer is specified by the vehicle manufacturer, their subsidiaries, or joint ventures.** ***Rationale for change:*** *Customer requirements are developed by vehicle manufacturers for application in their supply chain by the nature of the product realization process. Therefore, where the vehicle manufacturers are being certified, the vehicle manufactures define how customer approvals and/or input are managed.*

FAQ IATF	Clause	Questions and Answers
9	**8.4.2.2 Statutory and regulatory requirements and 8.6.5 Statutory and regulatory conformity**	**QUESTION 1:** **What is the perspective (on statutory and regulatory conformity)? What is considered sufficient evidence of conformity to applicable statutory and regulatory requirements (8.6.5)?** **ANSWER 1:** As defined in 8.3.3.1 g) and 8.3.4.2, the organization is required to have an approach to research, identify, obtain copies of, review, understand, and assure compliance with the statutory and regulatory requirements for the product they are manufacturing in the country where they are manufacturing products and the destination country where they are shipping the products to.

9 (cont.)	**8.4.2.2 Statutory and regulatory requirements (cont.)** **and** **8.6.5 Statutory and regulatory conformity (cont.)**	The intent of 8.4.2.2 is that the organization designs into their product development methodology/business process(es) and their supplier management methodologies/business process(es), one or more approaches for obtaining confirmation and evidence from their suppliers that the products and services being provided by the supplier comply with the statutory and regulatory requirements of the country where the supplier is manufacturing them, the country where the organization is using them, and the country where the organization ships their product to, if provided by the customer. The intent of 8.6.5 is to require the organization to check the records of conformance/compliance received from the supplier to assure that the lot code, batch number, or comparable traceability information for the product are covered by the evidence provided by the supplier. This could be done upon receipt from the supplier, or while the product is in inventory, but must be done prior to release of the product into the organization's production flow. **QUESTION 2:** **Did the intent of clause 8.4.2.2 change from ISO/TS 16949 to IATF 16949?** **ANSWER 2:** The intent of the clause did not change. The ISO/TS 16949 requirement was "All purchased product shall conform to applicable statutory and regulatory requirements". In this "passive voice" wording, the IATF decided their expectations were not clear. The new requirement is more explicit about what is to be done, when it is to be done, and what evidence is required to support compliance.

FAQ	IATF Clause	Questions and Answers
24	**8.4.2.2 Statutory and regulatory requirements**	**QUESTION 1:** **If the organization is not responsible for product design and is therefore only manufacturing products as per the customer´s design, is the organization then exempt from the requirements in 8.4.2.2?** **ANSWER:** No, all organizations regardless of their responsibility for product design must satisfy the applicable requirements of 8.4.2.2. The applicable requirements address purchased products, processes, and services for which the organization is responsible.
24 (cont.)	**8.4.2.2 Statutory and regulatory requirements (cont.)**	**QUESTION 4:** **What level of detail should be provided by the customer regarding the countries of destination? Would a generic statement like "every country globally" be an appropriate response?** **ANSWER:** No, a generic statement such as "every country globally" is not acceptable. The customer is expected to provide to the organization a specific list of countries where the vehicle(s) are initially sold. **QUESTION 5:** **Applicable statutory and regulatory requirements are often linked to the relevant use of a product. Some parts might become a safety-related product, depending on its use. Based on the before mentioned statement, is the customer required to provide the organization with detailed information about the intended use?** **ANSWER:** It is expected that the customer will provide to the organization information of the characteristics that are relevant for the identification of required controls to meet applicable statutory and regulatory requirements (e.g. special characteristics).

24 (cont.)	**8.4.2.2 Statutory and regulatory requirements (cont.)**	**QUESTION 2:** **Is the organization required to request a complete list of countries of destination from the customer if the list was not provided by the customer?** **ANSWER:** Yes, the organization is required to request a complete list of the countries of destination from the customer if the list was not provided by the customer. NOTE: ○ The "country of receipt" is where the organization is located. (Country of the manufacturing site) ○ The "country of shipment" is the customer's receiving location. (Country where the manufacturing site ships to) ○ The "country of destination" is the country where the vehicle is sold. (Country where the final product is initially sold) **QUESTION 3:** **What is the consequence if the customer does not provide the information on the countries of destination to the organization? What is the organization required to document in this situation?** **ANSWER:** If the organization claims that the customer did not provide the necessary information on the countries of destination, the organization should be able to produce written evidence (e.g. letters, emails, meeting minutes, etc.) of their efforts to obtain it.

10) Supplementary Notes

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

Clause	Section	Clarification Subjects
8.4.2.2	CBP	**SN19-1. If we just ship to our HQ or associated companies, do we have to deal with export legal requirements, i.e. for the 3 types of countries?**
8.4.2.2	CBP	**SN19-2. In the case of supply to a customer in the same country of our location, but finally exported; do we need to deal with statutory and regulatory requirements of the countries they export?**
8.4.2.2	CBP	**SN19-3. Customer should assist tor provide the information. To what level should they assist?**
8.1.2	CBP	**SN19-4. What kind of evidences to show we are controlling on confidentiality**
8.5.5.2	CBP	**SN19-5. What kind of evidences we need to show we do not have service agreement with any customers?**

SN19-1. If we just ship to our HQ or associated companies, do we have to deal with export legal requirements, i.e. for the 3 types of countries?

Yes. You have to. But you can count on their cooperation. If your contacts in HQ or associated companies are commercial people, there might be some protracted communications to be done. But eventually you will have it resolved.

SN19-2. In the case of supply to a customer in the same country of our location, but finally exported; do we need to deal with statutory and regulatory requirements of the countries they export to?

No, unlikely. They should be doing it as they are likely to be exporting other items to the same associated companies already. However, they may need your input for items they are not familiar with, e.g. in the case of accessories. You should assist in such cases.

SN19-3. Customer should assist to provide the information. To what level should they assist?

The customer should be familiar because they either operate in the those countries or work closely with the resident associates there. But it is your final responsibility to access such information. For country of destination, you should wait for the list from the customer. If there is no list coming forth, request for it. If there is no response, you responsibility stops there, (see FAQ-24) but keep the communications as evidence.

SN19-4. What kind of evidences to show we are controlling on confidentiality?

Such requirements can be found either in the SQM or purchase contracts. Your evidence of compliance is the records of your compliance activities. If it is signages required at the production or at the design office, make sure you have them. If it is email control e.g. max 10 GB limits, show the relevant evidence.

SN19-5. What kind of evidences we need to show that we do not have service agreement with any customers?

You just inform the auditor directly. If he/she wants to verify, he may request to see the purchase contracts. He may even check your measuring equipment master list to spot equipment based outside the main sites.

Exhibit 19-1. Statutory and Regulatory Requirements for Export

Statutory and Regulatory Requirements (Export)

No	Customer	Parts if applicable	Countries (indicate yes/no applicable)			S&R Handled by (Cust/Org)	Applicable laws
			Receipt	Shipment	Destination		
1	ABC	1000345CRQ	No	No	No	NA	NA
2	PQR	TWR-40 series	No	Yes	No	Organization	Destination. Japan: Special warning label on motor component
3	XYZ	M-335PP Series	Yes	Yes	Yes	Organization	Shipment: Japan. Green procurement Destination: EU. RoHS & Reach

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

- This is a quick summary of compliance to applicable statutory and regulatory requirements for exported products.
- If the compliance is handled fully by customer, then you don't have to worry too much. You just build to customer requirement.
- If customers disclose their destination and need you to comply to laws of the exported countries, then you cannot escape responsibility.
- This chart is useful to all relevant departments in the organization e.g. process engineering, purchasing, production and QC.
- If exact statutes or regulations can be stated, it is even better, although not mandatory

Exhibit 19-2. Post-Delivery Activities Determination

Post-Delivery Activities Determination

Business Line: aircon compressors

Criteria	Actual	Provision
Any statutory requirement in our products, including disposal?	No special requirement, except normal disposal regulations. This will be handled by the last point of service, the OEM service centres, or private service centres.	None
Potential undesired consequences associate with the product	No negative consequences conceivable.	None
Nature, use and intended lifetime of its products and services	No unusual hazards or inconveniences expected	None
Customer requirement for post delivery services	Performance Warranty as requested by Customers. No of years varies.	Compensation to abide by agreement. For management of individual claim cases, follow customer-specified method of handling.
Customer feedback that indicate post-delivery care is needed	Organization very familiar with this business, having been in it for 25 years. Nothing new has been introduced that we are not aware of.	None
Corporate strategy and policy in this area	To work with OEM customer as a team to service their final customer/consumer.	Case to case

Studied by: Approved by:

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

- This is a new requirement and quite a tough one to comply. Always try the customer for help first. They should be quite well familiar with it
- If you are not getting input from customer, you have to do the research yourself. This is a requirement of the standard

>> End of Chapter 19 <<

Chapter 20. Special Characteristics

Contents:

0) Introduction

There are only two closely-related clauses in this chapter. The reason why a whole chapter is devoted to there are generally not well understood and/or catered for. Some explanations and pointers are in order. Many NCs have been written on this clause alone.

1) 8.2.3.1.2 Customer-designated special characteristics (IATF16949)

(Requirement-paraphrase)

The organization shall conform to customer requirements for designation, approval documentation, and control of special characteristics.

*(*Highlights of the clause)

- (Ref to old Standards). There had been a clause 7.2.1.1 of the same title in the older standard of ISO/TS16949.
- There is no change in requirement, except a word 'approval' is added before documentation. See clause description.
- In general, customer requirements on use of special characteristics shall be complied

(Compliance best practice)

8.2.3.1.2 Customer-designated special characteristics

1. *To comply with this clause, the symbols shall be reflected in all process documents e.g. drawings, FMEA, Control Plan, Inspection Plan, WI and relevant work stations, where applicable.*
2. *For use of harmonized approach on SC identification, please refer to 8.3.3.3 below*

2) 8.3.3.3 Special Characteristics (IATF16949)

(Requirement-paraphrase)

The organization shall use a multidisciplinary approach to establish, document, and implement its process(es) to identify special characteristics, including those determined by the customer and the risk analysis performed by the organization, and shall include the following:

a) documentation of all special characteristics in the product and/or manufacturing documents the drawings (as required), risk analysis (such as FMEA), control plans, and standardised work/operator instructions; special characteristics are identified with specific markings and are documented in the manufacturing documents which show the creation of, and controls required, for these special characteristics

b) development of control and monitoring strategies for special characteristics of products and products and production processes;
c) customer-specified approvals, when required;
d) compliance with customer-specified definitions and symbols or the organization's equivalent symbols or notations, as defined in a symbol conversion table. The symbol conversion table shall be submitted to the customer, if required.

(Highlights of the clause)

- (Ref to old Standards). There had been a clause, 7.3.2.3 of the same title, in the old version of ISO/TS1694
- The previous requirements are retained in the new clause. Additional requirements are multidisciplinary approach to establish, document and implement the Special characteristics management process
- Special characteristics and the specific markings, may be provided by customer, or derived by the organization itself, from risk analysis etc.
- A harmonious approach to listing of SC is now allowed, with customer approvals
- The total requirements are given in a) to d) of the clause description

(Compliance best practice)

8.3.3.3 Special Characteristics

1. *To comply with this clause, SC have to be seen as special markings on FMEA, and cascaded down to control plan, inspection report and WI as applicable. You need to use the SC correctly on these process documents. I have often seen the 'class' column on process documents are wrongly used. See* ***Exhibit 20-1.***
2. *SC Indication on the work stations no longer is a must, as the work stations may not be dedicated. A press can be producing parts for many customers and for various industries, Indication on WI and/or inspection sheets should suffice.*
3. *You may want to make use of the harmonized approach permitted in this new standard. With this method. It will make things neater and easy to comply with.*
4. *When using this harmonized, or equivalent method, a conversion table shall be prepared, and submitted to customer, if applicable. See* ***Exhibit 20-2.***

3) SIs & FAQs

SI Nbr	IATF Clause	Description
6	**8.3.3.3 Special characteristics**	The organization shall use a multidisciplinary approach to establish, document, and implement its process(es) to identify special characteristics, including those determined by the customer and the risk analysis performed by the organization, and shall include the following: a) documentation of ~~all~~ special characteristics in the **product and/or manufacturing documents** ~~**drawings**~~ (as required), **relevant** risk analysis (such as **Process** FMEA), control plans, and standard work/operator instructions; special characteristics are identified with specific markings and are ~~**cascaded through each of these documents;**~~ **documented in the manufacturing documents which show the creation of, or the controls required, for these special characteristics**; ***Rationale for change:*** *Clarifies the documentation of special characteristics in the product and/or manufacturing drawings.*

4) Supplementary Notes

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

Clause	Section	Clarification Subjects
8.2.3.1.2 8.3.3.3	CBP	**SN20.1 What is special characteristics (SC)?**
8.3.3.3	CBP	**SN20.2 What is CC, how is it different from SC?**
8.3.3.3	CBP	**SN20.3 Who should be deciding on SC?**
8.3.3.3	CBP	**SN20.4 Can give examples of internally defined SC?**
8.3.3.3	CBP	**SN20.5 Do we need to get approval for harmonized approach to SC. The standard did not say so.**

SN20.1 What is special characteristic?

According to Clause 3.1. Terms and Definition: Special characteristics are product characteristics or manufacturing process parameters that can affect safety or compliance with regulations, fit, function, performance. Requirements, or subsequent processing of product.

SN20.2 What is CC (critical characteristic)? How is it different from SC?

Special Characteristics is a blanket term. Practitioners may break it further to suit their purpose. All sorts of classification are available: by nature (safety and quality), by criticality (A, B, C, D etc). They are all treated as Special Characteristics by IATF.

SN20.3 Who should be deciding on SC?

External SC are decided by customer. Internally SC are decided by own core team.

SN20.4 Can give examples of internally defined SC?

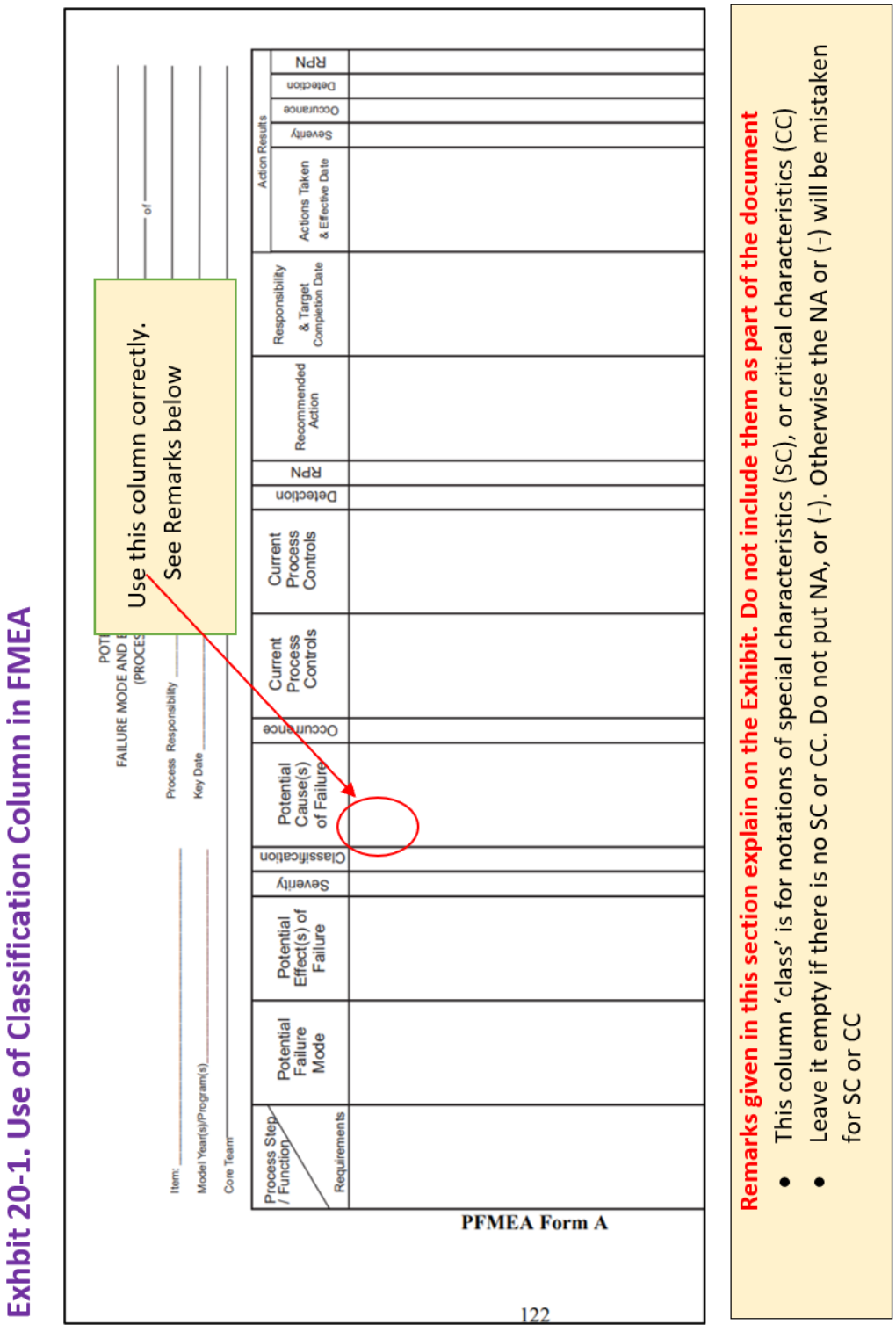
For some bulk materials, the width is important e.g. PVC or fabrics for seats. When too narrow, it is rejected because it does not meet customer specs. Too broad will result in rejects/waste. The second problem (too broad) is not a concern to customer. But to the organization, it is COPQ. Width for such processes are often designated as SC internally.

SN20.5 Do we need to get approval for harmonized approach to SC? The standard did not say so.

The standard states to submit the conversion table, if applicable. In practice, you need to get at least a no objection from the customer before implementing, otherwise there may be arguments later. If you are going to ask for no-objection, you might as well ask for approval. Their reply is an evidence of request and response of the customer.

5) Exhibits

Exhibit 20.-1.Use of Classification Column in FMEA & Control Plan



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

- This column 'class' is for notations of special characteristics (SC), or critical characteristics (CC)
- Leave it empty if there is no SC or CC. Do not put NA, or (-). Otherwise the NA or (-) will be mistaken for SC or CC

Exhibit 20-2. SC Conversion Table

Harmonized SC Symbol Approach

OEM	Proton	Perodua	Honda	Nissan	BMW	Harmonized Symbol
Type of SC	PROTON INSPIRING CONNECTIONS	PERODUa	HONDA	NISSAN		UNION Metal
Quality Critical	⊕	A	(Q)	OBD	(SC)	SC
Safety (if applicable)	?	?	?	?	?	?

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

- Some organization are producing parts that many car plants can use e.g. carpets and floor mats.
- Different OEM tend to have their own SC symbols. It is not practical to identify each and every one of these symbols on process documents, or at the work stations.
- A harmonized approach is allowed by IATF. Customers are also receptive to this idea, but you need to get consent before implementing.
- Keep documentary records of customer acceptance.

>> End of Chapter 20 <<

Chapter 21. Automotive Core Tools

Contents

0) Introduction

The purpose of this chapter is to cover the 5 automotive core tools. However, there can be no in-depth discussion, as it is impossible to cover the 5 core tools in a short chapter. For more information, consult the AIAG Reference manuals on these 5 tools. The 5 core tools are: a) APAP, b) FMEA, c) SPC, d) MSA, e) PPAP. Control Plan is considered part of APAP. The 5 core tools are not neatly discussed in the Standard, but mentioned here and there. Some with fuller discussions such as control plan and MSA. Others are just briefly mentioned such as FMEA, SPC and APAP/PPAP.
At the time of writing, new versions of the core tools are available for upgrading.

1) 8.3.4.4 Product Approval Process (IATF16949)

(Clause Description-Paraphrase)
The organization shall establish, implement, and maintain a product and manufacturing approval process conforming to requirements defined by the customer(s). The organization shall approve externally provided products and services per ISO 9001, Section 8.4.3, prior to submission of their part approval to the customer. The organization shall obtain documented product approval prior to shipment, if required by the customer. Records of such approval shall be retained. NOTE Product approval should be subsequent to the verification of the manufacturing process.

(Highlights of the clause)

- (Ref to old Standards). There was a clause, 7.3.6.3 of the same title, in the old version of ISO/TS16949.
- In the old version it was very simple: conform to a product and manufacturing process approval procedure recognized by the customer. In other words, there is no prescribed method from IATF. PPAP from AIAG can be used but not mandatory.
- The new version uses the form ‘defined’ instead of ‘recognized’ by the customer. The meaning has a slight difference but does not alter the result
- The new version extends the control to sub-supplier. You need to approve externally provided products and services prior to submission of the part approval to the customer
- Records of approval of externally provided products shall be retained
- NOTE said the obvious, only after verification of the manufacturing process, can approval be given.

(Compliance best practice)

8.3.4.4 Product Approval Process

1. *When we speak of design in IATF, we think of the APQP. For submission of data and document to customer, we extract them from APQP files*
2. *But in practice, many organizations do not start with APQP, but will base on PPAP directly for planning and for warrant submission. It saves time, no redundant work, and all the data and rules for approval are given here.*
3. *This is what the clause say, a method initiated by the customer. So you can safely use this method for product and project management. And there is no need to do both APQP and PPAP for the same project.*
4. *For submission, we have to approve info (e.g. ECN, PPAP) etc from sub-suppliers, before onward submission to customer. You should have evidence of this.*
5. *If customer does not specify a method, you can use an internally- defined method for PPAP, complying to the outputs specified in 8.3.5, 8.3.5.1, 8.3.5.2 as applicable. See **Exhibit 21-3.** Otherwise it is an non-compliance.*
6. *For project scheduling, do not use the chart given in **Exhibit 21-1**, as it is only a concept chart used for illustration on APQP. You should just use a Gantt Chart, and lay out your tasks according to sequence. Most importantly, your trial and mass production dates should be based on the master schedule, from the customer*
7. *Inputs from customer are usually drawings and technical specs, and PSW form**.** See **Exhibit 21-2**. This is not sufficient however. You need to ask for master schedule, a PPAP list, and lessons learned, if the part is new to you.*
8. *APQP and PPAP are automotive core tools with a deep level of knowledge. You need to read the AIAG reference manuals or attend such training courses for better understanding.*

2) 7.1.5.1.1 Measurement system analysis (IATF16949)

(Clause Description-Paraphrase)

Statistical studies on the variation present in the results of each type of inspection, measurement, and test equipment system identified in the control plan shall be studied. The analytical methods and acceptance criteria used shall be given in reference manuals. Other analytical methods and acceptance criteria may be used if approved by the customer. Records of customer acceptance of alternative methods shall be retained along with results from alternative measurement systems analysis

(Highlights of the clause)

(Ref to old Standards). This used to be known as 7.6.1 in the previous ISO/TS Standard. The previous requirements are the same as the new one, except for a rewording “reference” to “identified” (in the control plan)

The method used are generally either the AIAG MSA Reference Manual or other equivalents. All equipment identified in the control plan are subject to this study.

NOTE: For MSA studies, critical or special product or process characteristics should be given priority . Some organizations interpret that they only have to check the those equipment used for critical characteristics, which is incorrect.

(Compliance best practice)

7.1.5.1.1 Measurement system analysis

1. *Many organizations provide only GR&R studies instead of the full MSA. A full MSA shall include bias, linearity and stability studies.*
2. *Customer auditor acceptance is common with GR&R. See* ***Exhibit 21-4.*** *There is no specific directive for IATF auditors if GR&R alone is acceptable. In most cases IATF auditor will decide based on customer acceptance.*
3. *However if a customer specified AIAG reference manuals, then G&R is not adequate and the Organization must provide full MSA. For GR&R, attribute characteristics shall use the acceptable methods. This Attribute GR&R study is becoming important as visual and appearance characteristics are getting more emphasis in automotive.* See **Exhibit 21-5.**
4. *There is a NOTE at the bottom of the clause that is creating some confusion. It says "prioritization of MSA should focus on critical or special product or process characteristics". Some organizations interpret this as only equipment used to measure critical characteristics needs MSA. This is wrong, because ALL equipment specified in the control plan shall be provided with MSA studies. The statement just meant that when choosing a point to study a particular measuring equipment for MSA, it should be preferably be a critical point e.g. one that is designated as special characteristics.*

3) 8.3.5.1 D&D Outputs-Supplemental (product) IATF16949

This clause quite a drawn out discussion with lots of details. Refer to Chapter 22 for details.

(Highlight on the clause)

- The purpose for the clause appearing in this chapter is to show DFMEA as part of the output of Product Design
- To understand DMEA, AIAG FMEA Reference Manual should be consulted.

(Compliance best practice)

8.3.5.1 D&D Outputs-Supplemental

1. *This clause is quite a long discussion with lots of details. Refer to Chapter 22 for details. The clause requires DFMEA as the output, which is a core tool. See* ***Exhibit 21-6*** *for a specimen of DFMEA.*
2. *The core team shall be familiar with DFMEA for risk management and PPAP package compilation*
3. *To understand DFMEA, the design team should consult AIAG FMEA Reference Manual, or attend a specific training*

4) 8.3.5.2 Manufacturing Process Design Output (IATF 16949)

This clause quite a drawn out discussion with lots of details. Refer to Chapter 22 for details.

(Highlight on the clause)

- The purpose for the clause appearing in this chapter is to show DFMEA as part of the output of Manufacturing Process Design output.
- To understand PFMEA, AIAG FMEA Reference Manual should be consulted.

(Compliance best practice)

8.3.5.2 Manufacturing Process Design Output

4. *This clause quite a long discussion with lots of details. Refer to Chapter 22 for details. The clause requires PFMEA as an output, which is a core tool. See* ***Exhibit 21-7*** *for a specimen of PFMEA.*
5. *The core team shall be familiar with PFMEA for risk management and PPAP package compilation*
6. *To understand PFMEA, the design team should refer to AIAG FMEA Reference Manual, or attend a specific training*

5) 8.5.1.1 Control Plan (IATF16949)

(Clause Description-Paraphrase)

The organization shall develop control plans at, subsystem, component, and/or material level for the relevant manufacturing site and all product supplied, including those for processes producing bulk materials as well as parts. Family control plans are acceptable for bulk material and similar parts using a common manufacturing process. The organization shall have a control plan for pre-launch and production that shows linkage and incorporates information from the design risk analysis (if provided by the customer), process flow diagram, and manufacturing process risk analysis outputs (such as FMEA). The organization shall, if required by the customer, provide measurement and conformity data collected during execution of either the pre-launch or production control plans. The organization shall include in the control plan:

a) controls used for the manufacturing process control, including verification of job set-ups;
b) first-off/last-off part validation, as applicable;
c) methods for monitoring of control exercised over special characteristics defined by both the customer and the organization;
d) the customer-required information, if any;
e) specified reaction plan; when nonconforming product is detected, the process becomes statistically unstable or not statistically capable. The organization shall review control plans, and update as required, for any of the following:
f) the organization determines it has shipped nonconforming product to the customer;
g) when any change occurs affecting product, manufacturing process, measurement, logistics, supply sources, production volume changes, or risk analysis (FMEA) ;
h) after a customer complaint and implementation of the associated corrective action, when applicable;
i) at a set frequency based on a risk analysis. If required by the customer, the organization shall obtain customer approval after review or revision of the control plan

(Highlights of the clause)

- (Ref to old Standards). There had been a clause, 7.5.1.1 of the same title.
- Previous requirement were simpler; which is summarized in the main paragraph of the new clause (see above)
- The new requirements are: a), b), d), f) h) and i)
- Details of control plan compilation are now given in the clause description, too many to be transcribed here
- To really able to construct a control plan, AIAG APQP Reference Manual (Control Plan section) should be consulted.

(Compliance best practice)

8.5.1.1 Control Plan

1. *Control Plan, although is a part of APQP Manual, it is widely used for process control by production department.* ***Exhibit 21-8.***
2. *The new requirements on control plan are : a), b), d), f) h) and i) of clause description.*
3. *For new projects, the control plans are expected to comply to this new requirement. Some of the active parts should also be upgraded, because IATF auditors will invariably be using them for production audits*
4. *Verification of set-up is often missed out from Control Plan, and so it should be included back. See* ***Exhibit 21-9***
5. *There is also a need to include alternative or backup process control method in the Control Plan. This is discussed in Clause 8.5.6.1.1 in Chapter 12 & 23. See* ***Exhibit 12-5*** *for a specimen.*

6) 9.1.1.2 Identification of Statistical Tools (IATF16949)

(Clause Description-Paraphrase)

The organization shall determine the appropriate use of statistical tools. The organization shall verify that appropriate statistical tools are included as part of the advanced product quality planning (or equivalent) process and included in the design risk analysis (such as DFMEA) (where applicable), the process risk analysis (such as PFMEA), and the control plan.

(Highlights of the clause)

- (Ref to old Standards). There had been a clause, 8.1.1 identification of statistical tools, in the previous version of ISO/TS1694.
- The requirement was very simple: Appropriate statistical tools for each process shall be determined during advance quality planning and included in the control plan.
- There is basically no change. The full requirement is in the clause description.

(Compliance best practice)

9.1.1.2 Identification of Statistical Tools

1. *SPC is strongly encouraged by IATF especially in the earlier versions of ISO/TS. Like in 6 Sigma, SPC has been toned down somewhat. It is still used for controlling special characteristics. Organization can use it on any characteristic to control its variability.*
2. *The clause requires the organization to identify, during APQP stage, the kind of SPC to be used. Most people regards the XBar/R chart is equivalent to SPC. See* ***Exhibit-21-10****. But this is not true, there are many types of SPC, and XBar/R chart is only one type, and may not be suitable for your case.*
3. *SPC requirement shall be indicated in FMEA, control plan etc*

7) 9.1.1.3 Application of statistical concepts (IATF16949)

(Clause Description-Paraphrase)

Statistical concepts, such as variation, control (stability), process capability, and the consequences of over-adjustment, shall be understood and used by employees involved in the collection, analysis, and management of statistical data.

(Highlights of the clause)

- (Ref to old Standards). There had been a clause, 8.1.2 Knowledge of basic statistical concepts, in the previous version of ISO/TS16949.
- The old requirement was simple: Basic statistical concepts, such as variation, control (stability), process capability and over-adjustment shall be understood and utilized throughout the organization.
- Instead of throughout the organization, the new clause only requires relevant people to be understand. These are people involved in the collection, analysis, and management of statistical data. It is more practical

(Compliance best practice)

9.1.1.3 Application of statistical concepts

1. *In particular, organization must ensure the relevant people have the knowledge to construct/interpret the SPC charts correctly*
2. *Training on SPC is useful to ensure compliance. The training shall cover variation control, process capability and over-adjustments.*
3. *IATF auditors will know your level of competency on SPC, by looking at the charts you have produced.*

8) SIs & FAQs

FAQ	IATF Clause	Questions and Answers
6	**7.1.5.1.1 Measurement system analysis**	**QUESTION:** **Are MSA studies required for each instrument or device?** **ANSWER:** No. A complete statistical study on each single piece of equipment is not required. Instruments with the same characteristics (e.g. measurement range, resolution, repeatability, etc.) can be grouped and a sample instrument (representative of the gauge family) can be used for the statistical study.

9) Supplementary Notes

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

Clause	Section	Clarification Subjects
8.3.4.4	CBP	**SN21.1. If the PPAP list from customer is too simple, and does not including mandatory items in the clauses e.g MSA and SPC. Do I still have to do these missing items?**
8.3.5.1	CBP	**SN21.2. Am I allowed to change the FMEA format?**
8.5.1.1	CBP	**SN21.3. Why is Control Plan not a core tool by itself, but part of APQP?**
8.5.1.1	CBP	**SN21.4. Am I allowed to change the Control Plan format? Can I call it something else e.g. Process Management Plan, to avoid being confuse with control charts by the people?**
7.1.5.1.1	CBP	**SN21.5. For attribute GR&R, there are a lot of visual defects. Do we have to do one at a time, or I can do all at one time?**

9.1.1.2	CBP	**SN21.6. Customer asked for SPC only during PPAP submission, but did not say we need to do so during mass production. Do we need to include it in in our operations?**
9.1.1.3	CBP	**SN21.7 Some automotive parts are only running few days in a month. When we compile the monthly studies on CpK, we find the results looking odd. What is wrong?**

SN21.1. If the PPAP list from customer is too simple, and does not including mandatory items in the clauses e.g. MSA and SPC. Do I still have to do these missing items?

If it is a mandatory item in the clause, you have to produce it. You need not send the results to the customer, but you have to retain the records for IATF audit.

SN21.2. Am I allowed to change the FMEA format?

Yes, you can, but not advisable. Firstly the form is already very cramp, adding more columns will make it worse. Secondly it is well-proven to contain adequate information. I am not sure what else you can bring to the form that is not already there.

SN21.3. Why is Control Plan not a core tool by itself, but part of APQP?

Control Plan is contained in the APQP reference manual, which I also don't quite agree. It is so important that it should be the 6th core tool. All the more now that control plan is used so widely in this new version. It has also shifted from design zone to production/process control zone (Clause 8.3 to 8.5). But it does not really matter, you can always consider it as a separate tool. I always do.

.

SN21.4. Am I allowed to change the Control Plan format? Can I call it something else e.g. Process Management Plan, to avoid being confuse with control charts by the people?

Yes, you can change the format but not recommended. It is well established. If you change the format, it will be in the way of usage and reference. Yes, you can change the name of the tool. There are some organizations doing it. Its OK with IATF auditors.

SN21.5. For attribute GR&R, there are a lot of visual defects. Do we have to do one at a time, or can I do all at one time?

You can do all at one time. There are enough samples used (50), for you to plant in all sort of appearance defective parts for the study. Organize it well and you can get the same results.

SN21.6. Customer asked for SPC only during PPAP submission, but did not say we need to do so during mass production. Do we need to include it in in our operations?

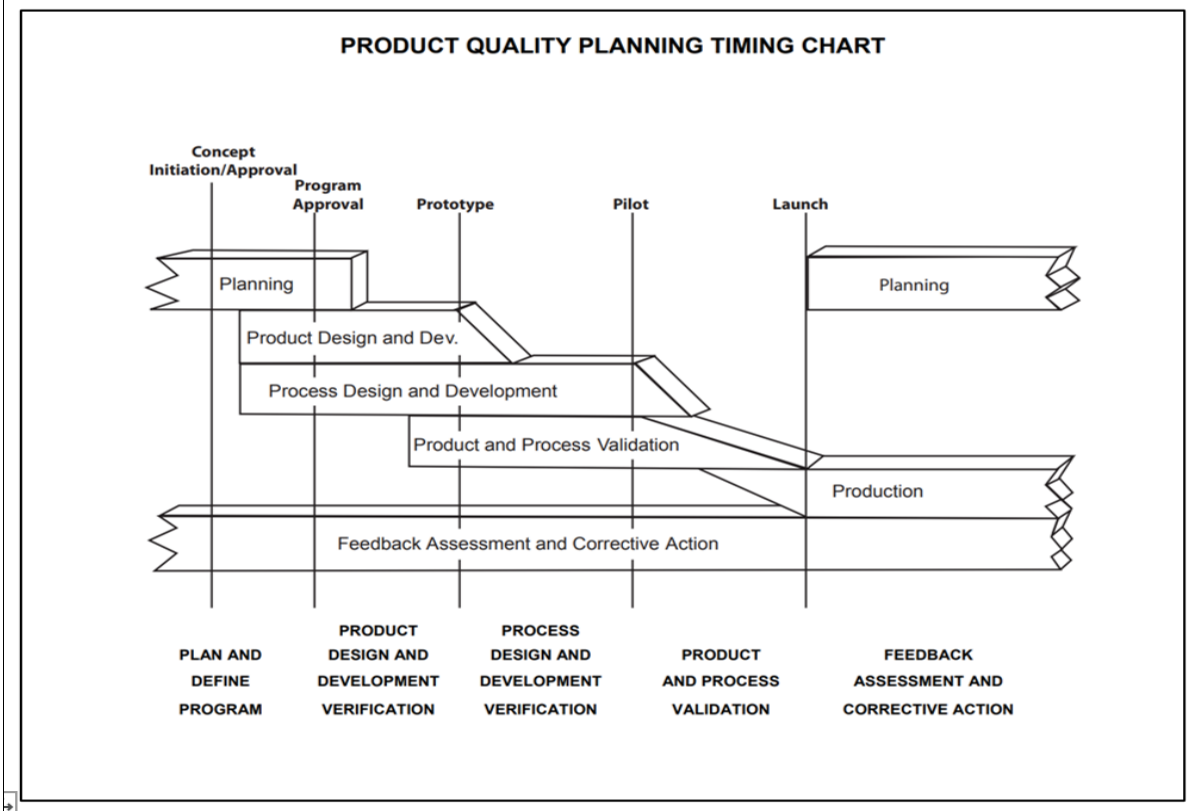
It is quite unlikely customers would not ask for SPC on special characteristics. You should recheck their SQM or reconfirm with them. But if it is really not needed, ask for a written confirmation and you can be exempted.

SN21.7. Some automotive parts are only running few days in a month. When we compile the monthly studies on CpK, we find the results looking odd. What is wrong?

SPC (Xbar/R) has to work with min 100 data to be accurate. If you do not have the samples in a month, extend it further, to say 3 months, or even 6 months. It is better to not to have results every month, than to have inaccurate results. Alternatively, you can run on a cumulative, or moving SPC, so that you can still have monthly data. However, some software has a limit on total data they can process.

10) Exhibits

Exhibit 21-1. APQP



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

- This is only a conceptual chart that shows the process is roughly divided into 5 phases and also their sequence. It is only a concept. You are not required to show linkage of your actual project plan to this APQP chart
- Using a Gantt Chart is more effective because all customers use that. Lay out all the PPAP items in sequence and provide timing for their execution.
- Most importantly is to follow the customer's timing, especially for the first trial and mass production.

Exhibit 21-2. PSW 600 Form

DAIMLERCHRYSLER Ford GM

Part Submission Warrant

Part Name _____ Cust. Part Number _____

Shown on Drawing No. _____ Org. Part Number _____

Engineering Change Level _____ Dated _____

Additional Engineering Changes _____ Dated _____

Safety and/or Government Regulation ☐ Yes ☐ No Purchase Order No. _____ Weight (kg) _____

Checking Aid No. _____ Checking Aid Engineering Change Level _____ Dated _____

ORGANIZATION MANUFACTURING INFORMATION

Organization Name & Supplier/Vendor Code

Street Address

City Region Postal Code Country

CUSTOMER SUBMITTAL INFORMATION

Customer Name/Division

Buyer/Buyer Code

Application

MATERIALS REPORTING

Has customer-required Substances of Concern information been reported? ☐ Yes ☐ No ☐ n/a

Submitted by IMDS or other customer format: _____

Are polymeric parts identified with appropriate ISO marking codes? ☐ Yes ☐ No ☐ n/a

REASON FOR SUBMISSION (Check at least one)

- ☐ Initial Submission
- ☐ Engineering Change(s)
- ☐ Tooling: Transfer, Replacement, Refurbishment, or additional
- ☐ Correction of Discrepancy
- ☐ Tooling Inactive > than 1 year
- ☐ Change to Optional Construction or Material
- ☐ Supplier or Material Source Change
- ☐ Change in Part Processing
- ☐ Parts Produced at Additional Location
- ☐ Other – please specify below

REQUESTED SUBMISSION LEVEL (Check one)

- ☐ Level 1 – Warrant only (and for designated appearance items, an Appearance Approval Report) submitted to customer.
- ☐ Level 2 – Warrant with product samples and limited supporting data submitted to customer.
- ☐ Level 3 – Warrant with product samples and complete supporting data submitted to customer.
- ☐ Level 4 – Warrant and other requirements as defined by customer.
- ☐ Level 5 – Warrant with product samples and complete supporting data reviewed at organization's manufacturing location.

SUBMISSION RESULTS

The results for ☐ dimensional measurements ☐ material and functional tests ☐ appearance criteria ☐ statistical process package

These results meet all design record requirements: ☐ Yes ☐ NO (If "NO" – Explanation Required)

Mold / Cavity / Production Process _____

DECLARATION

I affirm that the samples represented by this warrent are representative of our parts which were made by a process that meets all Production Part Approval Process Manual 4th Edition Requirements. I further affirm that these samples were produced at the production rate of ____ /__hours. I also certify that documented evidence of such compliance is on file and available for review. I have noted any deviations from this declaration below.

EXPLANATION/COMMENTS: _____

Is each Customer Tool properly tagged and numbered? ☐ Yes ☐ No ☐ n/a

Organization Authorized Signature _____ Date _____

Print Name _____ Phone No. _____ FAX No. _____

Title _____ E-mail _____

FOR CUSTOMER USE ONLY (IF APPLICABLE)

PPAP Warrant Disposition: ☐ Approved ☐ Rejected ☐ Other _____

Customer Signature _____ Date _____

Print Name _____ Customer Tracking Number (optional) _____

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

- This PSW form was originally a creation of AIAG, to specify what is needed for project submission for the 3 automotive companies in US. The level of submission tells you what is needed. But this is not really so useful, when it is opened to the world. Different OEM in Europe and Japan do not follow this exactly. It can still be used, but the information provided in PSW is not quite enough to start planning.
- European, Japanese, Koreans and Chinese OEM require more or different things. You need to ask from your customers accordingly e.g. master schedule, PPAP list, lessons learned if applicable.

Exhibit 21-3. PPAP Requirement

PPAP List

1. Design Records
A copy of the drawing. If the customer is responsible for designing, this is a copy of customer drawing that is sent together with the Purchase Order (PO). If supplier is responsible for designing this is a released drawing in supplier's release system.

2. Authorized Engineering Change Documents
A document that shows the detailed description of the change. Usually this document is called "Engineering Change Notice", but it may be covered by the customer PO or any other engineering authorization.

3. Customer Engineering Approval, if required
This approval is usually the Engineering trial with production parts performed at the customer plant. A "temporary deviation" usually is required to send parts to customer before PPAP. Customer may require other "Engineering Approvals".

4. Design Failure Modes and Effects Analysis (DFMEA), applied in special situations
A copy of the Design Failure Mode and Effect Analysis (DFMEA), reviewed and signed-off by supplier and customer.

5. Process Flow Diagram
A copy of the Process Flow, indicating all steps and sequence in the fabrication process, including incoming components.

6. Process Failure Modes and Effects Analysis (PFMEA)
A copy of the Process Failure Mode and Effect Analysis (PFMEA), reviewed and signed-off by supplier and customer. The PFMEA follows the Process Flow steps, and indicate "what could go wrong" during the fabrication and assembly of each component.

7. Control Plan
A copy of the Control Plan, reviewed and signed-off by supplier and customer. The Control Plan follows the PFMEA steps, and provides more details on how the "potential issues" are checked in the incoming quality, assembly process or during inspections of finished products.

8. Measurement System Analysis (MSA)
MSA usually contains the Gage R&R for the critical or high impact characteristics, and a confirmation that gauges used to measure these characteristics are calibrated.

9. Dimensional Results
A list of every dimension noted on the ballooned drawing. This list shows the product characteristic, specification, the measurement results and the assessment showing if this dimension is "ok" or "not ok". Usually a minimum of 6 pieces is reported per product/process combination.

10. Records of Material / Performance Test Results
A summary of every test performed on the part. This summary is usually on a form of DVP&R (Design Verification Plan and Report), which lists each individual test, when it was performed, the specification, results and the assessment pass/fail. If there is an Engineering Specification, usually it is noted on the print. The DVP&R shall be reviewed and signed off by both customer and supplier engineering groups. The quality engineer will look for a customer signature on this document. In addition, this section lists all material certifications (steel, plastics, plating, etc.), as specified on the print. The material certification shall show compliance to the specific call on the print.

11. Initial Process Studies
Usually this section shows all Statistical Process Control charts affecting the most critical characteristics. The intent is to demonstrate that critical processes have stable variability and that is running near the intended nominal value.

12. Qualified Laboratory Documentation
Copy of all laboratory certifications of the laboratories that performed the tests reported on section 10.

13. Appearance Approval Report (AAR)
A copy of the AAI (Appearance Approval Inspection) form signed by the customer. Applicable for components affecting appearance only.

14. Sample Production Parts
A sample from the same lot of initial production run. The PPAP package usually shows a picture of the sample and where it is kept (customer or supplier).

15. Master Sample
A sample signed off by customer and supplier, that usually is used to train operators on subjective inspections.

16. Checking Aids
When there are special tools for checking parts, this section shows a picture of the tool and calibration records, including dimensional report of the tool.

17. Customer-Specific Requirements
Each customer may have specific requirements to be included on the PPAP package. North America auto makers OEM (Original Equipment Manufacturer) requirements are listed on the IATF website.

18. Part Submission Warrant (PSW)
This is the form that summarizes the whole PPAP package. This form shows the reason for submission (design change, annual revalidation, etc.) and the level of documents submitted to the customer. There is a section that asks for "results meeting all drawing and specification requirements: yes/no" refers to the whole package.

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

- This list is taken from the internet and it has 18 elements. Most large OEM will ask for more, or something different. You have to follow customer requirement
- In the event you are dealing with smaller customers, and quite commonly they do not have a PPAP list, You can follow this list, or a modified one from this list, as your internal standard

Exhibit 21-4. GR&R

GAGE REPEATABILITY AND REPRODUCIBILITY DATA SHEET
VARIABLE DATA RESULTS

Part Number NUMBER	Gage Name	Appraiser A
Part Name NAME	Gage Number	Appraiser B
Characteristic — Specification: Lower / Upper	Gage Type	Appraiser C
Characteristic Classification	Trials 0 / Parts 0	Appraisers 0 / Date Performed

APPRAISER/ TRIAL #		PART 1	2	3	4	5	6	7	8	9	10	AVERAGE
1. A	1											
2.	2											
3.	3											
4.	AVE											X_a=
5.	R											r_a=
6. B	1											
7.	2											
8.	3											
9.	AVE											X_b=
10.	R											r_b=
11. C	1											
12.	2											
13.	3											
14.	AVE											X_c=
15.	R											r_c=
16. PART AVE ($\bar{Xp}$)												X= R_p=
17.	$(r_a + r_b + r_c)$ / (# OF APPRAISERS) =											R=
18.	(Max X - Min X) =											X_{DIFF}=
19.	R x D_4* =											UCL_R=
20.	R x D_3* =											LCL_R=

*D_4 =3.27 for 2 trials and 2.58 for 3 trials; D_3 = 0 for up to 7 trials. UCL_R represents the limit of individual R's. Circle those that are beyond this limit. Identify the cause and correct. Repeat these readings using the same appraiser and unit as originally used or discard values and re-average and recompute R and the limiting value from the remaining observations.

Notes:

TRO-QUA-F-001 26-Apr-06

GAGE REPEATABILITY AND REPRODUCIBILITY DATA SHEET
VARIABLE DATA RESULTS

Part Number NUMBER	Gage Name	Appraiser A
Part Name NAME	Gage Number	Appraiser B
Characteristic	Gage Type	Appraiser C
Characteristic Classification	Trials 0 / Parts 0	Appraisers 0 / Date Performed

Measurement Unit Analysis — **% Tolerance (Tol)**

Repeatability - Equipment Variation (EV)

EV = R x K_1 — % EV = 100 (EV/Tol)

Trials	K1
2	4.56
3	3.05

Reproducibility - Appraiser Variation (AV)

AV = $\{(X_{DIFF} \times K_2)^2 - (EV^2/nr)\}^{1/2}$ — % AV = 100 (AV/Tol)

Appraisers	2	3
K_2	3.65	2.70

n = number of parts
r = number of trials

Repeatability & Reproducibility (R & R)

R & R = $\{(EV^2 + AV^2)\}^{1/2}$ — % R&R = 100 (R&R/Tol)

Part Variation (PV)

PV = R_p x K_3 — % PV = 100 (PV/Tol)

Parts	K_3
2	3.65
3	2.70
4	2.30
5	2.08
6	1.93
7	1.82
8	1.74
9	1.67
10	1.62

Tolerance

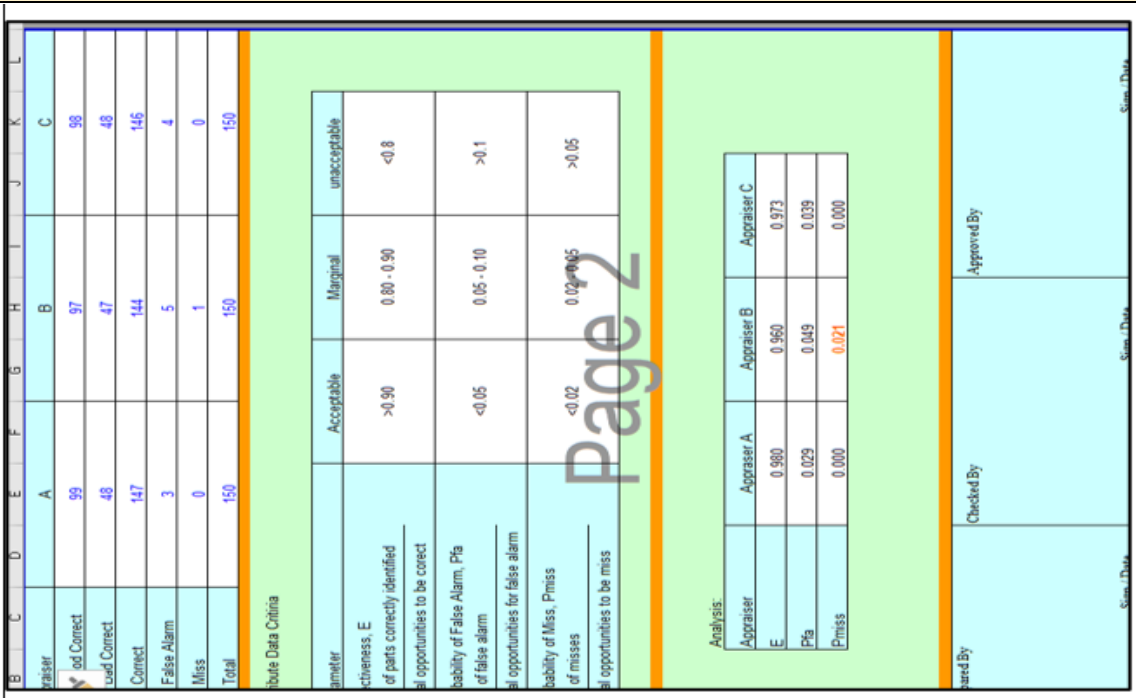
Tol = Upper - Lower
= Upper - Lower

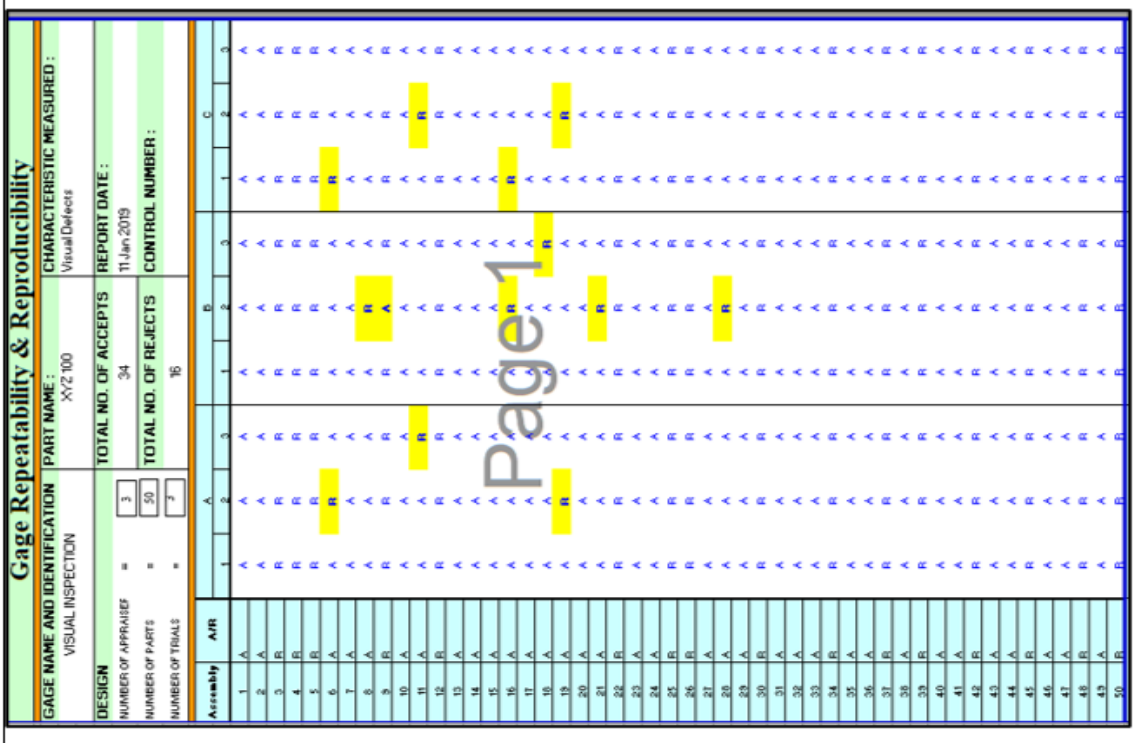
All calculations are based upon predicting 5.15 sigma (99.0% of the area under the normal distribution curve).
K_1 is 5.15/d_2, where d_2 is dependent on the number of trials (m) and the number if parts times the number of operators (g) which is assumed to be greater than 15.
AV - If a negative value is calculated under the square root sign, the appraiser variation (AV) defaults to zero (0).
K_2 is 5.15/d_2, where d_2 is dependent on the number of operators (m) and (g) is 1, since there is only one range calculation.
K_3 is 5.15/d_2, where d_2 is dependent on the number of parts (m) and (g) is 1, since there is only one range calculation.
d_2 is obtained from Table D_3, "Quality Control and Industrial Statistics", A.J. Duncan.

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

- This is often taken as MSA. It is not, as It is only part of an MSA. A full MSA will be GR&R + Linearity, stability and bias studies.
- Generally, IATF auditors will accept, if the customer did not specify to follow AIAG. If they do, that GR&R is not enough and therefore it is a nonconformance.
- Quite commonly, North American customers specify AIAG. So you need to read through their SQM carefully. Japanese, European and other Asian OEM tend to accept GR&R, in place of MSA.
- It is also common to see slight variations of the above. Organization often claims it is from customers or downloaded from the internet, that generated erroneous results. Under such circumstances, it is recommended that you cross check the results using the AIAG format.

Exhibit 21-5. Attribute GR&R

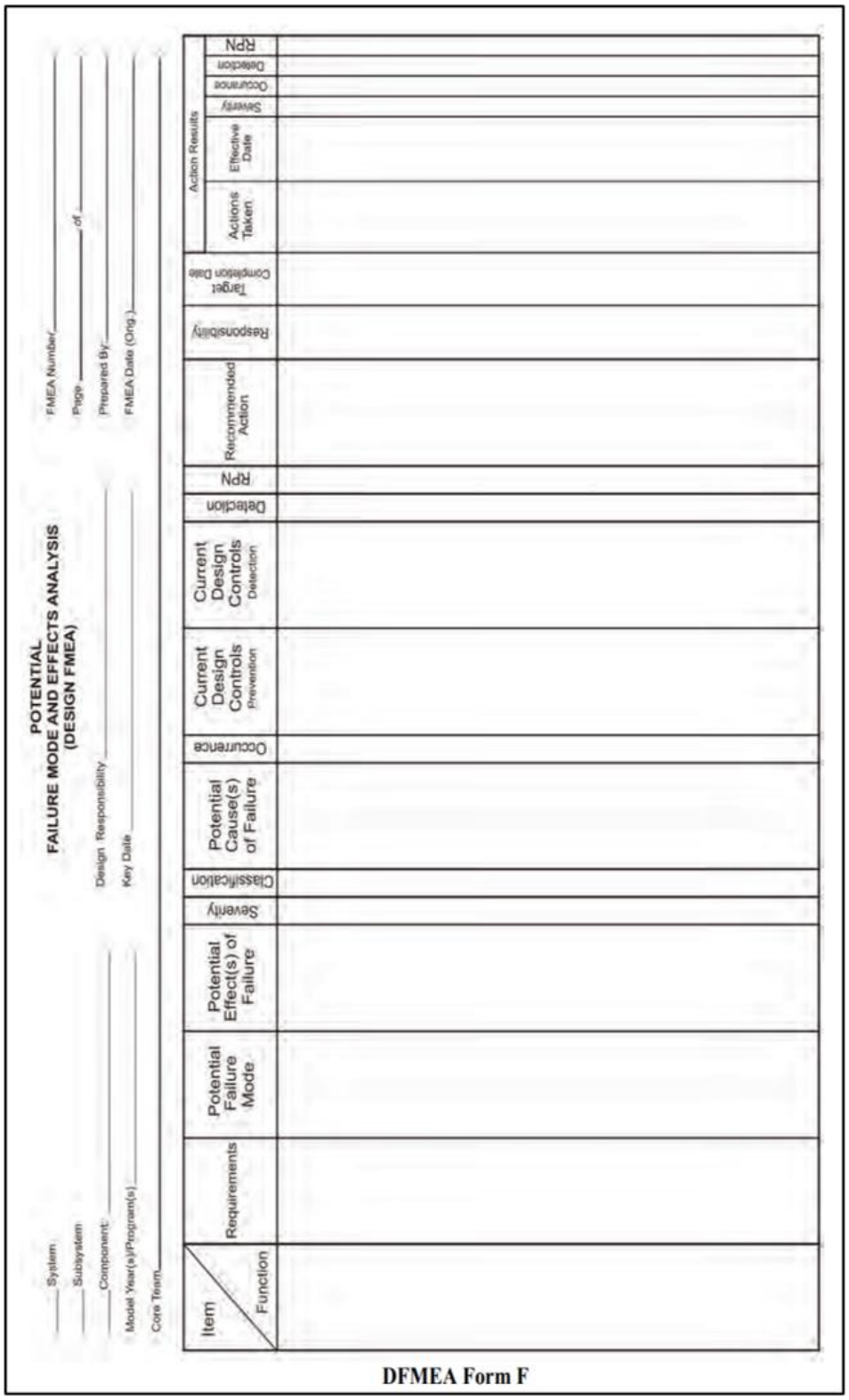




Remarks given in this section explain on the exhibit. Do not include them as part of the document

- Attribute GR&R is a modified GR&R for studying of 'yes/no', 'OK/Not OK' type of measurement systems
- The above is the long method which is acceptable to AIAG. Earlier on there is a short method, which is not in use now
- Alternatively, you can also use software such as Minitab. Minitab's presentation is totally different and you need to go through their tutorial to understanding and interpret
- For more details, consult the AIAG MSA Reference Manual

Exhibit 21-6 DMEA Form



POTENTIAL
FAILURE MODE AND EFFECTS ANALYSIS
(DESIGN FMEA)

System
Subsystem
Component
Model Year(s)/Program(s)
Core Team

FMEA Number
Page of
Prepared by:
FMEA Date (Orig.)

Design Responsibility
Key Date

Item / Function	Requirements	Potential Failure Mode	Potential Effect(s) of Failure	Severity	Classification	Potential Cause(s) of Failure	Occurrence	Current Design Controls Prevention	Current Design Controls Detection	Detection	RPN	Recommended Action	Responsibility	Target Completion Date	Action Results: Actions Taken	Action Results: Effective Date	Action Results: Severity	Action Results: Occurrence	Action Results: Detection	Action Results: RPN

DFMEA Form F

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

- DFMEA form was introduced by AIAG to standardize presentation of product risks by suppliers.
- This one is slightly different from the PFMEA, but many people did not notice. The difference is in the prevention and detection columns. So the 2 forms are not interchangeable

Exhibit 21-7 PMEA Form

POTENTIAL
FAILURE MODE AND EFFECTS ANALYSIS
(PROCESS FMEA)

FMEA Number _____
Page _____ of _____
Prepared By: _____
FMEA Date (Orig.) _____

Item: _____
Process Responsibility _____
Model Year(s)/Program(s) _____
Key Date _____
Core Team _____

Process Step / Function / Requirements	Potential Failure Mode	Potential Effect(s) of Failure	Severity	Classification	Potential Cause(s) of Failure	Occurrence	Current Process Controls	Current Process Controls	Detection	RPN	Recommended Action	Responsibility & Target Completion Date	Action Results: Actions Taken & Effective Date	Action Results: Severity	Action Results: Occurrence	Action Results: Detection	Action Results: RPN

PFMEA Form A

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

- PFMEA form was introduced by AIAG to standardize presentation by suppliers on manufacturing process risks.
- Note that there are some small differences between DFMEA and PFMEA. Make sure you are using the correct form
- There are some changes between the current format and the previous one. So if you are still using the old one, you should change over gradually

CONTROL PLAN

☐ Prototype ☐ Pre-Launch ☑ Production

Page 1 of 1

Control Plan Number 1240	Key Contact/Phone A. P. Smith 313-472-0001	Date (Orig.) 9/9/2007	Date (Rev.) 2/4/2008
Part Number/Latest Change Level 32123345 F	Core Team See attached list	Customer Engineering Approval/Date (If Req'd.)	
Part Name/Description I/P Clip (Plastic)	Organization/Plant Approval/Date	Customer Quality Approval/Date (If Req'd.)	
Organization/Plant Alm Plastic Co., Iowa Plant / Organization Code 34567J	Other Approval/Date (If Req'd.)	Other Approval/Date (If Req'd.)	

PART/ PROCESS NUMBER	PROCESS NAME/ OPERATION DESCRIPTION	MACHINE, DEVICE, JIG,TOOLS FOR MFG.	CHARACTERISTICS			SPECIAL CHAR. CLASS	METHODS					REACTION PLAN
			NO.	PRODUCT	PROCESS		PRODUCT/PROCESS SPECIFICATION/ TOLERANCE	EVALUATION/ MEASUREMENT TECHNIQUE	SAMPLE SIZE	SAMPLE FREQ.	CONTROL METHOD	
8	Injected mold plastic parts	Injection mold machine #22	12		Raw material (pellet dryer)		1% max. rel. humidity	Humidity gage on dryer	1	hour	Record sheet	Adjust dryer, dry material and requalify

EXAMPLES ARE FOR REFERENCE ONLY. REFER TO SPECIFIC CUSTOMER REQUIREMENTS.

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

- This is the control plan recommended by AIAG, but it is not mandatory.
- Many Japanese OEM do not follow this. They tend to have one with product control on one side, and process control on another side of the form.
- If you are using this, try to link up the steps with FMEA, so the risk management can be seen clearer. You can do that by having a reference no for each step.

Exhibit 21-9 Showing Setup in Control Plan

CONTROL PLAN (Molding)

Customer Name:	Beyonics		Part Name:	Lower Case (M1)					Part No.	BLA2SC00562A	
Process Flow		Machine, Device, Jig Tools for Manufacturing	Special/Char. Class Designation	Characteristics			Methods				Reaction Plan if Out of Control Conditions are Encountered
Process No.	Process Name			Print Ref. No.	Process Parameter	Product Characteristic	Product/Process Specification / Tolerance	Measurement Technique	Sample Size	Sample Freq.	Analysis Method	
1	Material Issuance to Production	n/a			n/a	n/a	PC XXXX	Visual	100%	every request	Material Request Form	Return to Store
2a	Material Preheating	Hopper Dryer	M			Temp / Time	90 ~ 100 C / 3~4 hrs	Timer / Thermo Controller		Setup / 4-hourly	* Mold Setup Form * Daily Mc Inspection Checklist	Adjust / Recheck
2b	Machine Setup	Injection Molding Mc SC120 ton				Temperature	Nozzle : 280 ~ 300 C Front : 280 ~ 300 C Middle : 275 ~ 295 C Rear : 260 ~ 280 C	Temperature Indicative		Setup / 4-hourly	* Mold Setup Form * Daily Mc Inspection	Adjust / Recheck
3	Sampling and Setup Inspection		M KPC			Appearance / Fitting Dimension	As per Inspection Instruction See Inspection Instruction for Specs.	Visual Inspection 1st piece buy-off TMS/Caliper	1 shot 1 shot	Setup Setup	Compare with Approved Samples Drawings / FAI / Data Sheet	Adjust / Recheck Adjust / Recheck
4	Mass Prodcution WIP	Injection Molding Mc SC 120 ton				Appearance Pressure Injection Cycle Time	As per I.I. 75 ~ 95 % 5.0 ~ 8.0 sec 40 ~ 45 sec	Visual Mc Actual Values / Gauges	1 shot	Continuous every 4 hrs	Approved / Limit Samples Daily Mc Inspection List / Molding Mc Parameter	Adjust / Recheck
5	In-Process Inspection (IPQC)		KPC			Appearance Dimension	As Per Inspection Instruction	Visual TMS / Caliper	1 shot	every 2 hrs every shift	Data Sheet X-bar R-Chart Cpk Analysis	Adjust / Recheck

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

- Setup verification is now a requirement and the step shall be written on the control plan. This is given in the red-framed line
- First-off verification is generally the validation of the setup, it is given in the blue-framed line
- In practice, the two go hand-in-hand and both are needed to be shown

Exhibit 21-10 SPC

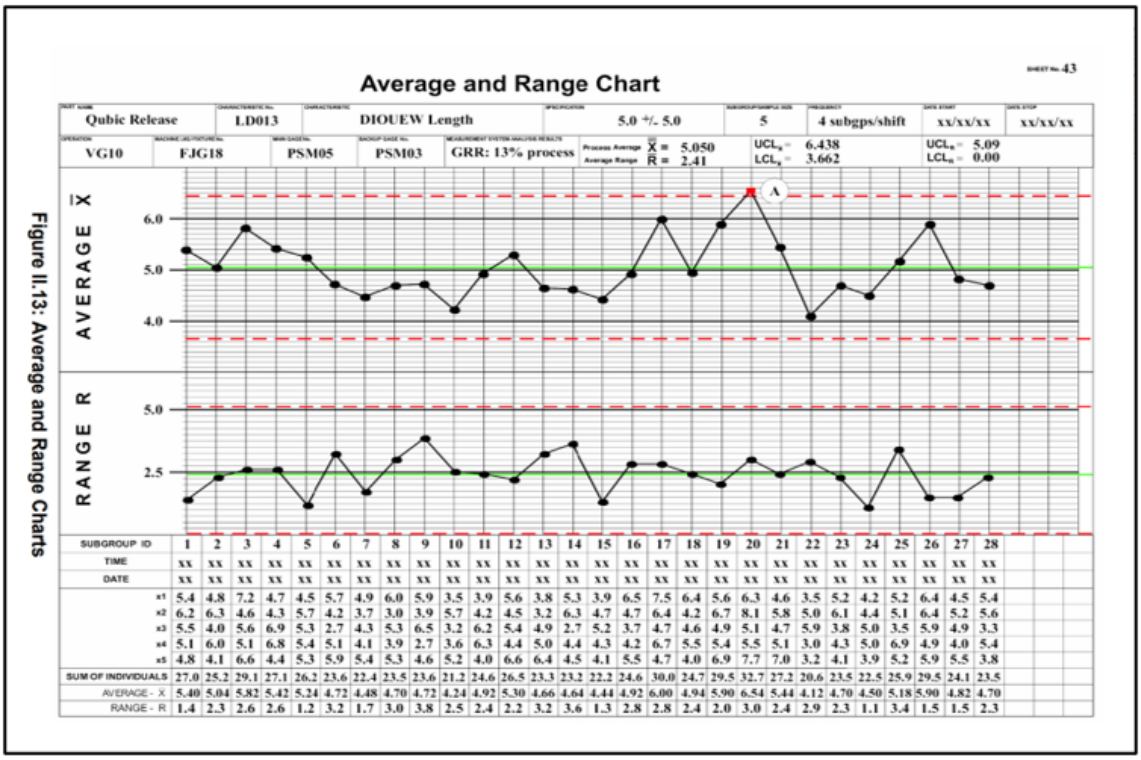


Figure II.13: Average and Range Charts

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

- This is a Xbar/R chart. Many people think that this is SPC. Yes, it is one of the SPC methods. There are others. Example: within Average-Range charts, there are other variation e.g. Xbar/S, IMR charts, Median & Range charts. There are also other forms of charts such as P chart, C chart and U chart etc.
- In most situation, Xbar/R chart is suitable. Note that this particular chart only show the graph. Most software now calculate the process capability (CPK, PPK etc) as well. Choose a chart that also give the process capability data and you can kill 2 birds with 1 stone.
- Besides the CpK, it is important to understand the Xbar/R chart because it gives warnings on upcoming problems. Actions can then be taken before problem hits you. You do this by studying the curves. You need to attend a SPC course or read up the SPC reference manual to understand

>> End of Chapter 21 <<

Chapter 22. Design & Development

0) Introduction

Design and Development has always been a large process. For ISO9001 you can be exempted, if you are not design responsible. For IATF, however, only product design can be exempted. Manufacturing design is always non-excluded. Even for process design alone, you are still subject to all these clauses except 8.3.2.2, 8.3.3.1, 8.3.5.1. Clause 8.3.4.3 may be included, depending on the contractual agreement. A good understanding should avoid any findings.

1) 8.2.2 Determining the requirement of products and services (ISO9001)

This clause has been discussed in detail in Chapter 19. Please refer.

2) 8.2.2.1 Determining the requirements for products and services – supplemental (IATF16949)

This clause has been discussed in detail in Chapter 19. Please refer.

3) 8.2.3.1.3. Organization manufacturing feasibility (IATF 16949)

(Clause Description-Paraphrase)

The organization shall utilize a multidisciplinary approach to conduct an analysis to determine if it is feasible that the organization's manufacturing processes are capable of consistently producing product that meets all of the engineering and capacity requirements specified by the customer.
The organization shall conduct this feasibility analysis for any manufacturing or product technology new to the organization and for any changed manufacturing process or product design. Additionally, the organization should validate through production runs, benchmarking studies, or other appropriate methods, their ability to make product to specifications at the required rate.

(Highlights of the clause)

- (Ref to old Standards). There was a similar clause, Clause 7.2.2.2 of the same title, in the previous version ISO/TS16949. The old clause was only a 1- line: "The organization shall investigate, confirm and document the manufacturing feasibility of the proposed products in the contract review process, including risk analysis"
- It is now expanded significantly to explain on the requirement, and to be feasible, the organization must meet all of the engineering and capacity requirements specified by the customer.
- Feasibility analysis is required only for any manufacturing or product technology new to the, or any changed manufacturing process or product
- Organization should validate through production runs, benchmarking studies, or other appropriate methods, their ability to make product to specifications at the required rate

*(Compliance best pra*ctice)

8.2.3.1.3. Organization manufacturing feasibility

1. *To comply with this clause, you need to conduct the feasibility study.*
2. *You can use the AIAG's "Team Feasibility Commitment "or equivalent to conduct the feasibility study. Conclude clearly whether it is feasible. See* ***Exhibit 22-1.***
3. *The last sentence of the clause "at the required rate", means capacity study is also required. See* ***Exhibit 22-2.***
4. *But the clause also said "changed manufacturing process or design change". In other words, project of existing technology or design may be exempted for the study*
5. *IATF Auditor will also look into open items in trial meetings, for follow-up actions. Make sure you have taken actions and update the records.*
6. *Validations, and any documentary approvals received (e.g. signed PSW, or 'spot' approvals, golden samples) etc. These things should be ready for audit.*

4) 8.3, 8.3.1 Design and development of products and services (ISO9001)

(Clause Description-Paraphrase)

The organization shall establish, implement and maintain a design and development process that is appropriate for the subsequent provision of products and services.

(Highlights of the clause)

- *(*Ref to old Standards). There was a similar clause, 7.3 Design and Development. in the previous version of ISO/TS16949. There were no description except a NOTE that says design can include product and manufacturing process. Design should include prevention rather than detection.
- The new clause added product and services to the title and some explanation of the purpose

- A documented process is required on design

(Compliance best practice)

8.3, 8.3.1 Design and development of products and services

1. *The clause requires a documented process. To comply, there must be a design procedure, or some written guides. See* ***Exhibit 22-3, and 22-4.***
2. *Turtle Diagram alone although is a written document, may not be acceptable as the procedure, as the information is too brief for such a complex process.*
3. *Design should include prevention rather than detection, and the message should be found in the procedure.*

5) 8.3.1 1 D&D General-Supplemental (IATF16949)

(Clause Description-Paraphrase)

The requirements of ISO 9001, Section 8.3.1, shall apply to both product and manufacturing process design and development. Additionally, they shall focus on error prevention rather than detection.

(Highlights of the clause)

- (Ref to old Standards). This was an addition NOTE to 7.3 of the previous version of ISO9001 by ISO/TS16949
- This IATF clause reminds that 8.3.1 is applicable to both product and manufacturing process. In other words, even if you are excluded from product design, this clause is still applicable.
- 'Prevention rather than detection' means preventive actions are preferred over detection.

(Compliance best practice)

8.3.1 1 D&D General-Supplemental

1. *'Prevention rather than detection' should be demonstrated in your risk analysis and design documentation*
2. *Therefore documentation such as FMEA, contexts of organization, contingency plans, and interested parties needs and expectations etc., should show prevention rather than detection, as a priority.*

6) 8.3.2 Design and development planning (ISO9001)

(Clause Description-Paraphrase)

Stages and controls for design and development depends on: (a) the nature, duration and complexity of the design and development activities; (b) the required process stages, including design reviews, (c) verification and validation activities; (d) the responsibilities and authorities involved, (e) the internal and external resource needs, (f) the need to control interfaces between persons involved, (g) involvement of customers and users, (h) the requirements for subsequent provision of products and services; (i) the level of control expected by customers and other relevant interested parties; (j) the documented information needed.

Author's note: For exact wordings, please refer to standard indicated after the clause title.

(Highlights of the clause)

- (Ref to old Standards). There was a similar clause, 7.3.1. of same title, in the previous version pf ISO/TS16949

- A lot more requirements had been added. The new element are: a) internal and external resources needed, b) and consideration to involve customers and users in the design. This is in line with the new risk-based thinking, and working with customers as a better method of satisfying customer requirement.

(Compliance best practice)

8.3.2 Design and development planning

1. *For non-automotive, written process/procedure is not a requirement. In practice, it is difficult to comply to all the requirements if they are not listed down.*
2. *A list of expected outcome /objectives (**Exhibit 22-5**) would suffice in the ISO9001 situation, where product design is involved. Otherwise it is excluded.*

7) 8.3.2.1 D&D Planning-supplemental(IATF16949)

(Clause Description-Paraphrase)

Design and development planning includes all affected stakeholders within the organization and, as appropriate, its supply chain. Examples of areas for using such a multidisciplinary approach include:
(a) project management (for example, APQP or VDA-RGA);
(b) product and manufacturing process design activities (for example, DFM and OFA), such as consideration of the use of alternative designs and manufacturing processes;
(c) development and review of product design risk analysis (FMEAs), including actions to reduce potential risks; (d) development and review of manufacturing process risk analysis (for example, FMEAs, process flows, control plans, and standardised work instructions).
NOTE A multidisciplinary approach typically includes the organization's design, manufacturing, engineering, quality, production, purchasing, supplier, maintenance, and other appropriate functions.

(Highlights of the clause)

- (Ref to old Standards). There was a similar clause, 7.3.1.1 Multidisciplinary approach. The clause was short with the purpose of preparing for product realization. It particularly requires the development of special characteristics, FMEA including actions to reduce risks, and control plan. Monitoring and review required.
- Now this clause is expanded. Multidisciplinary approach is used for many other situations. See (a) to (d)
- Typical composition of a multidisciplinary team consist of design, manufacturing, engineering, quality, production, purchasing, supplier, maintenance, and other appropriate functions.

(Compliance best practice)

8.3.2.1 D&D Planning-supplemental

1. *For IATF, only product design can be excluded. The documented process for manufacturing process design is still required.*
2. *Multifunctional approach is needed for both product and process design. Generally it means a permanent core team is required. The team is not an ad-hoc gathering of a few people, and disbanded after the design. Their responsibilities stay on until the product reaches its end-of-life.*
3. *For design documentation, you can choose APQP, RGA, VDA, Gannt chart etc, so long your customers do not object.*

4. *The items to be included are usually defined by customer, by way of a PPAP list, if available. Otherwise you use an internally defined list to guide the designed engineers.*
5. *The schedule shall correspond with customer's master schedule, such as trial and mass production dates.*
6. *D&D output can include DFM, DFA, FMEA, PFC, CP. WI, MSA, SPC, applicable functional tests etc. All the above are outputs that a IATF auditor will audit, so keep them handy.*

8) 8.3.2.2 Product Design Skills (IATF16949)

(Clause Description-Paraphrase)

Personnel with product design responsibility shall be competent to achieve design requirements and are skilled in applicable product design tools and techniques. Applicable tools and techniques shall be identified by the organization.

NOTE An example of product design skills is the application of digitized mathematically based data.

(Highlights of the clause)

- (Ref to old Standards). There was a similar clause, 6221 of same title, in the previous ISO/TS16949.
- Content remained the same. The new version mentioned that digitized mathematically-based data is an example of design skill, in NOTE section

(Compliance best practice)

8.3.2.2 Product Design Skills

1. *This applies to product design personnel only. They should be competent in using design software such as Catia, Autocad, Solidworks etc, as specified by customers. Keep the copies of certificates handy at the department*
2. *Software competency means formal training. Learning from friends and having a manual is not considered competent*
3. *Although not applicable to process design personnel, they should also be familiar with the design software because project may be using the drawings*
4. *Core tool competency is applicable both for process and product design personnel..*

9) 8.3.2.3 Development of product with embedded software (IATF16949)

(Clause Description-Paraphrase)

The organization shall use a process for quality assurance for their products with internally developed embedded software. A software development assessment methodology shall be utilized to assess the organization's software development process. Using prioritization based on risk and potential impact to the customer, the organization shall retain documented information of a software development capability self-assessment. The organization shall include software development within the scope of their internal audit programme

(Highlights of the clause)

- (Ref to old Standards). This is a totally new clause
- Organization need to have a process, for quality assurance with internally developed embedded software.
- organization shall also develop a software development assessment method to check on the software development process.

- Based on risk impact to customer, records of self-assessment shall be retained
- Internal audit shall include software development, if applicable

(Compliance best practice)

8.3.2.3 Development of product with embedded software

1. *If your organization is not be involved in this, you are off the hook.*
2. *But if it is, then you need to have a process, and a software development assessment methodology, to develop, test and manage changes or upgrades.*
3. *As explain the in FAQ-15, the methodology of development a software is not different from a hardware. In the case of a purchased part with embedded software, see Chapter 24.*
4. *Embedded software is a brand new subject. A software development assessment methodology to be adopt with records (sequencing etc). This then allows for self-assessment. Priority can be set using risk and potential impact to customers as the basis. Embedded software shall be included within the scope of their QMS. If design is outsourced, the supplier shall be responsible for self-assessment. See FAQ-15.*
5. *For records, if the software design is internal, records shall be maintained internally. However, if the design is outsourced, then the records shall be maintained by the supplier.*
6. *Organization's responsibility to ensure the records are indeed retained. This can be checked during internal. For supplier, this can be done via Second Party Audit. You should bring along an IT person to assist in the audit, if you are not familiar of configuration.*

10) 8.1.2 Confidentiality (IATF16949)

The clause has been discussed in detail in Chapter 19. Please refer.

11) 8.3.3 D&D Inputs (ISO9001)

(Clause Description-Paraphrase)

The organization shall determine the requirements essential for the specific types of products and services to be designed and developed. The organization shall consider:

(a) functional and performance requirements; (b) information derived from previous similar design and development activities; (c) statutory and regulatory requirements; (d) standards or codes of practice that the organization has committed to implement; (e) potential consequences of failure due to the nature of the products and services.

Inputs shall be adequate for design and development purposes, complete and unambiguous. Conflicting design and development inputs shall be resolved. The organization shall retain documented information on design and development inputs.

(Highlights of the clause)

- (Ref to old Standards). There was a similar clause, 7.2.2 same title, in the old version of ISO/TS1694. Previous requirement are reworded and retained.
- The new version is expanded. Point (d) & (e) are new and ending paragraph are also new.

(Compliance best practice)

8.3.3 D&D Inputs (ISO9001)

1. *See 8.3.3.1 for combined discussion.*

12) 8.3.3.1 Product Design Input (IATF16949)

(Clause Description-Paraphrase)

The organization shall identify, document, and review product design input requirements as a result of contract review. Product design input requirements include :

(a) product specifications including special characteristics,

(b) boundary and interface requirements;

(c) identification, traceability, and packaging;

(d) consideration of design alternatives;

(e) assessment of risks with the input requirements and the organization's ability to mitigate/manage the risks, including from the feasibility analysis;

(f) targets for conformity to product requirements including preservation, reliability, durability, serviceability, health, safety, environmental, development timing, and cost;

(g) applicable statutory and regulatory requirements of the customer-identified country of destination, if provided;

(h) embedded software requirements.

The organization shall have a process to deploy information gained from previous design projects, competitive product analysis (benchmarking), supplier feedback, internal input, field data, and other relevant sources for current and future projects of a similar nature.

NOTE One approach for considering design alternatives is the use of trade-off curves.

(Highlights of the clause)

- (Ref to old Standards).There was a similar clause, 7.3.2.1 of the same title in the previous version ISO/TS16949.
- This clause is applicable only where product design is involved. Otherwise it can be omitted.
- The new clause had expanded to include some new elements in (d). (e), (g),(h). for setting targets, health, safety, environmental etc can be included where applicable.
- Need to deploy info gained from previous design projects, benchmarking, supplier feedback, internal input filed data are still required
- Total requirements are given from (a) to (h) in the clause description above.

(Compliance best practice)

8.3.3.1 Product Design Input

1. *This clause is for IATF and the earlier one 8.3.3 is for ISO9001.*
2. *First the requirements of customer shall be available before starting to design.*
3. *A few other things can be added to make the design more effect such as: a) Organization's own need, b) important experiences from previous design activities, c) compliance to relevant standards and codes of practice etc.*
4. *Ensure to get a copy of customer requirement for PPAP, so your output can be planned, and checked before submission.*
5. *There is also a need to ensure there is no conflicting D&D input. This can be easily done by listing out the input, objectives & expected output.* ***See Exhibit 22-5.***

13) 8.3.3.2 Manufacturing Process Design Input (IATF16949)

(Clause Description-Paraphrase)

The organization shall identify, document, and review manufacturing process design input requirements including:

a) product design output data including special characteristics;

b) targets for productivity, process capability, timing, and' cost;

c) manufacturing technology alternatives;

d) customer requirements, if any;
e) experience from previous developments;
f) new materials;
g) product handling and ergonomic requirements; and
h) design for manufacturing and design for assembly.

The manufacturing process design shall include the use of error-proofing methods to a degree appropriate to the magnitude of the problem(s) and commensurate with the risks encountered.

(Highlights of the clause)

- (Ref to old Standards). There had been a clause, 7.3.2.2 of same title, in the previous version of ISO/TS1694 .
- Previous requirement are found in a), b), d), e), while the new ones are c), f), g) and h)
- Ending paragraph also requires use of error-proofing methods to a degree appropriate to the magnitude of the problem(s) and commensurate with the risks encountered.

(Compliance best practice)

8.3.3.2 Manufacturing Process Design Input

1. *All the requirements, from a) to h) of the clause description, shall be complied*
2. *Do up a Project Schedule to manage the planning work. See* ***Exhibit 22-6***
3. *Input generally include: design objectives (output and specs summary of customer. Statutory, Regulatory and own requirements), customer schedule, lessons learned, product drawings and/or specs,*
4. *Lessons learnt are from internal manufacturing records, FMEA history etc. Some OEM customers requires continuous recording during operations. This makes things easier when developing new parts. Some other organizations would keep them in the system (hardcopy of e-copy) to be retrieved easily*
5. *If your organization is making the product for the first time, the customer should be able to furnish lessons learned*
6. *Functional tests on products are still required, but expected to be much less as compared to product design*

14) 8.3.3.3 Special Characteristics (IATF16949)

This clause has been discussed in Chapter 20. Please refer

15) Customer-designated Special Characteristics (IATF16949)

This clause has been discussed in Chapter 20. Please refer

16) 8.3.4 Design & Development Controls (ISO9001)

(Clause Description-Paraphrase)

The organization shall apply controls to the design and development process to ensure that:

a) the results to be achieved are defined;
b) reviews are conducted to evaluate the ability of the results of design and development to meet requirements;
c) verification activities are conducted to ensure that the design and development outputs meet the input requirements;
d) validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use;

e) any necessary actions are taken on problems determined during the reviews, or verification and validation activities; f) documented information of these activities is retained.

NOTE Design and development reviews, verification and validation have distinct purposes. They can be conducted

(Highlights of the clause)

- (Ref to old Standards). There had been similar clauses, 7.3.4 D&D Review, in the previous version of ISO9001.
- The old requirements are retained in b) and c) of the new clause. Items a) d) and e) have been mentioned over and over in this chapter. The presence here is just to fill up the pieces for the control concept. Note the change in title from 'review ' to 'control'.
- Compliance requires implementing a) to e)

(Compliance best practice)

8.3.4 Design & Development Controls

1. *This clause is excluded for ISO, if not design responsible. For IATF this is not fully exempted.*
2. *This is a concept clause, actual implementation will be carried out at various stages of the project. You are only required to understand the intent and ensure compliance. There is generally no need to produce any additional documentation here as evidence*

17) 8.3.4.1 Monitoring (IATF16949)

(Clause Description-Paraphrase)

Monitoring Measurements at specified stages during the design and development of products and processes shall be defined, analysed, and reported with summary results as an input to management review (see Section 9.3.2.1).

When required by the customer, measurements of the product and process development activity shall be reported to the customer at stages specified, or agreed to, by the customer.

NOTE When appropriate, these measurements may include quality risks, costs, lead times, critical paths, and other measurements.

(Highlights of the clause)

- (Ref to old Standards). There had been a clause, 7.3.4.1.of same title, in the previous version of ISO/TS16949.
- The entire previous requirement is covered by first paragraph of the new version. Next paragraph is new, about provided information on process development activity to customers. Details shall be agreed with customer.

(Compliance best practice)

8.3.4.1 Monitoring

1. *This is a concept clause, actual implementation will be carried out by other departments, or at different stages of the project.*
2. *Updated status shall be reported to the customer if required. This is also an agenda item in the Management Review to report on this item*

18) 8.3.4.2 Design and Development Validation (IATF16949)

(Clause Description-Paraphrase)

Design and development validation shall be performed in accordance with customer requirements, including any applicable industry and governmental agency-issued regulatory standards. The timing of design and development validation shall be planned in alignment with customer-specified timing, as applicable.

Where contractually agreed with the customer, this shall include evaluation of the interaction of the organization's product, including embedded software, within the system of the final customer's product.

(Highlights of the clause)

- (Ref to old Standards). There was a similar clause 7.3.6. Design & Development Validation in the previous version of ISO/TS16949. The requirements of the old version are retained in the new version
- The new version requires D&D Development to be performed according customer, industry, statutory and regulatory requirements.
- The timing of D&D Validation shall be planned in alignment with customer-specified timing. New elements added in the last para, evaluation of interaction of program products, including embedded software in final customer product.

(Compliance best practice)

8.3.4.2 Design and Development Validation

1. *Validation is often stated on the project schedule and method prescribed by customer.*
2. *Problem often arises when 2 suppliers are involved in related parts. Example: in the case of paint supply, the paint for the car body should be same as the one for the bumpers. Otherwise possibility of different shades are very high.*
3. *Clarify such issues well ahead, or you have problem resolving validation later on*

19) 8.3.4.3 Prototype Program (IATF16949)

(Clause Description-Paraphrase)

When required by the customer, the organization shall have a prototype programme and control plan. The organization shall use, whenever possible, the same suppliers, tooling, and manufacturing processes as will be used in production.

All performance-testing activities shall be monitored for timely completion and conformity to requirements. When services are outsourced, the organization shall include the type and extent of control in the scope of its quality management system to ensure that outsourced services conform to requirements (see ISO 9001, Section 8.4).

(Highlights of the clause)

- *(Ref to old Standards). There had been similar clauses,* 7.3.6.2 of same title, in the previous version of ISO/TS16949.
- All old requirements are taken into the new clause, but reworded for better clarity.

Compliance best practice

8.3.4.3 Prototype Program

1. *Prototype program means producing the first design samples.*
2. *This is generally the responsibility of the customer, or via a specialist prototype company. However, customer may also appoint the production company to do this, due to the availability of facilities. This is generally outside the scope of manufacturing process design, and should require a separate contract.*
3. *By standard practice, you must use normal material, facilities that represent normal production conditions. You should not use specially selected items because you would have problem later, when comes to mass production*

20) 8.3.4.4 Product Approval Process (IATF16949)

This clause has already been discussed in Chapter 21. Please refer

21) 8.3.5 D&D Outputs (ISO9001)

(Clause Description-Paraphrase)

The organization shall ensure that design and development outputs:

a) meet the input requirements;

b) are adequate for the subsequent processes for the provision of products and services;

c) include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria;

d) specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision.

The organization shall retain documented information on design and development outputs.

(Highlights of the clause)

- (Ref to old Standards). There had been a clause, 7.3.3 of the same title, in the old version of ISO9001.
- The old requirement are retained, except Information for purchasing has been removed.
- The new versions reads a) to d), with requirement for documented information on the output

(Compliance best practice)

8.3.5 D&D Outputs

Output should link to and meet the objectives determined at the start of the project. See ***Exhibit 22-5.***

22) 8.3.5.1 D&D Outputs-Supplemental (product) (IATF16949)

(Clause Description-Paraphrase)

The product design output shall be expressed in terms that can be verified and validated against product design input requirements. The product design output shall include but is not limited to the following, as applicable:

a) design risk analysis (FMEA);

b) reliability study results;

c) product special characteristics;

d) results of product design error-proofing, such as DFSS, DFMA, and FTA;

e) product definition including 3D models, technical data packages, product manufacturing information, and geometric dimensioning & tolerancing (GD& T);

f) 2D drawings, product manufacturing information, and geometric dimensioning & tolerancing (GD&T);
g) product design review results;
h) service diagnostic guidelines and repair and serviceability instructions;
i) service part requirements;
j) packaging and labeling requirements for shipping. NOTE Interim design outputs should include any engineering problems being resolved through a trade-off process.

(Highlights of the clause)

- (Ref to old Standards). There had been a clause, 7.3.3.1 of the same title, in the previous version of ISO/TS16949.
- All previous requirement are retained but re-worded. More details included from a) to j). New items include: 3D, 2D, GD&T, service part requirements, packaging and labelling requirement for shipping.
- Total requirement are given in a) to j) stated in the Clause description.

(Compliance best practice)

8.3.5.1 D&D Outputs-Supplemental (product)

1. *This clause is about generating the output stated in in a) to j) of Clause description*
2. *Method/standard of tests may be decided by customer and in customer formats*
3. *Some of these tests are done by 3rd party, HQ. technical partners etc. Make sure they have ISO/IEC 17025 certification because they are considered independent labs. However HQ can be exempted from ISO/IEC17015, if they are IATF-certified and declared as remote locations to the organization. Tests they do, under the situation, are OK and within their internal lab capability*

23) 8.3.5.2 Manufacturing Process Design Output (IATF16949)

(Clause Description-Paraphrase)
The organization shall document the manufacturing process design output in a manner that enables verification against the manufacturing process design inputs. The organization shall verify the outputs against manufacturing process design input requirements. The manufacturing process design output shall include but is not limited to the following:
a) specifications and drawings;
b) special characteristics for product and manufacturing process;
c) identification of process input variables that impact characteristics;
d) tooling and equipment for production and control, including capability studies of equipment and process(es);
e) manufacturing process flow charts/layout, including linkage of product, process, and tooling; f) capacity analysis;
g) manufacturing process FMEA;
h) maintenance plans and instructions;
i) control plan (see Annex C);
j) standardised work and work instructions;
k) process approval acceptance criteria;
l) data for quality, reliability, maintainability, and measurability;
m) results of error-proofing identification and verification, as appropriate;
n) methods of rapid detection, feedback, and correction of product/manufacturing process nonconformities.

(Highlights of the clause)

- (Ref to old Standards). There had been a clause, 7.3.3.2 of the same title, in the old version of ISO/TS16949.
- All previous requirement were retain in the new version with additional requirements in (b),(c), (d), and (f).
- Total requirement is therefore items a) to n) given in the clause description above.

(Compliance best practice)

8.3.5.2 Manufacturing Process Design Output

1. *The requirements stated in a) to n) given in the clause description is a requirement of the standard. They have to be met, even if not stated in customer PPAP. In practice, some flexibilities are given for non-essential analysis if justified. Example, due to the nature of the rubber parts, SPC is not required.*
2. *Project implementation, evidence and records shall be retained.*
3. *The results must match the requirements given in PPAP, PSW etc. You can do more, but not less. Design objectives stated must be met. Otherwise it is not considered as approved.*
4. *Approvals are generally given via PSW, a separate email, or onsite approval on meeting minutes, or samples etc. Some would give a purchase order, instead of approval, is still acceptable, although not so ideal.*

24) 8.3.6 D&D Changes (ISO9001)

(Clause Description-Paraphrase)

The organization shall identify, review and control changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements. The organization shall retain documented information on:

a) design and development changes;
b) the results of reviews;
c) the authorization of the changes;
d) the actions taken to prevent adverse impacts.

.

(Highlights of the clause)

- (Ref to old Standards). There had been a similar clause, 7.3.7 of same title in the previous version of ISO/TS16949.
- Previous requirements are included in this new version. New requirement is to demonstrate authorization of the change, and to take actions to prevent adverse effects.
- Total requirement are therefore given in a) to d) of clause description.

Compliance best practice

8.3.6 D&D Changes

1. *Changes occur quite frequently during design stages. They have to be controlled*
2. *Use ECN form to manage changes arising from verification, validation, review or customer requests.*
3. *You can use your own ECN form if not specified otherwise.* ***Exhibit 12-12*** *is an ECN form.*

25) 8.3.6.1 D&D Changes-supplemental (IATF16949)

(Clause Description-Paraphrase)

The organization shall evaluate all design changes after initial product approval, including those proposed by the organization or its suppliers,

a) for potential impact on fit, form, function, performance, and/or durability.

b) these changes shall be validated against customer requirements and approved internally, prior to production implementation.

c) If required by the customer, the organization shall obtain documented approval, or a documented waiver, from the customer prior to production implementation.

d) For products with embedded software, the organization shall document the revision level of software and hardware as part of the change control

(Highlights of the clause)

- (Ref to old Standards). This is a totally new requirement
- For compliance, a) to d) above shall be implemented

(Compliance best practice)

8.3.6.1 D&D Changes-supplemental

1. *This clause is about further changes after product approval*
2. *Even after initial product approval, changes may still be required, most often coming from the customers. If this happens, mass production will be delayed.*
3. *Organization shall use ECN to control changes. See* ***Exhibit 12-12***

26) 7.5.3.2.2 Engineering Specifications (IATF16949)

This clause has already been discussed in Chapter 17. Please refer.

27) SIs & FAQs

SI Nbr	IATF Clause	Description
10 *deleted*	**8.4.2.3.1 Automotive product-related software or automotive products with embedded software**	**See SI 15, issued November 2018, effective January 2019.**
15	**3.1 Terms and definitions for the automotive industry**	**embedded software** **Embedded software is a specialized programme stored in an automotive component (typically computer chip or other non-volatile memory storage) specified by the customer, or as part of the system design, to control its function(s). To be relevant in the scope of IATF 16949 certification, the part that is controlled by embedded software must be developed for an automotive application (i.e., passenger cars, light commercial vehicles, heavy trucks, buses, and motorcycles; see Rules for achieving and maintaining IATF Recognition, 5th Edition, Section 1.0 Eligibility for Certification to IATF 16949, for what is eligible for "Automotive").** **NOTE: Software to control any aspect of the manufacturing process (e.g., machine to manufacture a component or material) is not included in the definition of embedded software.** ***Rationale for change:*** *Minimize confusion regarding embedded software and what is applicable.* *Deleted IATF 16949 FAQ 10.*

FAQ	IATF Clause	Questions and Answers
25	8.3 Design and Development of products and services	**QUESTION** **What constitutes product design responsibility for an organization?** **ANSWER** If an organization receives from its customer a fully defined engineering specification for the parts it is making (make to print), the organization would not be product design responsible. Where the organization does not receive a fully defined engineering specification for the parts it is making, the organization is product design responsible. In all cases, the organization is responsible for manufacturing process design.
15	8.3.2.3 Development of products with embedded software	**QUESTION:** **What is the acceptable method to assess a supplier's software development capability?** **ANSWER:** The intent of IATF 16949, Section 8.3.2.3 is to apply the same level of rigor to the development of software as is expected in the development of hardware parts. Just like parts, software has defined performance, operating conditions, known inputs, specified outputs, parameters of environment (e.g. size of the file), regulatory requirements (if any), known failure modes, usage profiles, variability of conditions of operation, etc. The planning, designing, writing, testing, confirming and production validation phases in the development of software are not very different in concept from the development of hardware parts. IATF 16949 provides a robust framework to validate that all necessary steps have been taken to design, verify, and produce hardware parts that continue to meet specification in mass production. While similar in concept, those steps are not the same for the development of software. Therefore, a different set of criteria are used to evaluate the methods used to develop software. Those criteria are not included in IATF 16949; therefore, other methods are referred to, such as Automotive SPICE and CMMI. There may be other acceptable methods available identified by some customers. Each customer may have a preferred tool to assess supplier software development capability. The organization should ask their customer(s) to confirm the acceptable assessment tool. Each customer may also specify a different approach used (e.g., customer on-site assessment, supplier self-assessment, or a combination of both). The role of the IATF 16949 internal or external auditor is not to have the knowledge to conduct the Automotive SPICE or CMMI assessments. However, the internal or external auditor should be familiar enough with the assessments to be able to recognize when a software assessment requirement has not been met and that there are corrective action plans in place, with the

28. Supplementary Notes

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

Clause	Section	Clarification Subjects
8.3.5.2	CBP	**SN22.1. Some customers are in the habit of not giving their approval, but give a P/O. Is this OK?**
8.3.2.2	CBP	**SN22.2. What are the usual problem, with external designer?**
8.3.2, 8.3.2.1	CBP	**SN22.3. Shall I do the project schedule on another document, or can I create on same page provide by customer?**
8.3.4	CBP	**SN22.4. Where are the verification, validation, and review steps in an actual customer guided PPAP?**
8.3.5, 8.3.5.1	CBP	**SN22.5. What happen if HQ is doing a functional test, but it does not have ISO/IEC 17025?**
8.3.5.2	CBP	**SN22.6. If there are some output specified for manufacturing really not available, is it a finding?**

SN22.1. Some customers are in the habit of not giving their approval, but giving a P/O instead. Is this OK?

In real situation, IATF Auditor normally accepts. But this actually is not OK. We are taking approval as a design review. P/O can be for another trial order. In a way, IATF auditors are also representing

customers, and customers should do the correct thing. Breaking the rules here and there is just making the job of the IATF auditors difficult. They should play by the rules, just like everyone of us.

SN22.2. What are the usual problem, with external designers? How can we improve on this area?
External designers (remote location) are usually ignorant of the IATF requirement on design. They should be given a copy of the relevant procedure, because they will have to come under your QMS. Training shall also be provided. Otherwise they will come out quite badly in audit.

SN22.3. Shall I do the project schedule on another document, or can I create on same page provided by customer?
Either way is OK. Perhaps the second option is better, because you can refer to the customer schedule easily. Some OEM actually specify that way. **Exhibit 22-6** is one such example.

SN22.4. Where are the verification, validation, and review steps in an actual customer guided PPAP?
Some OEM visits in stages to assist the organization to complete the PPAP, so they are guiding the suppliers all the way. Verification and validation results are generated after each stage meeting. So verification and validation are found in every stage. Review however, is the trial meetings (both internal and external) conducted, including final approval.

If you are not lucky to have customers coming around so often, your design team should schedule verification, validation, and review internally, by conducted by the core team.

SN22.5. What happen if HQ is doing a functional test, but it does not have ISO/IEC 17025?
Onsite check on your HQ will have to take place by the IATF auditor. That will mean extra effort and cost. If the CB can arrange an auditor near your HQ to audit then you can save some cost. Alternatively, request your customer to issue a letter of acceptance.

SN22.6. If there are some output specified for manufacturing process design are really not available, is it a finding?
Technically yes. But you can explain to the IATF auditor, e.g. no new training and WI are required because the existing ones are applicable. IATF auditors do accept flexibilities based on the reasons given.

29) Exhibits

Exhibit 22-1.Team Feasibility Form from AIAG

TEAM FEASIBILITY COMMITMENT

Customer: _____ Date: _____

Part Number: _____ Part Name: _____

Revision Level _____

Feasibility Considerations

Our product quality planning team has considered the following questions.
The drawings and/or specifications provided have been used as a basis for analyzing the organizations ability to meet all specified requirements. All "no" answers are supported with attached comments identifying our concerns and/or proposed changes to enable the organization to meet the specified requirements.

YES	NO	CONSIDERATION
		Is product adequately defined (application requirements, etc. to enable feasibility evaluation?
		Can Engineering Performance Specifications be met as written?
		Can product be manufactured to tolerances specified on drawing?
		Can product be manufactured with process capability that meet requirements?
		Is there adequate capacity to produce product?
		Does the design allow the use of efficient material handling techniques?
		Can the product be manufactured within normal cost parameters? Abnormal cost considerations may include:
		- Costs for capital equipment?
		- Costs for tooling?
		- Alternative manufacturing methods?
		Is statistical process control required on the product?
		Is statistical process control presently used on similar products?
		Where statistical process control is used on similar products:
		- Are the processes in control and stable?
		- Does process capability meet customer requirements?

Conclusion

☐ Feasible	Product can be produced as specified with no revisions.
☐ Feasible	Changes recommended (see attached).
☐ Not Feasible	Design revision required to produce product within the specified requirements.

Approval

_____ Team Member/Title/Date

_____ Team Member/Title/Date

_____ Team Member/Title/Date

_____ Team Member/Title/Date

_____ Team Member/Title/Date

_____ Team Member/Title/Date

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

- This Team Feasibility Commitment format is taken from the AIAG PPAP Manual
- It provides a simple, systematic yet effective way to conduct a feasibility study by a multidisciplinary team
- The part on capacity which is only a 1-liner , and needs to have backup data
- The conclusion is important and yet some organizations will go through the rituals without making a conclusion.

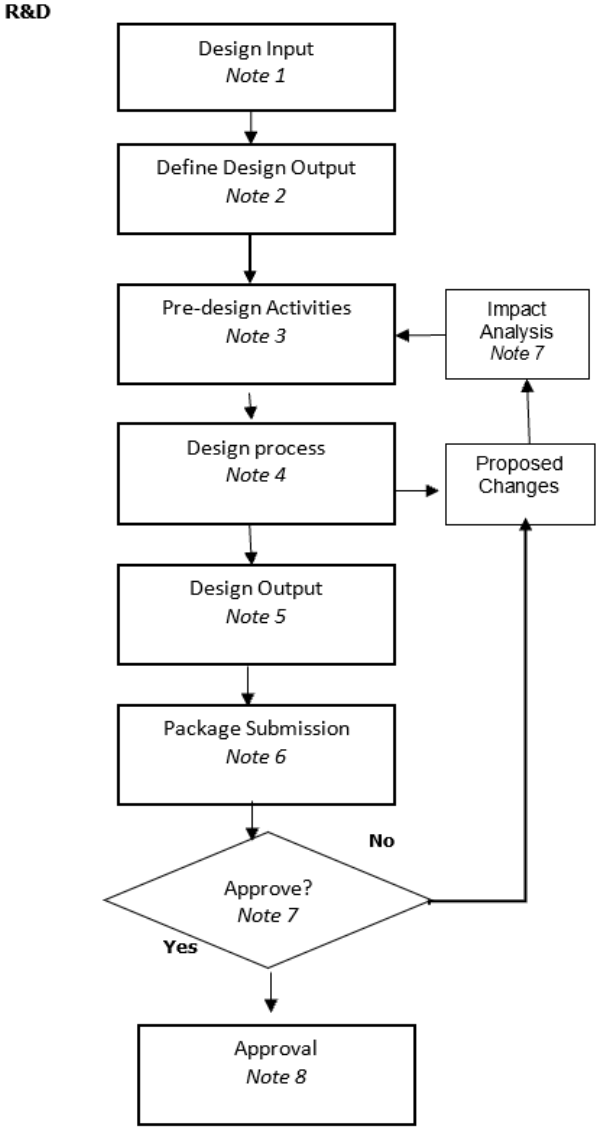
Exhibit 22-2. Capacity Study Specimen

	Total	M/C 1	M/C 2	M/C 3	M/C 4	M/C 5	M/C 6	M/C 7	M/C 8
Rated capacity. pc/hr	9000	1000	1000	1000	1000	1000	1000	1500	1500
Efficiency	-	70%	75%	80%	80%	80%	80%	90%	90%
Actual Avail capacity	**7350**	**700**	**750**	**800**	**800**	**800**	**800**	**1350**	**1350**
Current Demand									
Flextronics	3400						800	1300	1300
Signmax	1400	700	700						
Celetex	1600			800	800				
Demand Total	**6400**	**700**	**700**	**800**	**800**	**0**	**800**	**1300**	**1300**
%	87%	100%	93.3	100%	100%	0%	100%	96.3%	96.3%
Potential customer									
Newbos	1000								
Conclusion: Not to accept									

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

- There are many methods for capacity planning based on nature of the products. The above case is by machine and looks complicated. Multistep manufacturing may need to assess each step to look for bottlenecks. The tendency is customer will specify their format to be used.
- The above case is rejected by customer because: a) current demand is 87% of available capacity, b)) only M/C 5 is available but can produce 800 pc, not 1000 pc as demanded by customer
- However, if the organization can justify acceptance by: a) Improving machine efficiency, b) running overtime/run an extra shift, c) Increasing capacity (buy new machines)
- The proposed idea is subject to customer acceptance. Customer also look into other factors before approving e.g. people competency, QC and maintenance capability etc during the extra hours

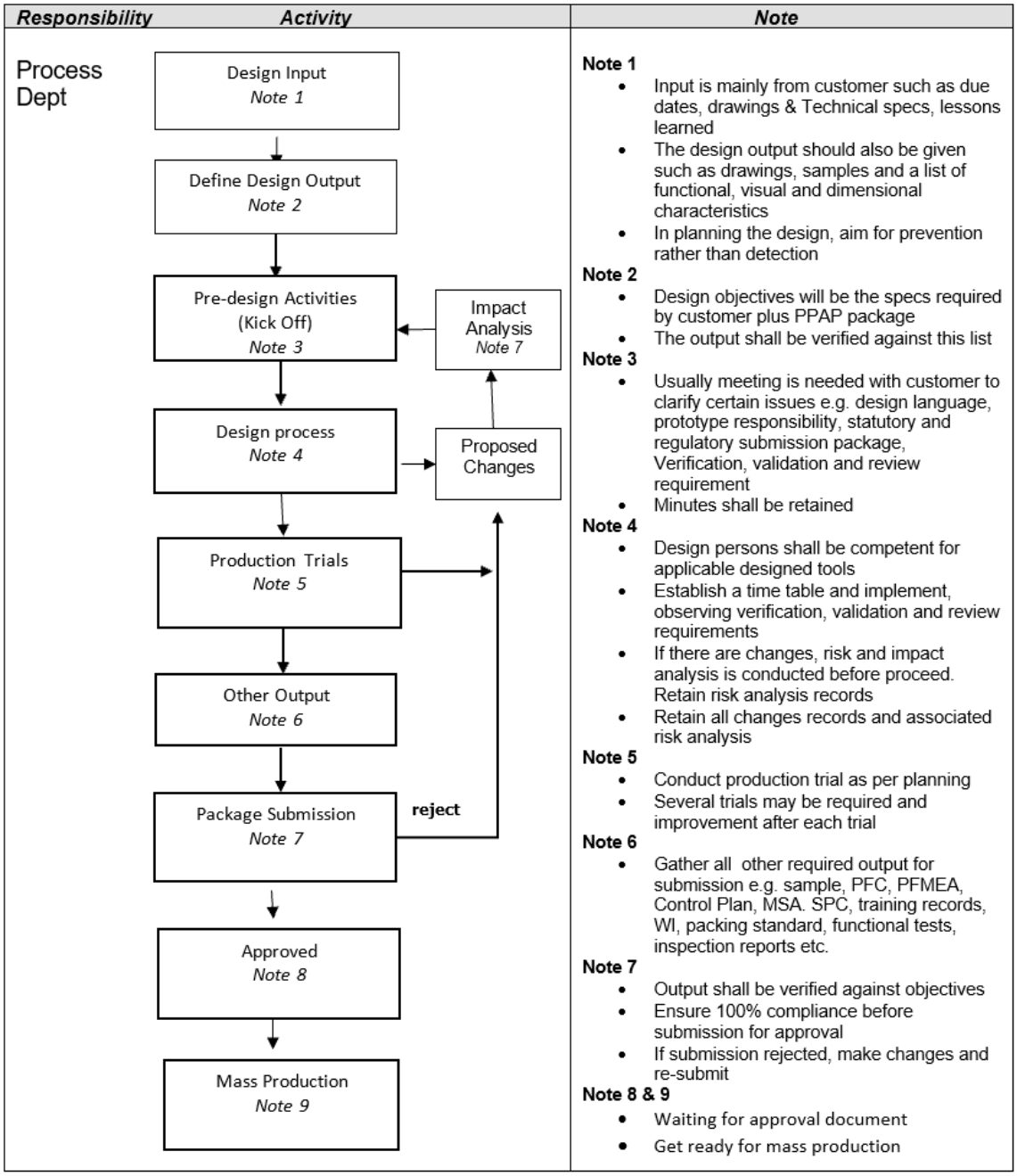
Exhibit 22-3 Product Design Process

Responsibility	*Activity*	*Note*
R&D		**Note 1** • Input is mainly from customer such as due dates, concept drawing, lessons learned • The design output should also be given such as drawings, samples and a list of functional, visual and dimensional characteristics • In planning the design, aim for prevention rather than detection **Note 2** • Summarize the intended outcome in a Design Objective List • The output shall be verified against this list **Note 3** • Usually meeting is needed with customer to clarify certain issues e.g. design language, prototype responsibility, statutory and regulatory submission package, Verification, validation and review requirement • Minutes shall be retained **Note 4** • Design persons shall be competent for applicable designed tools • Establish a time table and implement, observing verification, validation and review requirements • If there are changes, risk and impact analysis is conducted before proceed. Retain risk analysis records • Retain all changes records and associated risk analysis **Note 5** • Gather all output in the required for submission e.g. prototype, drawings 2D and 3D, DFMEA, Control Plan, functional test, visual, dimension etc. **Note 6** • Output shall be verified against objectives • Ensure 100% compliance before submission for approval **Note 7** • Follow up on approval • There may be issues with the submission which shall be attended to **Note 8** • Submit as per customer requirement • Follow up on approval • Carry out any changes required

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

- This is a specimen for product design of a plastic injection moulding company
- This general process flow is a requirement, but you need to use with a PPAP or customer guide

Exhibit 22-4 Process Design Process



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

- This is a sample of manufacturing design procedure. It is needed because it is a requirement of the standard
- The flow is rather similar to a product design
- PPAP is still required to go with this general guideline

Exhibit 22-5 DD Input & Objectives

Design Objectives

Project: XRC 11000. Hinge Bracket

Design Input	Description/Objectives	(Design Output)
PPAP/PSW	Detail requirement to be followed	100% followed. OK
Drawing/Sample	Drawings to be followed, including the 'note' items	All translated into inspection dimensions. Frequency agreed with customer. OK
Customer Schedule	Customer master scheduled to be followed	Fully followed. Customer delayed by 2 months, scheduled revised and follow customer's new schedule. OK
National Codes, standards, or Statutory Requirement	None	OK
Lessons Learnt	2 points on the welding line problems. Tested solution provided by customer.	These are points and solution have been included in FMEA and control plan. OK
Other Management Requirement	None	None. OK
Function and performance Requirement	Need salt spray test 96 hours	Provides salt spray test 96 hours for every lot. OK Test results included in PPAP. OK
Potential consequences of failure due to nature of the product and what we are expected to do	None	None. OK
Any conflicting design that needs to be resolved	None	None
Feasibility study to be done	Before start of project. Engineering and quality feasibility and capacity study for 600,000 pc/year	Feasibility and capacity done, on customer format and OK by customer

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

- The above table shows an idea on criteria on the left, target/expectations in the middle, and actual output on the right. The list can be much longer than shown here. It may also include design document e.g. DFMEA, Control Plan, final drawings, functional test reports, SOD compliance tests etc
- For product design list down all customer's critical and concern points and how they are to be fulfilled. Example functional tests, dimension or other performance targets, and appearance checks as per inspection agreement. The center column shall be completed before design. **The output will only be filled before PPAP submission to ensure 100% compliance.**
- For Process design, document may include PFMEA, Control Plan, Work Instructions, Packing standard, Inspection, RoHS /SOD analysis, Inspections reports, MSA, SPC, evidence of Lessons Learnt have been verified and validated.

Exhibit 22-6. Project Schedule

Project Schedule

Project: TCSH-RR

No	Tasks	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dev
	(Customer master Schedule)												
1	---2												
2	Trail									15/9			
3	--												30/12
4	Maspro												
	(Organization Project Schedule)												
1	Drawings, data , PSW from customer												
2	Lessons learned from internal records												
3	Team Feasibility Commitment, including capacity study												
4	Process Flow Chart												
5	Design objectives												
6	PFMEA												
7	Control Plan for Pilot Trial												
8	WI, Inspection plans, packing instructions, preparation, SC management												
9	Operator Training												
10	Trial Runs (together with customer)				1/4		1/6		1/8				
11	Results compilation, FA, revised FMEA, Control Plan, revised WI, MSA, CpK, Supplier list, CSR list, shopfloor planning, checking aids, as agreed with customer												
12	PPAP submission according to customer requirement										x		
13	Approval												
14	Mass Production											1/11	

Remarks given in this section explain on the Exhibit. Do not include them as part of your working document

- This is a specimen of project planning. It is done on hardcopies. There are also customers that require you to upload onto their portals e.g. BMW
- In this example, the customer master schedule is placed on top, upon which the organization will plan theirs to meet important deadlines such as trial and mass production
- The PPAP requirements are listed down from item 1) to 14) in this particular case

>> End of Chapter 22 <<

Chapter 23. Production and Process Control

Contents:

0) Introduction

This chapter is about production, and there are a lot of requirements. Control Plan is now placed in production area of application, instead of design in the previous version. Control Plan now must also control a few more loose areas e.g. start up and use of alternative methods. Process Effectiveness and Efficiencies, with some redefinitions via SI-12, has been discussed in Chapter 14, and they have to be reported in Management Review. Some focussed discussions are therefore necessary.

1) 8, 8.1 Operation planning and control (ISO9001)

(Clause Description-paraphrase)

A process is needed to meet the requirements for the provisions of products and services, and to implement actions determined in clause 6. The organization shall:

a) determine the requirements for the products and services
b) establish criteria for 1) the processes, 2) the acceptance of products and services
c) determine resources needed to achieve conformity to the products and service requirements
d) implement control of the processes in accordance with the criteria
e) determining, maintaining and retaining documented information to demonstrate: 1) confidence that the processes have been carried out as planned 2) conformity of products and services to their requirements

The organization shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adversary effects. The organization shall ensure outsources process are controlled.

(Highlights of the clause)

- (Ref to old Standards). There was a similar clause, 7.1 Planning of Product Realization, in the previous version of ISO/TS16949.
- The requirements were rewritten but the gist had generally remained.
- Additional emphasis is noted on resources, control on unintended changes and outsourcing.
- Total requirements are a) to e) given in the clause description above.

(Compliance best practice)

8, 8.1 Operation planning and control

1. *This is a concept clause, actual implementation will be carried out by many departments.*
2. *You are only required to understand the intent and ensure compliance. There is generally no need to produce any additional documentation here as evidence.*

2) 8.1.1 Operation planning and control-supplemental (IATF16949)

(Clause Description-paraphrase)

When planning for product realization, the following topics shall be included:

(a) Customer product requirement and technical specifications,

(b) Logistics requirements

(c) Manufacturing feasibility,

(d) Project planning,

(e) Acceptance criteria

(Highlights of the clause)

- (Ref to old Standards). There had been a similar clause, 7.1.1 Planning of product realization-supplemental, in the previous version of ISO/TS16949.
- It has been expanded substantially. In the last version, it only mentioned point (a), the rest are therefore new additions.

(Compliance best practice)

8.1.1 Operation planning and control-supplemental

1. *All the requirements (a) to (e) of the Clause Description above, must be complied*
2. *As stated in 8.1, this is really a concept clause. IATF would unlikely be checking these items on the shop floor or elsewhere.*
3. *Point (a) can be found in Customer PPAP or APQP documentation. You need to show how product requirements and technical specs are based on*
4. *Logistics (point b) generally means packing and delivery requirement.*
5. *Manufacturing feasibility (point c) is evaluation of a product or project by a multifunctional team. This should be already part of the PPAP package. See* ***Exhibit 22-1***
6. *Project planning (point d) should also be part of PPAP. However, project timing are often subject to changes, so you should produce the latest version.*
7. *Acceptance criteria (Point e) are either given in the quality agreement, or customer acceptance of your control plan, wherever are stated*

3) 8.5, 8.5.1 Control of production and service provision (ISO9001)

(Clause Description-Paraphrase)

The organization shall implement production and service provision under controlled conditions. Controlled conditions shall include, as applicable:

a) the availability of documented information that defines:

1) the characteristics of the products to be produced, the services to be provided, or the activities to be performed;

2) the results to be achieved;

b) the availability and use of suitable monitoring and measuring resources;
c) the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met;
d) the use of suitable infrastructure and environment for the operation of processes;
e) the appointment of competent persons, including any required qualification;
f) the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;
g) the implementation of actions to prevent human error;
h) the implementation of release, delivery and post-delivery activities.

NOTE Suitable infrastructure includes appropriate manufacturing equipment required to ensure product compliance. Monitoring and measuring resources include appropriate monitoring and measuring equipment required to ensure effective control of manufacturing processes.

(Highlights of the clause)

- (Ref to old Standards).There had been similar clauses, 7.5, 7.5.1 Control of Production and Service Provision, in the previous version of ISO9001.
- Previous requirements in retained in a), b), c) and h)
- Additional requirements include provision of appropriate infrastructure and work environment, competency, validation, and taking steps to prevent human error.
- The scope is wide and common to find a deviation which falls into this clause. It may be found anywhere, from receiving to outgoing. Need to train your people at various stations to ensure compliance. You should also arrange frequent checks

(Compliance best practice)

8.5, 8.5.1 Control of production and service provision

1. *This is a concept clause, actual implementation will be carried out by many fronts.*
2. *You are only required to understand the intent and ensure compliance. There is generally no need to produce any additional documentation as evidence.*

4) 8.5.1.1 Control Plan (IATF16949)

This clause has already been discussed in detail in Chapter 21, Core tools. Please refer.

5) 8.5.1.2 Standardized work-operator instructions and visual standards (IATF16949)

(Clause Description-Paraphrase)

The organization shall ensure that standardised work documents are: a) communicated to and understood by the employees who are responsible for performing the work; b) legible; c) presented in the language(s) understood by the personnel responsible to follow them; d) accessible for use at the designated work area(s). The standardised work documents shall also include rules for operator safety.

(Highlights of the clause)

- (Ref to old Standards). There had been a similar clause, 7.5.1.2. Work Instructions.
- The old requirement were: “The organization shall prepare documented work instructions for all employees having responsibilities for the operation of processes that impact product quality. These instructions shall be accessible for use at the work station. These instructions shall be

derived from sources such as the quality plan, the control plan and the product realization process"

- The old requirement was not mentioned but should be taken as still valid
- The new version added new requirements, a) to d). Note that safety rules shall be part of the WI.

(Compliance best practice)

8.5.1.2 Standardized work-operator instructions and visual standards

1. *To comply, a) to d) of Clause Description above shall be implemented*
2. *IATF auditors can easily check this in a) PPAP audit, b) production line audit.*
3. *Include in your WI, a language the operator can understand. Also include the safety precautions where apply. See* ***Exhibit 23-1.***

6) 8.5.1.3 Verification of job set-up (IATF16949)

(Clause Description-Paraphrase)

The organization shall: a) verify job set-ups when performed, such as an initial run of a job, material changeover, or job change that requires a new set-up; b) maintain documented information for set-up personnel; c) use statistical methods of verification, where applicable; d) perform first-off/last-off part validation, as applicable; where appropriate, first-off parts should be retained for comparison with the last-off parts; where appropriate, last-off-parts should be retained for comparison with first-off parts in subsequent runs; e) retain records of process and product approval following set-up and first-off/last-off part validations

Exhibit 8-21 First piece, IPQC and last piece.

(Highlights of the clause)

- (Ref to old Standards). There had been a similar clause, 7.5.1.3 of the same title, in the previous version of ISO/TS16949.
- The previous version was simple: "Job set-ups shall be verified whenever performed, such as an initial run of a job, material changeover or job change. Work instructions shall be available for set-up personnel. The organization shall use statistical methods of verification where applicable"
- The new version emphasis on use of first and last off, and retention of the parts for comparisons.
- The verification data shall be recorded and product and process approval

(Compliance best practice)

8.5.1.3 Verification of job set-up

1. *The line and machine setting need to be checked before start-up and recorded. The design settings or parameters are usually available onsite for reference. But seldom recorded, because organizations have not caught on to this new requirement. It is time to get on board now.*
2. *From this confirmation, the first-off parts are sent for buy-off verification by QC.*
3. *Last piece is only where applicable, so it is still optional*

7) 8.5.1.4 Verification after shutdown (IATF16949)

(Clause Description-Paraphrase)
The organization shall define and implement the necessary actions to ensure product compliance with requirements after a planned or unplanned production shutdown period.

(Highlights of the clause)

- (Ref to old Standards). This is a totally new requirement.
- The requirement is about conducting a setup verification and first-off buy-off if production was interrupted (planned or unplanned), resulting in a long stoppage.
- Some of the events that can cause the above are: mould down for repair, and maintenance, unplanned shutdown, planned but long shutdown, emergency drills etc.

(Compliance best practice)

8.5.1.4 Verification after shutdown

1. *When long stoppage occurs, whether planned or otherwise, the products may deteriorate over time. Therefore a repeat buy-off is needed.*
2. *Before resuming mass production, the process and machine setting shall be verified again, followed by first-piece buyoff.*
3. *The above 2 steps must be incorporated in the production or QC procedures.*

8) 8.5.6 Control of changes (ISO9001)
This clause has been discussed in Chapter 12. Please refer

9) 8.5.6.1 Control of changes-supplemental (IATF16949)
This clause has been discussed in Chapter 12. Please refer

10) 8.5.6.1.1 Temporary Change of Process Controls (IATF16949)
This clause has been discussed in Chapter 12. Please refer

11) 5.1.1.2 Process Effectiveness & Efficiency (IATF16949)
(Clause Description-Paraphrase)
Top management shall review the product realization processes effectiveness and efficiency of the quality management system and support processes to evaluate and improve their effectiveness and efficiency the organization's quality management system. The results of the process review activities shall be included as input to the management review.

(Highlights of the clause)

- (Ref to old Standards). There had been a similar clause, 5.1.1 Process efficiency, in the previous version of ISO/TS16949. It was a very simple requirement of 1 sentence: Top management shall review the product realization processes and the support processes to assure their effectiveness and efficiency.
- The new requirement needs the organization to review QMS processes' effectiveness and efficiency of the quality management system.
- This clause has been revised by SI-12 to be a non-production clause. The earlier requirement to review product realization processes and the support processes are deleted from the clause. Fortunately, SI-13, added back requirement for process efficiency to be studied. Otherwise it will be a point of conflict with 7.1.3.1 and 9.1.1.1.

(Compliance best practice)

5.1.1.2 Process Effectiveness & Efficiency

1. *This clause is now both for overall QMS and Production control (SI-13). QMS control has been discussed in Chapter 11. The production control portion is discussed here.*
2. *A process study shall be conducted periodically for efficiency study, to ensure the committed targets are achieved. See* ***Exhibit 23-3.*** *The acceptable frequency is annually.*
3. *The study should be based on risk and conducted on some indicators on manufacturing processes e.g. cycle time, output, capacity utilization, yield and scraps etc can be used.*

12) SIs & FAQs

SI Nbr	IATF Clause	Description
12	**5.1.1.2 Process effectiveness and efficiency**	Top management shall review the ~~**product realization processes**~~ **effectiveness and efficiency of the quality management system** ~~**and support processes**~~ to evaluate and improve ~~**their effectiveness and efficiency**~~ **the organization's quality management system**. The results of the process review activities shall be included as input to the management review (see Section 9.3.2.1.). ***Rationale for change:*** *Clarified that not every process requires an efficiency measure. The organization needs to determine which processes require efficiency measures within their quality management system. Additionally, the organization's problem-solving processes need to have an effectiveness review conducted by the organization's management.*

FAQ	IATF Clause	Questions and Answers

NUMBER	IATF 16949 REFERENCE	QUESTIONS AND ANSWERS
23	**8.5.1.3 Verification of job set-ups**	**QUESTION:** **If first-off/last-off part validation is not performed or appropriate for a specific type of manufacturing process, are such records to be maintained per 8.5.1.3 e)?** **ANSWER:** As stated in 8.5.1.3 d), first-off/last-off part validation is performed only when it is applicable and appropriate. Where the validation is not performed because it is not applicable or appropriate, there is no requirement to maintain records.

13) Supplementary Notes

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

Clause	Section	Clarification Subjects
8.5.1	CBP	**SN23.1 How we can avoid findings on 8.5.1, Process control?**
8.5.1.2	CBP	**SN23.2. Is it really necessary to change all control plan to the new requirement, as some of parts are not active and going for EOL (end-of-life) soon. And it is also difficult to change all WI, to include safety precautions, within short period.**
8.5.1.3	CBP	**SN23.3 Is first-off verification equivalent set up verification?**
8.5.1.3	CBP	**SN23.4. Are there still people referring to WI to set up, instead of recording the set up?**

8.5.1.3	CBP	**SN23.5. Should first piece be conducted by production or QAQC people?**
5.1.1.2	CBP	**SN23.6. Can I show routine data e.g OEE, instead of running special process study?**

SN23.1 How we can avoid findings on 8.5.1, Process control?

Honestly it is difficult, due to the wide scope under audit. And IATF auditors are required to spend about 35% of their audit time in this area. You can lessen the likelihood, by being thorough with you internal audit and manufacturing process audit. Find the weaknesses and improve them before the IATF auditors arrive.

SN23.2. Is it really necessary to change all control plan to the new requirement, as some of parts are not active and going EOL (end-of-life) soon. And it is also difficult to change all WI, to include safety precautions, within short period.

Technically yes, you need to change all. But you can do something here to lessen the stress. Change the Control Plans and WI for the new and active parts first. You can put up a schedule to show a plan to eventually change all the active parts; and IATF auditors should be able to accept. If an inactive part is suddenly required to be produced, you can quickly change the Control Plan and WI. This JIT method should save you a lot of time.

SN23.3 Is first-off verification equivalent setup verification?

No. First-off verification is on the characteristics of the product being produced. Setup verification is about the settings of the process or machines and facilities. First-off verification results will also decide if the process/machine setting is correct. The two things go as a pair, before mass production**.**

SN23.4. Are there still people referring to WI to set up, instead of recording the set up?

Yes, but getting rare. For some simple intermediate steps, this may be most practical and still acceptable. IATF Auditors would not be too rigid on this.

SN23.5. Should first piece be conducted by production or QAQC people?

For independence, it is better to be done by QAQC people. In most cases, both production and QAQC are doing it. The production people will be checking while running the first-offs. Once it is stabilized, samples are sent to QAQC to formally buy-off.

SN23.6. Can I show routine data e.. OEE, instead of running special process study?

No, that is not the intent of ISO/IATF. They want you to zero in on weak links to do some improvement. Overall data like OEE will mask off a lot of weaknesses, especially when it is achieving the target set.

14) Exhibits

Exhibit 23-1 WI with safety caution, and in local language

Work Instruction			
Part Name: Starter	Date: 16/07/05	Description : Carbon Assembly	Rev No : 0
Doc No : WI-STR-012	Page 1 of 2	Approval By :	

	Description	Safety Precaution
	Step 1. Remove old carbon Buangkan Carbon yang lama dengan cutter kalau tidak cukup pajang atau rosak.	 
	Step 2. Prepare surface for spot welding Pakai Machine Grinner membersihkan tempat yang nak "Spot Welding".	 
	Step 3. Sport weld new carbon on carbon holder "Spot Welding" Carbon baru ke atas Carbon Holder. Pastikan Carbon di ada tempat yang betul dan lekat.	 

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

- This is a specimen that WI is written in the local language, that operators can understand
- Safety instructions is also given at every step

Exhibit 23-2 Manufacturing Process Efficiency Study (Process Study)

Date 12 Feb 2020			
Process/Machine Selected: Blow Moulding Machine LX180		Customer: VFM Motors	
Commitment with customer Customer: 1600 pc per day (2 shifts)		Internal efficiency target: 120 pc per hour (rate 135 pc/hour)	Study Period Full year 2019
Actual Performance		To customer	Internal Target
1	Commitment	1600 pc/day (2 shifts)	120 pc/hour
2	Actual	465000 pc/ year	465000/5400 hours
3	Analysis	1550 pc/day	103 pc/ hour
4	Performance	96.9%	85.8%
5	Variation	-3.1%	-14.2%
	Judgement+/-5%	OK	NG
6	New Target	Expect to increase to 1800 pc	130 pc/hour

Recommendations

1. To increase output rate of machine to 130 pc/hour, so that operations can be within 2 shifts for better efficiency
2. Need an improvement project

Results (list out the data generated from the study, or include as attachment

- Study done in Mar to Jun 2020. Can raise output to 125 pc/day.
- Main strategy is to reduce breakdown, by improving maintenance
- Project report attached.

Conclusion

Project is successful. Efficiency is improved by 21.3%.1.

We to increase better machine maintenance to 3 month preventive maintenance, instead of 6 months. Preventive maintenance can be done over the weekend

Management Comments

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

- The above case is monitoring of committed production capacity as per contract. It may also be conducted on process capability Cpk, or something equivalent.
- This case shows some improvement needed as the orders are expect to increase, and internal efficiency is somewhat lacking. An improvement project followed
- There may be cases where performances are satisfactory, no improvement actions will then be acceptable

>> End of Chapter 23 <<

Chapter 24. Purchasing and Control of External Providers

Contents:

0) Introduction

This is another long chapter. Purchasing and outsourcing are becoming very important in manufacturing and therefore deserve more attention. This area has seen the inclusion of many new clauses. IATF auditors tend to spend a lot of time here, besides on the production floor. A good understanding of the requirement is therefore recommended.

1) 8.4, 8.4.1Control of Externally Provided processes, products and services (ISO9001)

(Clause Description-Paraphrase)

The organization shall ensure that externally provided processes, products and services conform to requirements. The organization shall determine the controls to be applied to externally provided processes, products and services when: (a) products and services from external providers are intended for incorporation into the organization's own products and services; (b) products and services are provided directly to the customer(s) by external providers on behalf of the organization; (c) a process, or part of a process, is provided by an external provider as a result of a decision by the organization.

The organization shall determine and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. The organization shall retain documented information of these activities and any necessary actions arising from the evaluations

(Highlights of the clause)

- (Ref to old Standards). There was a similar clause, 7.4.1 Purchasing Process, in the previous version ISO/TS16949.

- In the old version, it requires the organization to purchase conforming to requirements. Controls on the supplier and purchased products shall depends on impact to quality. Supplier's selection is on their ability to supply products to requirement.
- It also required Criteria for selection, evaluation, and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained
- All the previous requirements are retained in the new clause, and expanded.
- The new clause expands the scope the various type of external provided products and services that need control. See a) to c)
- Extend of control depending on impact somehow has been removed.
- Note that there is a change of terminology: suppliers are now referred to as "external providers"

(Compliance best practice)

8.4, 8.4.1 Control of Externally Provided processes, products and services

1. *This requirements is for ISO9001.*
2. *To comply with ISO9001, 2 important documents are (a) approved supplier list, (b) re-evaluation results. A procedure on supplier selection will make full compliance.*
3. *There is also a lot of latitude allowed for ISO9001, as to what suppliers to control and how to control.*
4. *As this discussion is written for automotive, follow the next clause 8.4.1.1 and other IATF clauses below, for compliance*

2) 8.4.1.1 General-supplemental (IATF16949)

(Clause Description-Paraphrase)

The organization shall include all products and services that affect customer requirements such as subassembly, sequencing, sorting, rework, and calibration services in the scope of their definition of externally provided products, processes, and services.

(Highlights of the clause)

- (Ref to old Standards). This was part of the old 7.4.1, now elevated to be a clause.
- The Clause compliance is straightforward and does not need much clarification.
- Total compliance will include 8.4.1 and 8.4.1.1. The latter spells out what areas can be outsourced or purchased.
- Take note that calibration shall be managed like materials and services.

(Compliance best practice)

8.4.1.1 General-supplemental

1. *The clause spells out the controls you must have on external providers, including outsourcing*
2. *Your approved supplier list **(Exhibit 24-1)** shall have all suppliers involved for: direct materials, indirect materials, critical services e.g. calibration, transportation and maintenance services for critical machines.*
3. *With the new version, there are a lot emphasis on safety, and statutory and regulatory compliances.*
4. *You should start to grade your suppliers to meet the requirements of the new IATF version.. The recommended grading is: A: Safety-Related, B: Regulatory-Related, C: Quality-Critical, D: Normal Purchases.*

3) 8.4.1.2 Supplier Selection Process (IATF16949)

(Clause Description-Paraphrase)

The organization shall include all products and services that affect customer requirements such as subassembly, sequencing, sorting, rework, and calibration services in the scope of their definition of externally provided products, processes, and services. Supplier selection process The organization shall have a documented supplier selection process. The selection process shall include:

a) an assessment of the selected supplier's risk to product conformity and uninterrupted supply of the organization's product to their customers;

b) relevant quality and delivery performance;

c) an evaluation of the supplier's quality management system;

d) multidisciplinary decision making; and

e) an assessment of software development capabilities, if applicable.

Other supplier selection criteria that should be considered include the following: volume of automotive business (absolute and as a percentage of total business); — financial stability;

— purchased product, material, or service complexity;

— required technology (product or process);

— adequacy of available resources (e.g., people, infrastructure);

— design and development capabilities (including project management); manufacturing capability;

— change management process;

— business continuity planning (e.g., disaster preparedness, contingency planning); logistics process;

— customer service.

(Highlights of the clause)

- (Ref to old Standards). Selection of suppliers was part of 7.4.1 in the old version of ISO9001/IATF16949. It has been elevated to be a clause on its own.
- The Clause although long, is quite straightforward and does not need much clarification.
- There are 2 sets of requirements. Point a) to e) are 'shall' items and must be available for selection decision.
- The second part of criteria are "should" items. It is in your discretion whether to obtain those information. A point to highlight is you must have a documented criteria for supplier selection

(Compliance best practice)

8.4.1.2 Supplier Selection Process

1. *You should use a supplier application form, or equivalent, to process supplier selection. All the requirements can be listed down in the form. This can be filled by supplier and returned. It can then be verified by your team, and recommendations made for management approval. See **Exhibit 24-2** for a specimen.*
2. *For suppliers producing parts to your specs, onsite audits shall be part of the evaluation. The onsite audit report shall be attached to the documents for decision making.*
3. *For suppliers who are just distributors for some well-known manufacturers e.g. resins from Dupont, onsite audit may not be required. Product specs and manufacturer's ISO9001 cert should suffice.*
4. *You now need to include in your documentation how the decisions are made (e.g. on point system).*

4) 8.4.1.3 Customer-directed sources (also known as "direct-buy" (IATF16949)

(Clause Description-Paraphrase)
When specified by the customer, the organization shall purchase products, materials, or services from customer-directed sources. All requirements of Section 8.4 (except the requirements in IATF 16949, Section 8.4.1.2) are applicable to the organization's control of customer-directed sources unless specific agreements are otherwise defined by the contract between the organization and the customer.

(Highlights of the clause)

- (Ref to old Standards). There had been a similar clause, 7.4.1.3. Customer-approved sources, in the previous version of ISO/TS16949.
- The requirements were retained in concept with different wordings
- The requirement now is “comply to customer specification on suppliers, if directed so, control of the directed- supplier is still organization's , unless there is an agreement between you and the customer stating otherwise”
- Note that although the supplier is nominated by the customer, the responsibility of ensuring their performance still belong to the organization

(Compliance best practice)

8.4.1.3 Customer-directed sources (also known as “direct-buy”)

1. *This type of suppliers are nominated by customer and you need to abide*
2. *But take note that the responsibility to ensure quality and service is still yours. So they have to be managed just like any other type of suppliers*
3. *You need to provide evidence that a supplier is nominated, if there are no selection records. Email records, vendor meeting, project meeting etc should be retained. Otherwise you risk getting a finding*

5) 8.4.2 Type of extend of control (ISO9001)

(Clause Description-Paraphrase)
The organization shall ensure that externally provided processes, products and services do not adversely affect the organization’s ability to consistently deliver conforming products and services to its customers. The organization shall:
a) ensure that externally provided processes remain within the control of its quality management system;
b) define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;
c) take into consideration: 1) the potential impact of the externally provided processes, products and services on the organization’s ability to consistently meet customer and applicable statutory and regulatory requirements; 2) the effectiveness of the controls applied by the external provider;
d) determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements

(Highlights of the clause)

- (Ref to old Standards). This is a totally new requirement.
- This is concept clause, but the requirement spelt out in a) to d) shall be complied to
- For control, the extend is based on risks

(Compliance best practice)

8.4.2 Type of extend of control

1. *The requirement spelt out in a) to d) of the clause description, shall be complied*
2. *To comply with this clause, external providers shall be evaluated. You can evaluate them on a real-time basis, i.e. with every delivery. You can also evaluate them on a fixed timing say, quarterly, 6-montly, annually. You need to do a summary for management review. See **Exhibit 24-3**.*

6) 8.4.2.1 Type of extend of control-supplemental (IATF16949)

(Clause Description-Paraphrase)

The organization shall have a documented process to identify outsourced processes and to select the types and extent of controls used to verify conformity of externally provided products, processes, and services to internal (organizational) and external customer requirements.

The process shall include the criteria and actions to escalate or reduce the types and extent of controls and development activities based on supplier performance and assessment of product, material, or service risks.

(Highlights of the clause)

- (Ref to old Standards). This is a totally new requirement.
- A doc process needed to identify outsourced processes and to select types and extend of controls.
- SN Then use to controls. Incorporating requirement can be both yours and customers.

(Compliance best practice)

8.4.2.1 Type of extend of control-supplemental

1. *This clause is specially on control of outsourcing*
2. *Organization should spell out the controls required, in a documented information e.g. Procedure, Compliance Matrix etc. This is however seldom seen. See **Exhibit 24-4** for a specimen.*
3. *Internal and customer requirements shall be included in the controls. Control priority shall be based on risk and supplier performance*
4. *The automotive critical criteria shall also be monitored: premium freight, customer disruption and special status notification. See **Exhibit 22- 7.***

7) 8.4.2.2 Statutory and regulatory requirements (IATF16949)

This clause has been discussed in Chapter 19. Please refer

8) 8.4.2.3 Supplier QMS development (IATF16949)

(Clause Description-Paraphrase)

The organization shall require their suppliers of-automotive products and services to develop, implement, and improve a quality management system certified to ISO 9001, unless otherwise authorized by the customer [e.g., item a) below], with the ultimate objective of becoming certified to this Automotive QMS Standard.

Unless otherwise specified by the customer, the following sequence should be applied to achieve this requirement:

a) compliance to ISO 9001 through second-party audits;

b) certification to ISO 9001 through third-party audits; unless otherwise specified by the customer,
c) certification to ISO 9001 with compliance to other customer-defined QMS requirements (such as Minimum Automotive Quality Management System Requirements for Sub-Tier Suppliers [MAQMSR] or equivalent) through second-party audits;
d) certification to ISO 9001 with compliance to IATF 16949 through second-party audits;
e) certification to IATF 16949 through third-party audits (valid third-party certification of the supplier to IATF 16949 by an IATF-recognized certification body).

(Highlights of the clause)

- (Ref to old Standards). There had been a similar clause, 7.4.1.2 of the same title, in the previous version of ISO/TS16949. .
- Previous requirements are retained, with more methods provided. See clause details above. However, Option a) has been removed by SI-8. Suppliers therefore shall have min ISO9001certification by accredited CB, unless waiver given by customer.
- There are also some other minor modifications of the clause by SI-8. Refer below for details.

(Compliance best practice)

8.4.2.3 Supplier QMS development

1. *To demonstrate all relevant suppliers are certified to ISO/IATF, you need copies of their current certificates.*
2. *Check if the certificates are genuine otherwise it is a finding. In recent years, there are certificates issued from unaccredited CB. And of late, there are also fake AB (Accreditation Body). Accredited AB are generally the national standards organizations of each member state (country), and within the IAF. You need to check the CB, and AB to see if they are traceable back to IAF. See* ***Exhibit 24-5.***
3. *You also need to check if suppliers have actually been audited every year. Ask for the audit report to make sure it is still valid. See* ***SN23-10*** *for explanation.*

9) 8.4.2.3.1 Automotive product-related software or automotive products with embedded software (IATF16949)

(Clause Description-Paraphrase)

The organization shall require their suppliers of automotive product-related software, or automotive products with embedded software, to implement and maintain a process for software quality assurance for their products. A software development assessment methodology shall be utilized to assess the supplier's software development process. Using prioritization based on risk and potential impact to the customer, the organization shall require the supplier to retain documented information of a software development capability self-assessment.

(Highlights of the clause)

- (Ref to old Standards). This clause is totally new
- Refer chapter 19 for background info. 8.4.2.3 This is a job done by design team, The clause same, expect responsibility by suppliers
- to check supplier's software development process. Don by done by supplier
- Self- assessment using responsibility to be supplier

(Compliance best practice)

8.4.2.3.1 Automotive product-related software or automotive products with embedded software

This has been discussed in Clause 8.3.2.3, Chapter 22. Please refer.

10) 8.4.2.4 Supplier monitoring (IATF16949)

(Clause Description-Paraphrase)

The organization shall have a documented process and criteria to evaluate supplier performance in order to ensure conformity of externally provided products, processes, and services to internal and external customer requirements.

At a minimum, the following supplier performance indicators shall be monitored:

a) delivered product conformity to requirements;

b) customer disruptions at the receiving plant, including yard holds and stop ships;

c) delivery schedule performance;

d) number of occurrences of premium freight.

If provided by the customer, the organization shall also include the following, as appropriate, in their supplier performance monitoring:

e) special status customer notifications related to quality or delivery issues;

f) dealer returns, warranty, field actions, and recalls.

(Highlights of the clause)

- (Ref to old Standards).There was a similar clause 7.4.3.2, of the same title, in the previous version of ISO/TS16949.
- The 3 critical controls for customer satisfaction from the previous lists are listed as: b) customer disruption, d) premium freight, e) special status remained to be controlled
- a) and b) are common KPI for purchasing. Item f) probably refers to OEM only.
- Note that for b), yard holds and stop ships are considered as customer interruptions
- Essentially only b) d) and e) needs to be ensure reporting

(Compliance best practice)

8.4.2.4 Supplier monitoring

1. *You need to ensure the 3 critical automotive criteria are fulfilled: b) d) and e) of clause description. Note that the tracking shall be 'event-count' and not 'value'.*
2. *This tracking is important, as the results will be used for supplier performance evaluations. See* ***Exhibit 24-6.***
3. *There is also a similar set of controls by the sales department, but that is monitoring on your own performance to satisfy the customers. However, you can derive your supplier control data from there.*

11) 8.4.2.4.1 Second-party audits (IATF16949)

(Clause Description-Paraphrase)

The organization shall include a second-party audit process in their supplier management approach. Second-party audits may be used for the following:

a) supplier risk assessment;

b) supplier monitoring;

c) supplier QMS development;

d) product audits;
e) process audits.

Based on a risk analysis, including product safety/regulatory requirements, performance of the supplier, and QMS certification level, at a minimum, the organization shall document the criteria for determining the need, type, frequency, and scope of second-party audits.

The organization shall retain records of the second-party audit reports. If the scope of the second-party audit is to assess the supplier's quality management system, then the approach shall be consistent with the automotive process approach.

NOTE Guidance may be found in the IATF Auditor Guide and ISO 19011.

(Highlights of the clause)

- (Ref to old Standards).This is a totally new requirement.
- The audit can be used to check on several purposed, see a) to e)
- Criteria for need, type, frequency, and scope of second-party audits.
- Retain audit records and follow up action
- If for general QMS audit, then automotive process audit shall be used
- Meaning if the audit is not for the entire QMS, the audit method can differ.

(Compliance best practice)

8.4.2.4.1 Second-party audits

1. *Clause 8.4.2.4.1 is written quite fragmentedly, a Supplier Audit Model is proposed to linked up the various requirements for systematic management. Clause 8.4.2.5 can also be included. See **Exhibit 24-7** for details.*
2. *Other useful specimens for this clause:*
   a) *Second-party Audit Schedule **Exhibit 24-8.***
   b) *Second Party audit report **Exhibit 24-9***
   c) *Specific objectives audit report checklist **Exhibit 24-10***
   d) *General QMS audit report checklist/Self-audit checklist **Exhibit 24-11***

12) 8.4.2.5 Supplier Development (IATF16949)

(Clause Description-Paraphrase)

The organization shall determine the priority, type, extent, and timing of required supplier development actions for its active suppliers. Determination inputs shall include but are not limited to the following:

a) performance issues identified through supplier monitoring (see Section 8.4.2.4);
b) second-party audit findings (see Section 8.4.2.4.1);
c) third-party quality management system certification status;
d) risk analysis. The organization shall implement actions necessary to resolve open (unsatisfactory) performance issues and pursue opportunities for continual improvement.

(Highlights of the clause)

- (Ref to old Standards). This is a totally new requirement.
- Active suppliers based on needs from a) to d)

(Compliance best practice)

8.4.2.5 Supplier Development

1. *This area of development is on improvement of weaknesses found*
2. *There are many sources and areas to cover. To be realistic, you need to be pragmatic, as you do not have much time for this.*
3. *Just select areas of weaknesses that relate to your problem now, e.g. request a supplier to improve their problem-solving knowledge. You may tell them to attend an external training. And you visit to follow-up and verify improvement.*

13) 8.4.3 Information for external providers (ISO9001)

(Clause Description-Paraphrase)

The organization shall ensure the adequacy of requirements prior to their communication to the external provider. The organization shall communicate to external providers its requirements for:

a) the processes, products and services to be provided;

b) the approval of:

1) products and services;

2) methods, processes and equipment;

3) the release of products and services;

c) competence, including any required qualification of persons;

d) the external providers' interactions with the organization;

e) control and monitoring of the external providers' performance to be applied by the organization;

f) verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises.

(Highlights of the clause)

- (Ref to old Standards).There had been a similar clause, 7.4.2 Purchasing Information, in the previous version of ISO9001.
- Last time a) c). QMS requirement not mentioned, but expected
- This is meant to inform suppliers of the requirements a) to f)

(Compliance best practice)

8.4.3 Information for external providers

1. *P/O normally has product description, quantity, price and expected date of delivery.*
2. *Other information given a) to f) of Clause Description, are generally contained in contracts, and therefore there is no need to repeat them on the P/O.*

14) 8.4.3.1 Information for external providers-supplemental (IATF16949)

(Clause Description-Paraphrase)

The organization shall pass down all applicable statutory and regulatory requirements and special product and process characteristics to their suppliers and require the suppliers to cascade all applicable requirements down the supply chain to the point of manufacture.

(Highlights of the clause)

- (Ref to old Standards). This is a totally new requirement.
- Pass down all applicable statutory and regulatory requirements, special product and process characteristics, all the way to the point of manufacture.

(Compliance best practice)

8.4.3.1 Information for external providers-supplemental

1. *Ensure all applicable statutory and regulatory requirements, special product and process characteristics, are passed down the line, all the way to the supply chain*
2. *The best time to inform suppliers is when awarding the contract.*

15) 7.2.4. Second Party Auditor Competency (IATF16949)

(Clause Description-Paraphrase)
The organization shall demonstrate the competence of the auditors undertaking the second-party audits. Second-party auditors shall meet customer specific requirements for auditor qualification and demonstrate the minimum following core competencies, including understanding of: (a) the automotive process approach to auditing, including risk based thinking; (b) applicable customer and organization specific requirements; (c) applicable ISO 9001 and IATF 16949 requirements related to the scope of the audit; (d) applicable manufacturing process(es) to be audited, including PFMEA and control plan; (e) applicable core tool requirements related to the scope of the audit;(f) how to plan, conduct, prepare audit reports, and close out audit findings.

(Highlights of the clause)

- (Ref to old Standards). This is a totally new requirement.
- Second-party auditors shall be competent a) to f)

(Compliance best practice)

7.2.4. Second Party Auditor Competency

1. *The requirement of a) to f) of Clause Description, shall be listed in a document showing qualification of a second party auditor. See* ***Exhibit 33-4***
2. *For convenience in management, this information is generally listed together with the internal auditors lists.*

16) SIs & FAQs

SI Nbr	IATF Clause	Description
8 ***Revised***	**8.4.2.3 Supplier quality management system development**	The organization shall require their suppliers of automotive products and services to develop, implement, and improve a quality management system **(QMS) with the ultimate objective of eligible organizations becoming certified to this Automotive QMS Standard.** **Using a risk-based model, the organization shall define a minimum acceptable level of QMS development and a target QMS development level for each supplier.** ~~**certified to ISO 9001, unless otherwise**~~ **Unless otherwise** authorized by the customer ~~**[e.g., item a) below],**~~ **a QMS certified to ISO 9001 is the initial minimum acceptable level of development. Based on current performance and the potential risk to the customer, the objective is to move suppliers through the following QMS development progression:** ~~**with the ultimate objective of becoming certified to this Automotive QMS Standard. Unless otherwise specified by the customer, the following sequence should be applied to achieve this requirement:**~~ ~~**a) compliance to ISO 9001 through second-party audits;**~~ b) certification to ISO 9001 through third-party audits; unless otherwise specified by the customer, suppliers to the organization shall demonstrate conformity to ISO 9001 by maintaining a third-party certification issued by a certification body bearing the accreditation mark of a recognized IAF MLA (International Accreditation Forum Multilateral Recognition Arrangement) member and where the accreditation body's main scope includes management system certification to ISO/IEC 17021; c) certification to ISO 9001 with compliance to other customer-defined QMS requirements (such as Minimum Automotive Quality Management System Requirements for Sub-Tier Suppliers [MAQMSR] or equivalent) through second-party audits; d) certification to ISO 9001 with compliance to IATF 16949 through second-party audits;
8 (cont.) ***revised***	**8.4.2.3 Supplier quality management system development**	e) certification to IATF 16949 through third-party audits (valid third-party certification of the supplier to IATF 16949 by an IATF-recognized certification body). NOTE: The minimum acceptable level of QMS development may be compliance to ISO 9001 through second-party audits, if authorized by the customer. ***Rationale for change:*** *Clarified the expected supplier quality management system development progression. This approach supports the "Risk Based Thinking" concept emphasized throughout Section 8.4 of the standard.* ***Additional clarification added with "as applicable" in the first paragraph to address those organizations that are not eligible for IATF 16949 certification (examples including but not limited to the following: scrap metal suppliers, trucking companies who provide transport and logistics support, etc.).***
7	**8.4.2.1 Type and extent of control - supplemental**	The organization shall have a documented process to identify outsourced processes and to select the types and extent of controls used to verify conformity of externally provided products, processes, and services to internal (organizational) and external customer requirements. The process shall include the criteria and actions to escalate or reduce the types and extent of controls and development activities based on supplier performance and assessment of product, material, or service risks. **Where characteristics or components "pass through" the organization's quality management system without validation or controls, the organization shall ensure that the appropriate controls are in place at the point of manufacture.** ***Rationale for change:*** *Clarify the organization's responsibilities for pass through characteristics.*

15	**3.1 Terms and definitions for the automotive industry**	**embedded software** **Embedded software is a specialized programme stored in an automotive component (typically computer chip or other non-volatile memory storage) specified by the customer, or as part of the system design, to control its function(s). To be relevant in the scope of IATF 16949 certification, the part that is controlled by embedded software must be developed for an automotive application (i.e., passenger cars, light commercial vehicles, heavy trucks, buses, and motorcycles; see Rules for achieving and maintaining IATF Recognition, 5th Edition, Section 1.0 Eligibility for Certification to IATF 16949, for what is eligible for "Automotive").** **NOTE: Software to control any aspect of the manufacturing process (e.g., machine to manufacture a component or material) is not included in the definition of embedded software.** ***Rationale for change:*** *Minimize confusion regarding embedded software and what is applicable.* *Deleted IATF 16949 FAQ 10.*

FAQ	IATF Clause	Questions and Answers
15	**8.3.2.3 Development of products with embedded software**	**QUESTION:** **What is the acceptable method to assess a supplier's software development capability?** **ANSWER:** The intent of IATF 16949, Section 8.3.2.3 is to apply the same level of rigor to the development of software as is expected in the development of hardware parts. Just like parts, software has defined performance, operating conditions, known inputs, specified outputs, parameters of environment (e.g. size of the file), regulatory requirements (if any), known failure modes, usage profiles, variability of conditions of operation, etc. The planning, designing, writing, testing, confirming and production validation phases in the development of software are not very different in concept from the development of hardware parts. IATF 16949 provides a robust framework to validate that all necessary steps have been taken to design, verify, and produce hardware parts that continue to meet specification in mass production. While similar in concept, those steps are not the same for the development of software. Therefore, a different set of criteria are used to evaluate the methods used to develop software. Those criteria are not included in IATF 16949; therefore, other methods are referred to, such as Automotive SPICE and CMMI. There may be other acceptable methods available identified by some customers. Each customer may have a preferred tool to assess supplier software development capability. The organization should ask their customer(s) to confirm the acceptable assessment tool. Each customer may also specify a different approach used (e.g., customer on-site assessment, supplier self-assessment, or a combination of both). The role of the IATF 16949 internal or external auditor is not to have the knowledge to conduct the Automotive SPICE or CMMI assessments. However, the internal or external auditor should be familiar enough with the assessments to be able to recognize when a software assessment requirement has not been met and that there are corrective action plans in place, with the
15 (cont.)	**8.3.2.3 Development of products with embedded software**	appropriate resources assigned. The IATF 16949 internal and external auditor should also know if the customer participates in that software development assessment and how that is documented.
16	**8.4.2.4.1 Second-party audits**	**QUESTION:** **If there is low risk with an organization's supplier(s), are 2nd party audits required? What is the intent?** **ANSWER:** The risk-based thinking approach, driven by ISO 9001:2015, needs to be incorporated for supplier management. The risk analysis needs to be completed and depending on the results of the risk assessment (see below), then a 2nd party audit may not be required. To support the risk analysis, the organization needs to consider criteria such as: supplier certification status, commodity complexity, new product launch(es), significant employee turn-over, product quality issues, delivery issues, customer specific requirements, and other risks to the organization or to their customer(s).

17) Supplementary Notes

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

Clause	Section	Clarification Subjects
8.4.1, 8.4.1.1	CBP	**SN24.1. What are some of the important pitfalls in external provider selection process?**
8.4.1.2	CBP	**SN24.2. What is the purpose for auditing potential suppliers onsite?**
8.4.1.2	CBP	**SN24.3. How do we evaluate non-direct suppliers e.g. transporter, or calibration labs?**
8.4.1.3	CBP	**SN24.4. If nominated supplier are not performing e.g. on quality and on-time delivery, what can we do?**
8.4.1.3	CBP	**SN24.5. For nominated suppliers, do I still have to fill up an application form, since we do not have to approve?**
8.4.2.1	CBP	**SN24.6. Why outsourced suppliers need to be given extra control?**
8.4.2.4	CBP	**SN24.7. Some outsourced processes cannot be checked by incoming QC, as we do not have the facilities or equipment. What can we do?**
8.4.2.3	CBP	**SN24.8. Why do we insist on service providers such as transporters, machinery repair workshop, tooling suppliers, to have ISO9001? Does it mean all suppliers?**
8.4.2.3	CBP	**SN24.9. How to check on bona fide and fake CB & AB?**
8.4.2.3	CBP	**SN24.10. Is the valid ISO9001 certificate a fool-proof way to check the validity of certification?**
8.4.2.4	CBP	**SN24.11. What is the meaning of special status?**
8.4.2.4	CBP	**SN24.12. Why IATF only wants event count (frequency) for 3 critical, and not the value?**
8.4.2.4.1	CBP	**SN24.13. Are nearby suppliers given same privilege for self-audit, instead of onsite audit?.**
8.4.2.4.1	CBP	**SN24.14. What are the pitfall of self-audit system? What can we do to make it work?**
8.4.2.4.1	CBP	**SN24.15. What if despite of several improvement attempts, the suppliers still fail to get the minimum passing mark?**
8.4.2.4.1	CBP	**SN24.16. What if despite warning, dishonesty still prominent in the self-audit process by a particular supplier?**
8.4.2.4.1	CBP	**SN24.17. Must all su*pplier auditors be qualified at core tools?***
8.4.2.4.1	CBP	**SN24.18. How do we decide on which suppliers to conduct second party audit?**

SN24.1. What are some of the critical pitfalls in external provider selection process?

3 common ones are:

a) selection process is not intended to be effective. Verifications are not checked properly or, assumed. It is like filling up the form for formality

b) no onsite audit for critical materials or components, especially those made to specifications

c) technical products are purchased based on price, and there is no technical pre-qualification before purchase

SN24.2 What is the purpose for auditing potential suppliers onsite?

Not all suppliers need to be audited before selection. Those acting as distributers for manufacturers e.g. (a Dupont distributers) you probably don't need to visit because the material is customer-directed. The distributers are only keep inventory and doing delivery. There is nothing much to see except on inventory system and logistics.
But for a supplier producing parts based on your specs , there is a lot of things that can go wrong, from quality to ontime delivery, which can be traced back their operations and facilities. An onsite audit will allow you to detect weaknesses to base your decision on selection. Should you decide to appoint even under imperfect conditions, you still have a chance to help them improve by pointing out the weaknesses.

SN24.3 How do we evaluate the performance of non-direct suppliers e.g. transporter, or calibration labs?

Usually direct and indirect materials are evaluated on real-time basis. When a shipment arrives, judgement is made, and this is summarized every month. For services, you can do an annual instead of monthly to save time. See **Exhibit 24-3**. Note that the 3 critical customer satisfaction criteria, are also to be evaluated as they are equally applicable.

SN24.4. If nominated supplier are not performing e.g. on quality and on-time delivery, what can we do?

You can feedback to customers and let them deal with the situation. If you have someone proven on your supplier list, you may also propose to the customer, as a possible replacement.

SN24.5. For nominated suppliers, do I still have to fill up an application form, since we do not have to approve?

Yes, you should still do. The form has a lot of information you may need to manage the supplier. Remember the responsibility of managing the supplier is still yours?

SN24.6. Why outsourced suppliers need to be given extra control?

Outsourced supplier are away from your site, control is harder. What is more relevant is some of these suppliers are specialists in their own right, and you know very little about their technology and knowhow. Examples are painting and plating. To be in some control, you need to define early what can be checked at your end. Otherwise you are assuming a very high risk.

SN24.7. Some outsourced processes cannot be checked by incoming QC, as we do not have the facilities or equipment. What can we do?

Yes you can check. What you mean is you do not have facilities to measure or test. That's not a mandatory requirement of IQC. IQC can be based on submitted data from the suppliers, or third party lab, depending on your agreement with them. These are often known as certificate of conformance, Outgoing report, mil cert, cert of analysis etc. You can still generate a report based on such information.

SN24.8. Why do we insist on service providers such as transporters, machinery repair workshop, tooling suppliers, to have ISO9001? Does it mean all suppliers?

There is no exemption given to service providers. They have to be ensured of conforming to requirements, your requirements. See 8.4.1.
There is a lot of latitude given. Your priority should be those that can affect quality (e.g. calibration lab), delivery (e.g. transporter), reliability (e.g. maintenance & repair services). The rest can be left alone.

SN24.9. How to check on bona fide and fake CB & AB?

Real ABs are part of the IAF. In fact most of them are national standards institutes of member countries. In other words, they are the owners of ISO in Geneva. Some examples are UKAS (UK), ANAB (USA), DKKKS (Germany). Cofrac (France), DSM (Malaysia), BSP (Singapore). The fake ones are just private companies . You can check on the website of ISO if a particular AB is bona fide .
Fake CB can either be without accreditation from a bona fide AB, with dishonest intent. It is good money when you do not have to share with any upline. Many a time, customers do not know the difference. Another possibility is the CB got an accreditation from a fake AB. Check on the AB, and check on the AB on MLA website. See **Exhibit 24-5.**

SN24.10. Is the valid ISO9001 certificate a fool-proof way to check the validity of certification ?

Not so. Certificates are given out for 3 year, subject to surveillance audits. If your supplier stops after the first year, the old cert can still be used to give a false impression that the certificate is still valid. This comes about because the CB did not retrieve the certificates once issued, all the more with e-certs, which is impossible to delete once mailed out. If in doubt you can check the CB website for status of the certification, or request a copy of the audit report by CB. The second method has some side benefits, you can also see what the report says about your supplier and any weaknesses (NC, OFI), that can give you some advance warning of trouble.

SN24.11. What is the meaning of special status?

The full term is .special status notification' from customers. This is a negative thing, saying you are have big issue with quality or delivery. You are generally not allowed to bid for new business anymore. Your shipment will also be under strict surveillance through QC arrangements & special marking etc. If you still take it easy, this will be the beginning of the end.

SN24.12. Why IATF only wants event count for 3 critical customer satisfaction criteria, and not the value?

For IATF, the event-count will tell frequency of occurrence that further investigation can be done. Further investigation will surface root cause of problems e.g. production, QAQC, purchasing or others. The value may have some significance to your organization, but not IATF. You can compile both data in your total controls. See **Exhibit 24-6.**

SN24.13. Can nearby suppliers be given same privilege for self-audit, instead of onsite audit?.

The suggested self-audit method is to save some cost for the organization. But extending the same for everyone, including the local suppliers is defeating the purpose. Second-party audit is to audit suppliers at onsite to check on compliances and non-compliances. Using the self-audit to avoid the second party is going against the intent of IATF. It is not acceptable.

SN24.14. What are the pitfalls of self-audit system? What can we do to make it work?

The most common pitfall is suppliers giving good score to the questions asked. With a high score, a second party audit is avoided. There are also some who will score full marks to all questions. This is an indication of the person responsible is either flaunting the system or do not understand. Warning should be given. Most suppliers would do it to a certain degree. You have the history with them to judge if the scores are reasonable. If not, you call out on them and request a re-score.

SN24.15. What if despite of several improvement attempts, the suppliers still fail to get the minimum passing mark?

An onsite audit will be in order. You can get them to pay for the cost, or part of it, to encourage improvement.

SN24.16. What if despite warning, dishonesty still is prominent in the self-audit process by a particular supplier?

You should consider to suspend or terminate the supplier.

SN24.17. Must all *su*pplier auditors be qualified at core tools?

No, not all. Some second party auditors are only required to check on non-technical processes. For example, if you are auditing purchasing and stores, you do not need core tool competency. If you audit production processes, or QC, PPAP, then core tools are needed. Just make sure the non-core tool competent auditors do not audit core-tool activities.

SN24.18. How do we decide on which suppliers to conduct second party audit?

You should first classify your suppliers to signify the degree of criticality. Critical supplier should be audited irrespective of performance. Frequency of say once in 1-3 years should be reasonable.

The rest of the suppliers will be audited based on their performance and also evaluation results. The model suggested in this manual allows self-audit to cut down your involvement. When self-audit still not meeting the cut, the suppliers will be audited. There are also some other reasons for auditing the supplier. See **Exhibit 24-7.**

Exhibit 24-1. Approved Supplier List

Approved Supplier List

S/N	Supplier Name / Address	Approved scope	Classification	Current Qualification	Appointed Since
1	Platmax	Electroplating services	B	ISO9001	2012

Classification: A: Safety-Related, B: Regulatory-Related, C: Quality-Critical, D: Normal Purchases

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

- This ASL has an extra column, classification. In this example, suppliers are classified into 4 classes. You can decide on your own categories
- The main purpose is to draw extra attention on the critical ones. The classification also helps to decide which suppliers need to be audited (second party) due to critical nature.

Exhibit 24-2 Supplier Selection Information

Vendor Information		
Company Name		
Address		
Telephone	Fax	E-mail
Year incorporated	Years in business	Paid-up Capital
Contact Person, Designation and Hand-phone No.		
Specializes in the supply of		Recommended by whom?
Plant built-up area	Branches built-up area	
Manpower		
Management System certified? ☐ No ☐ Yes, ISO 9001:2015, Others (Specify)		
2 Major customers serving currently	Annual Sales Turnover for last 3 years	
2 Major Production Machineries and numbers	Major Quality/testing Equipment and numbers	
Capacity available and delivery lead time *Price and Payment Term (please provide separately)		
Declaration: I/we the undersigned confirmed that the information furnished above is true.		
Name: Designation:	Signature, date & Company Stamp:	
For office use: 1. Any checking of sample? If yes, result? 2. Any site visit/audit? If yes, result? 3. Overall result: poor/ satisfactory/ good (circle)		
Evaluated by Name, signature & date	Recommendation: ☐ OK; Given Provisional Status ☐ Not Good Enough, decline Approved by: Date"	

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

- This is actually an application form. Each section shall be filled and evaluated
- The evaluation shall be based on all the information and data. Request suppliers to provide attachment as necessary. Verify data and conduct onsite audit, if necessary
- Recommendation is made by the lead assessor, and approved by relevant authority

Exhibit 24-3 Supplier Evaluation including 3 critical

Type of Supplies	Year	Venue	Date
Metal	2019	Conference Room	2-4-2020
Evaluators XXX (purchasing), XXX (warehouse), XXX (Production-user)			

No	Evaluation Areas		1 (totally unacceptable), 2 (Poor), 3 (Borderline), 4 (Good), 5 (Outstanding)									
			Supplier A		Supplier B		Supplier C		Supplier D			
	A. Standard criteria											
S1	Quality		5		4		5		2			
S2	On-time Delivery		5		5		5		5			
S3	Service & Helpfulness		4		4		5		5			
S4	Pricing		3		4		3		4			
S5	Response Speed		4		5		4		5			
		Total	21/25		22/25		22/25		21/25			
		%	84%		88%		88%		84%			
	B. Automotive Criteria	***Deduction/Case***	Cases	-%	Cases	-%	Cases	-%	Cases	-%	Cases	-%
A1	**Caused line down**	**10%**										
A2	**Caused premium freight**	**5%**	2	10%	1	5%						
A3	**Caused special status notice**	**Status suspended**							1	X		
		Net %		74%		83%		88%		Hold		
		Recommend to use	Yes/No		Yes/No		Yes/No		Yes/No		Yes/No	
		Management Approval										

3 critical automotive controls

Ratings/Decision Guide: 71% or above (use), 51-70 %, (Need improvement) 0-50%, (not to use /terminate).

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

- This is an annual evaluation summary on suppliers. In this example, similar suppliers are group in clusters, for evaluation and comparison.
- For materials, supplier performance is generally evaluated on every 'shipment' basis. There may be some calculations to be done to get to this step.
- For service suppliers (transporters, calibration labs, critical maintenance contractors), they can be evaluated directly, once a year, using this form
- What is interesting is section B that evaluates on the '3 critical automotive controls'. These are very important criteria and demerits points are given for occurrences. For special status, the supplier status is suspended immediately until resolved

QMS Compliance Matrix
ISO9001:2015(Black Fonts) IATF16949:2016 (Blue Fonts)

ISO16949:2016 Requirement	Compliance Details	Relevant Document Location
8.4.1.3 Customer-directed sources (also known as "direct-buy"	Customer-directed sources for supplies shall be adopted, with documentary evidence. However, the organization continues to apply the control on these external providers, as in 8.4.1.3, unless exempted by the customers.	QP6-1 Purchasing
8.4.2 Type of extend of control	Maintain control of both the external providers and well as their supplied item or work. QP6-1 provides the control in selection, regular monitoring of performance. External providers are subject to periodic re-evaluation. Linkage of external providers' performance to resulting output is established. For externally provided products and services, incoming quality inspections or evaluations are performed.	QP6-1 Purchasing
8.4.2.1 Type of extend of control-supplemental	Each outsourced processes is control tightly. The type and extend of controls is determined, to ensure meeting requirements (both internal and customer requirements). Relevant outsourced suppliers are briefed and compliance method agreed on. Depending on actual performances and associated risks, controls is tightened or reduced. This is explained on each outsourcing plan.	QP6-1 Purchasing
8.4.2.2 Statutory and regulatory requirements	Documented process to ensure externally provided processes, products and services conform to statutory and regulatory requirements of: a) Shipment country, b) receiving country, c) final destination country. The last one is required only if provided.	QP6-1 Purchasing
8.4.2.3 Supplier QMS development	In accordance with the requirement of IATF16949, external providers shall be ... minimum to ISO9001, unless documented waiver is given by customers. QPXXX Purchasing	

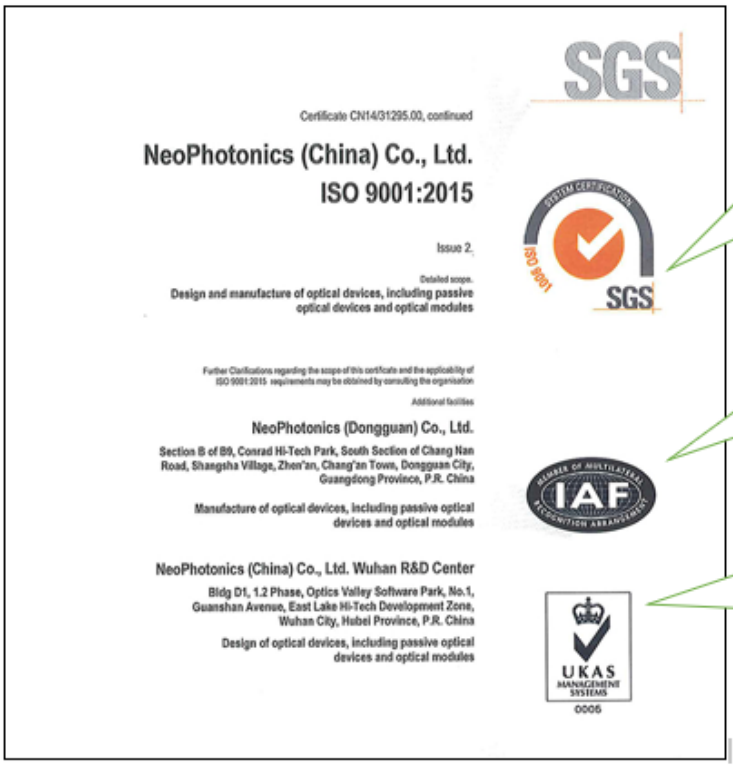
Control of outsourcing can be described in the compliance matrix to replace the need for a documented procedure

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

- This is taken out of a Compliance Matrix. The control method on outsourcing is explained here briefing , under the clause 8.4.2.1, and further refer to outsourcing plans.
- This is only one method of illustrating on the approach. The message can also be written on procedures, or the QM, if a full manual is used.

Exhibit 24-5. IAF & AB on authenticity of certificates

Exhibit 24-5 Authenticity of ISO Certificates



SGS

Certificate CN14/31295.00, continued

NeoPhotonics (China) Co., Ltd.
ISO 9001:2015

Issue 2.

Detailed scope.
Design and manufacture of optical devices, including passive optical devices and optical modules

Further Clarifications regarding the scope of this certificate and the applicability of ISO 9001:2015 requirements may be obtained by consulting the organisation

Additional facilities

NeoPhotonics (Dongguan) Co., Ltd.
Section B of B9, Conrad Hi-Tech Park, South Section of Chang Nan Road, Shangsha Village, Zhen'an, Chang'an Town, Dongguan City, Guangdong Province, P.R. China
Manufacture of optical devices, including passive optical devices and optical modules

NeoPhotonics (China) Co., Ltd. Wuhan R&D Center
Bldg D1, 1.2 Phase, Optics Valley Software Park, No.1, Guanshan Avenue, East Lake Hi-Tech Development Zone, Wuhan City, Hubei Province, P.R. China
Design of optical devices, including passive optical devices and optical modules

SYSTEM CERTIFICATION ISO 9001 SGS

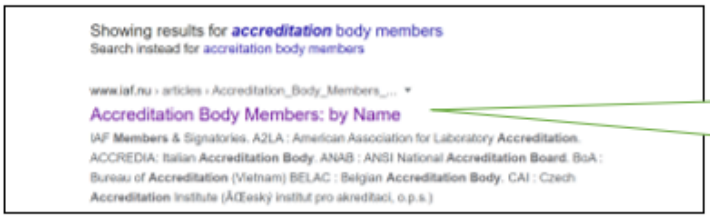
IAF

UKAS MANAGEMENT SYSTEMS 0006

This is Certification Body. Licenced from Accreditation body

This is managing ISO Certification

This is the Accredited Body, which is appointed by IAF- Check this



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A2LA : American Association for Laboratory Accreditation
AA : Akkreditierung Austria (Accreditation Austria)
ACCREDIA: Italian Accreditation Body
ANAB : ANSI National Accreditation Board
ATS : Accreditation Body of Serbia (ATS)
BoA : Bureau of Accreditation (Vietnam)

Exhibit 24-2. Supplier Tracking on 3 automotive critical criteria

Month	Compiled by	Approved by

No/ Supplier No	Supplier Name	Caused line down	Caused premium freight (inbound)	Caused premium freight (outbound)	Caused special status notice	Remarks/ deviation Details
1	SALX	0	1	0	0	Material ran short. Cost absorbed by supplier. OFI
2	Premier Metal	0	2	0	0	Problem due to customer ramp up demand, customer pays for extra freight. OK
3	HDrD Transport	1	0	0	0	Transport truck broke down. Transported rush another consignment from factory here. Miss timing by 1 hour. NG demerit point and compensation

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

- This is a recording form for tracking the performances of suppliers on the 3 automotive critical criteria
- The results will be used for year-end evaluation. See Exhibit 24-3.

Exhibit 24-7. Second Party Audit Management Model

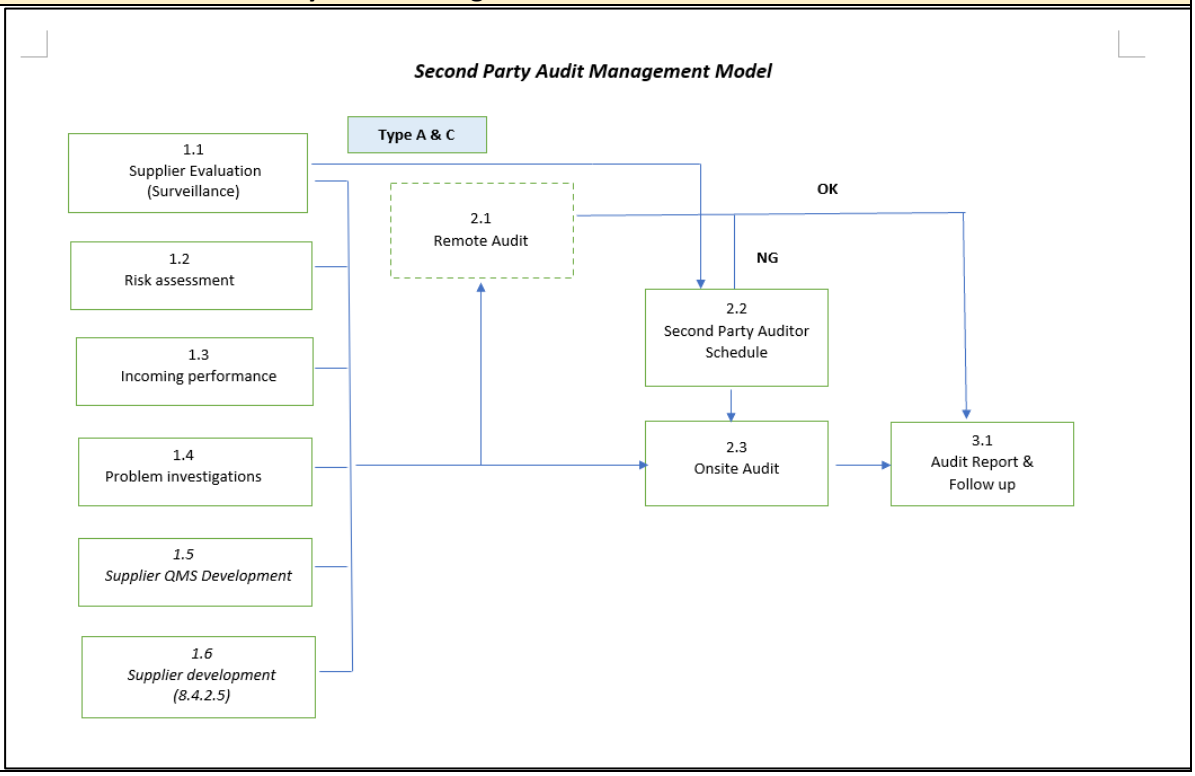


Exhibit 24-7. Page 2

(Second Party Audit Guidelines)

Step	Description	Application	Frequency of 2P Audit	Audit Objectives & Repor
1.1	Supplier Evaluation	• Failing supplier evaluation, conducted by the organization	Type A & C: once every once in 3 years Type B&D Failing min marks (70%)	General
1.2	Risk assessment	• Risks on quality and safety pertaining to Risk and Opportunity studies • Specific area to assess e.g. statutory and regulatory, safety, inventory system, preservation system etc	As required	Specific
1.3	Poor performance	• Incoming quality or delivery, certification issues by CB audits. Frequent or significant incoming quality or delivery problems	As required	Specific
1.4	Problem investigations	• Linkage from organization's production or quality problem, or from final customer. Investigation of a specific problem from organization's internal problems, or final customers' problems.	As required	Specific
1.5	Supplier QMS Development	• Where a further progress in QMS system is required by the organization, or final customer, e.g. from ISO9001 to IATF 16949. • An supplier is requested to upgrade its QMS from ISO9001 to IATF 16949. Example a metal stamping supplier	As agreed	Specific
1.6	Supplier development (8.4.2.5)	• Development of supplier's knowledge or capabilities.	As agreed	Specific

Exhibit 24-7. Page 3

Step	Description	Application	Frequency	Remarks
2.1	Remote Audit	• Suppliers situated far away e.g. foreign countries or >100 km away, may be granted remote-audit instead of onsite audit • Further exemption can be given to suppliers having no performance problem and passing self-audit with >90%.	Type A&C: once every once in 3 years Foreign suppliers- self audit Type B&D Failing min marks (70%)	NA
2.2	Second Party Auditor Schedule	• A schedule to coordinate dates for second party audits	The schedule is prepare at beginning of year, but modified as time progresses	NA
2.3	Onsite Audit	• As Standard requirement of 8.4.2.4.1. • When remote audit not granted • When failing remote audit <80%	As applicable	NA
3.1	Audit Report & Follow up	• Audit Report shall summarize findings pertaining to the audit objectives. • Except from 1.1, which is general and uses full QMS audit report, other audits are specific and can use specific objective reports	After each audit	NA

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

- Second-party audit is one of the hardest clauses to comply. Various degree of compliances is seen, but somehow something is missing, or not quite right.
- We link up the various requirements and sub-requirements into a flow chart to guide compliance
- When applied this way, the second party audit can be a very useful tool to develop your suppliers too

Exhibit 24-8. Second Party Audit Schedule

Second Party Audit Schedule

Category: A. Supplier surveillance, B. Risk Assessment, C. Incoming Performance, D. Problem Investigation, E. QMS Development, F. Supplier development

No	Supplier	Type	Objectives	P/A	Jan 18	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
1	Supplier AA	A	Full QMS audit	Plan		x										
				Actual												
2	Supplier BB	B	Inventory system to ensure no interruption of supply	Plan			x									
				Actual												
3	Supplier CC	A	Full QMS	Plan				x								
				Actual												
4	Supplier DD	C	Check on Frequent issue of plating thickness	Plan					x							
				Actual												
5	Supplier EE	E	QMS upgrade to IATF16949, Check on progress	Plan										x		
				Actual												
6	Supplier FF	F	NCP and CAPA competency to increase	Plan			x					x				
				Actual												
7	Supplier GG	D	Welding complaint from customer. Supplier is GG for the complaint	Plan												
				Actual												
8				Plan												
				Actual												
9				Plan												
				Actual												
10				Plan												
				Actual												
				Actual												

Note that there is no planned date for urgent cases

Exhibit 24-9. Second Party Audit Report

Supplier Audit Report

Supplier:	**Date**
Star Polymers	10 Jul 2019

Type:

☐ Supplier surveillance ☑ Risk Assessment ☐ Incoming Performance

☐ Problem Investigation ☐ QMS Development ☐Supplier development

Objectives of Audit

1. To study their inventory system in supporting our new product XYZ

Audit Team:

Leader: Roland (QMR), Siva (purchasing), Fauzi (Warehouse)

Audit Plan:

1. understand their current inventory method
2. understand how they provide stock to cater for all their customers
3. understand how the forecast provided to them in taken into the system
4. take the real case of the next 6 months against their stock levels for judgement

Conclusions

1. They are using Min stock as basis of stock-keeping, min 2 months in warehouse, 1 month in transit.
2. The data is based on forecast from customers. If no forecast, historical ordering pattern x 0.8 will be used. Sometimes call up customer to verify
3. Our forecast is taken as Point 2 above.
4. Take the real case of next 6 months. EXW2000 needs average 2000 kg/month. From the orders place with manufacturers, the quantity is 6000-8000 kg. OK. There is another customer, requiring 4000kg per month. Therefore the inventory system is satisfactory.

Follow-up Actions

1. Supplier request if we can provide rolling forecast so that they can estimate better

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

- What normally seen in the field, is the supplier audit team will submit a QMS checklist with notes, as the report. This is OK for normal surveillance audit, but not suitable for specific-objective audits.
- This is a specimen for second-party audit that can be used for all types of audits
- Attachments are: a) for full QMS audit report, attach a full QMS audit checklist , b) for specific-objective audits, attach an open checklist with supporting evidences.

Exhibit 24-10. Specific Objective 2P Audit Checklist

Supplier Audit Checklist

(Specific Objective Checklist)

Supplier	Date

Auditors	Auditees

No.	Check Item	OK?	Finding Notes

Auditor (Sign & Date) _____

Exhibit 24-11. Full QMS 2P Audit Checklist

Second Party Audit Checklist

(Full QMS System Audit)

Supplier _____ Auditor _____

Date _____ Auditees _____

Tick ( ) self-assessment ( ) onsite audit

SN	Audit Area	Audit Notes, Yes/No, Compliance Evidence	Max Marks	Score
1	**Management**			
1.1	Quality Policy and roles defined.		2	
1.2	Company organization and responsibilities defined		2	
1.3	Involvement of Top Management in Quality Matters		2	
1.4	Internal Quality Audit		2	
1.5	Accreditation to ISO9001; IATF16949, ISO13485; ISO22000 or equivalent where applicable		2	
2	**Quality Planning**			
2.1	Control Plan or Quality Plan defined		2	
2.2	Customer product requirement		2	
3	**Purchasing Process**			
3.1	Supplier selection & audit program		2	
3.2	Approved vendor list		2	

Exhibit 24-11. Page 2

12	**Manpower**			
12.1	Training program		2	
12.2	Competency		2	
13	**Improvement**			
13.1	Corrective Action - 8D		2	
13.2	CA closure and effectiveness		2	
	Total Score		100.0	
	Grade			
	Recommendations			

Prepared by:

Overall Result (Initial Selection)
90 - 100 : A – Recommended
75 - 89 : B - Acceptable, need attention
50- 74 : C - Improvement before appointment
< 49 : D - Not Recommended

Overall Result (Second Party Audit)
90 - 100 : A – Remain on ASL
75 - 89 : B - Acceptable, need attention
50- 74 : C - Improvement before confirmation
< 49 : D – Suspend/Terminate

Office Use- Management

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

- This questionnaire/ checklist can be used for both onsite audit and self-audit by supplier
- Note that only 2 out of 9 pages are shown here due to space constraints

>> End of Chapter 24 <<

Chapter 25. Performance Monitoring and Analysis

Contents:

0) Introduction

This seems to be a short topic because they are conceptual clauses, about planning, checking, and taking actions - 3 elements of the PDCA cycle. There are related chapters in this book: a) 9.1.1, top management is responsible of setting QMS control and KPI flows; b) 9.1.1.1, QAQC decides on what kind of controls, inspections and methods on products, and related processes; c) chapter 30 describes the details of QAQC activities.

1) 9, 9.1, 9.1.1 Monitoring, measurement, analysis and evaluation (ISO9001)

(Clause Description-Paraphrase)

The organization shall determine:

a) what needs to be monitored and measured;

b) the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;

c) when the monitoring and measuring shall be performed;

d) when the results from monitoring and measurement shall be analysed and evaluated.

The organization shall evaluate the performance and the effectiveness of the quality management system. The organization shall retain appropriate documented information as evidence of the results. (no non-achievement actions)

(Highlights of the clause)

- (Ref to old Standards). There had been a similar clause 8.1 Measurement, analysis and improvement, in the previous version of ISO9001
- The new clause is re-configuration of the title. No change in meaning.
- Compliance is stated as a) to d) above.
- The effectiveness of QMS shall be evaluated and records retained

(Compliance best practice)

9, 9.1, 9.1.1 Monitoring, measurement, analysis and evaluation

1. *This is a concept clause, actual implementation will be carried out by many fronts, with records*
2. *You are only required to understand the intent and ensure compliance. There is generally no need to produce any additional documentation here as evidence.*
3. *QMR shall be monitoring overall QMS performance, on behalf of Management. Detail process and product monitoring is decided and managed by engineering/QA, in reference with customers.*

2) 9.1.1.1 Monitoring & measuring of manufacturing Process (IATF16949)

(Clause Description-Paraphrase)

The organization shall perform process studies on all new manufacturing (including assembly or sequencing) processes to verify process capability and to provide additional input for process control, including those for special characteristics.

NOTE For some manufacturing processes, it may not be possible to demonstrate product compliance through process capability. For those processes, alternate methods such as batch conformance to specification may be used.

The organization shall maintain manufacturing process capability or performance results as specified by the customer's part approval process requirements. The organization shall verify that the process flow diagram, PFMEA, and control plan are implemented, including adherence to the following:

a) measurement techniques;
b) sampling plans;
c) acceptance criteria;
d) records of actual measurement values and/or test results for variable data;
e) reaction plans and escalation process when acceptance criteria are not met.

Significant process events, such as tool change or machine repair, shall be recorded and retained as documented information. The organization shall initiate a reaction plan indicated on the control plan and evaluated for impact on compliance to specifications for characteristics that are either not statistically capable or are unstable. These reaction plans shall include containment of product and 100 percent inspection, as appropriate. A corrective action plan shall be developed and implemented by the organization indicating specific actions, timing, and assigned responsibilities to ensure that the process becomes stable and statistically capable. The plans shall be reviewed with and approved by the customer, when required. The organization shall maintain records of effective dates of process changes.

(Highlights of the clause)

- *(Ref to old Standards). There had been a similar clause* 8.2.3.1 of the same title, in the previous version of IATF16949.
- Previous requirements are retained as a)-d). Point e) is new requirement
- Note that there are 3 portions to this clause.
- Portion A is to conduct CpK studies on new manufacturing processes.
- Portion B is about maintaining process capabilities and performances of existing processes.
- Portion C is about preparedness to support reaction plans when the expected results are not met. This includes recording of significant process events such as tool change or machine repair. Reaction plans indicated on the control plan shall be studied for effectiveness. Reaction plan shall included containment and 100% inspection.
- Corrective action plans shall be developed indicating specific actions, timing, and assigned responsibilities to ensure that the process becomes stable and statistically capable. The corrective action shall be reviewed with and approved by the customer, when required.
- The organization shall maintain records of effective dates of process changes.
- NOTE mentioned some flexibility for cases where CpK cannot be carried out. A full corrective action plan to ensure process continue to be capable, can be used

(Compliance best practice)

9.1.1.1 Monitoring & measuring of manufacturing Process

1. *There are 3 portions of requirement in this clause to deal with.*

2. *For Portion A, new processes capability studies need to be done and submitted as part of PPAP package. You just need to show a PPAP for last year as evidence. Therefore no special work needed to be done here.*
3. *Portion B, requires re-evaluation some existing processes to show ability to maintain committed efficiency or process capabilities. Priority should be based on contractual agreement with customers.*
4. *Portion C) is on process documents verifications. These document shall be verified against actual operations. Manufacturing process audit is one area how this is done. You can show this as evidence.*
5. *Portion C also requires 'containment' part of control plan to be used more actively. 100% inspection shall be standard practice for characteristics that are either statistical incapable, or having problem in meeting specified controls.*
6. *Corrective action plans shall be reviewed with and approved by the customer, where required.*

3) 9.1.3 Analysis and evaluation (ISO9001)

(Clause Description-Paraphrase)

The organization shall analyse and evaluate appropriate data and information arising from monitoring and measurement. The results of analysis shall be used to evaluate:

a) conformity of products and services;
b) the degree of customer satisfaction;
c) the performance and effectiveness of the quality management system;
d) if planning has been implemented effectively;
e) the effectiveness of actions taken to address risks and opportunities;
f) the performance of external providers;
g) the need for improvements to the quality management system.
NOTE Methods to analyse data can include statistical techniques.

((Highlights of the clause)

- (Ref to old Standards). The current Points a) and b) were mentioned in 8.1 and 8.2.1 of the old ISO9001 standard.
- More requirements have been added as c) to g)
- The new requirements are additional monitoring areas such as QMS, planning, risks and opportunities, external provides, improvement.
- NOTE mention use of statistical techniques.

(Compliance best practice)

9.1.3 Analysis and evaluation

1. *This is a concept clause, actual implementation will be carried out by many fronts.*
2. *You are only required to understand the intent and ensure compliance. There is generally no need to produce any additional documentation here as evidence.*
3. *The key items listed are already monitored by automotive organization, and therefore it is not expected to be a problem*

4) 9.1.3.1 Prioritization (IATF16949)

This clause has been discussed in detail in Chapter 11, please refer.

4) SIs & FAQs

No SIs & FAQs for this Chapter

5) Supplementary Notes

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

Clause	Section	Clarification Subjects
9.1.1.1	CBP	**SN25.1. Must process capability conducted only on during PPAP stage?**
9.1.1.1	CBP	**SN25.2. What are other examples of significant process event changes?**
9.1.1.1	CBP	**SN25.3. For containment action, there is not much space in the control plan to list out the details. What can we do?**
9.1.1.1	CBP	**SN25.4. When there are changes after review to the process and control plan, do we need to provide training?.**

SN25.1. Must process capability be only conducted during PPAP stage?

No. you can initiate the study on your own, even not for PPAP purposes. But any new process for PPAP is subject to capability study.

SN25.2. What are other examples of significant process event changes?

Material changes, people changes, measuring equipment changes, method changes, sampling changes.

SN25.3. For containment action, there is not much space in the control plan to list out the details, what can we do?

You can prepare the information separately on another document, and displayed or kept in a clear folder near the relevant stations. But try your best to squeeze in the information, or rely on training if the points cannot explain well.

SN25.4. When there are changes after review to the process and control plan, do we need to provide training?

Of course, that goes without saying. Do not assume that people have the initiative to read up or find out. It is better to err on the safe side.

6) Exhibits

There is no Exhibit for this Chapter

>> End of Chapter 25 <<

Chapter 26 Customer Satisfaction & Feedback, Post Delivery Activities

Contents:

0) Introduction

This is about the real thing about the future of your organization. How satisfied the customer is on your products and services. It will also decide future business opportunities. Clause 10.2.5 warranty and Clause 10.2.6 Customer complaint and Field Failure Test Analysis are critical matters. They are therefore added to the discussion pool here. The topic of Post-deliver activities are also included here as this is part of the services.

1) 9.1.2 Customer Satisfaction (ISO9001)

(Requirement-paraphrase)

The organization shall monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled. The organization shall determine the methods for obtaining, monitoring and reviewing this information.

NOTE Examples of monitoring customer perceptions can include customer surveys, customer feedback on delivered products and services, meetings with customers, market-share analysis, compliments, warranty claims and dealer reports.

(Highlights of the clause)

- (Ref to old Standards). There had been a similar clause 8.2.1 of the same title in the older version of ISO9001.
- Old requirements are all retained. Internal customers removed in the old NOTE.
- The total requirement is: i) monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled: ii) The organization to determine the methods for obtaining, monitoring and reviewing this information.
- New NOTE clarified that meeting with customers, market share analysis are acceptable feedback channels.

(Compliance best practice)

9.1.2 Customer Satisfaction

1. *The clause focusses on customer perception on the organization's performance*
2. *The most common method used is still customer satisfaction survey, although there are several other ways allowed, as stated in the NOTE of Clause Description.*

3. *In automotive, scorecards are common from customer, and they are more accurate than customer satisfaction survey. If you have scorecards, you can do away with the customer satisfaction survey*
4. *For CSS, you design a feedback form to survey for quality, delivery, response and pricing. It should not be too detail, as we only need an indication. Points of concern can be followed up with telephone, email or personal visits.*
5. *The returns shall be studied and acknowledged. The returns shall also be totalled up and averaged. Positive comments should be acknowledged by expressing appreciation. Negative comments must be looked into, investigated, and communicated until resolved. IATF auditor will look at this area, in every audit.*
6. *You may want to separate the returns into automotive and non-automotive. because the targets are different. Non-automotive tends to be easier and automotive harder. When the returns arrive, you compile on 2 lists and evaluate from different perspectives.*
7. *The score can be an qualitative indicator e.g. 1 to 5, with 5 being the best. You can set your own targets for the organization, e.g.: quality 4/5, delivery 5/5, response 4/5, and pricing 3/5. The returns will be compared with these targets.*

2) 9.1.2.1 Customer Satisfaction-supplemental (IATF16949)

(Requirement-paraphrase)

Customer satisfaction with the organization shall be monitored through continual evaluation of internal and external performance indicators to ensure compliance to the product and process specifications and other customer requirements. Performance indicators shall be based on objective evidence and include but not be limited to the following:

a) delivered part quality performance;
b) customer disruptions;
c) field returns, recalls, and warranty (where applicable);
d) delivery schedule performance (including incidents of premium freight);
e) customer notifications related to quality or delivery issues, including special status.

The organization shall monitor the performance of manufacturing processes to demonstrate compliance with customer requirements for product quality and process efficiency. The monitoring shall include the review of customer performance data including online customer portals and customer scorecards, where provided.

(Highlights of the clause)

- (Ref to old Standards). There had been a similar clause, 8.2.1.1, of the same title, in the previous version of ISO/TS16949.
- The formal 3 critical customer satisfaction indicators are retained
- Explained clearer of performance of realization means product and process specs and other customer requirements, 'special status' to be added for monitoring.
- Online customer portals and customer scored cards added to scope of monitoring
- Process review to be conducted to comply with customer requirements for product quality and process efficiency.

(Compliance best practice)

9.1.2.1 Customer Satisfaction-supplemental

1. *3 additional customer satisfaction indicators are: a) customer interruption (including line down, yard holds), b) premium freight, and c) special notifications on special status. There are highly critical.*
2. *Some of these data are monitored internally a) and b), while c) is informed by the customer, or via their portals.*
3. *These data should be best monitored internally, as KPI. See **Exhibit 26-1.** And actions can be taken immediately if any score is unsatisfactory, as they are critical.*
4. *Scorecard and customer portal feedback have been mentioned. Authorized persons must track and evaluate performance data and take actions where necessary*
5. *Process review, as one of the feedback mentioned in the clause, is normally done once a year, by production, and reported in Management Reviews*

3) 10.2.5 Warranty Management Systems (IATF16949)

(Requirement-paraphrase)

When the organization is required to provide warranty for their product(s), the organization shall implement a warranty management process. The organization shall include in the process a method for warranty part analysis, including NTF (no trouble found). When specified by the customer, the organization shall implement the required warranty management process.

(Highlights of the clause)

- (Ref to old Standards). This is a totally new requirement.
- This subject is a closely-related to customer complaints
- Warranty generally arises from actions of final customer, e.g car owners. So there generally is a lag between shipment and warranty claims.
- To comply, organization shall have a process to handle warranties. If customer specifies a their process, compliance is mandatory
- Another requirement is to provide a report on the investigation, including NTF (no trouble found).

(Compliance best practice)

10.2.5 Warranty Management Systems

1. *Warranty handling needs a procedure. It tends to be very different from customer to customer and the procedure should spell out how it is done for the various customers*
2. *You should start off with a generic, with a special remark that customer specified method shall be used, where applicable. Only when it gets too confusing, additional procedures should then be considered. See **Exhibit 26-2.***
3. *Every warranty case shall be recorded, investigated and provided with a concluding report, including cases of NTF (No Trouble Found). See **Exhibit 26-3.***
4. *OEMs have their own processes usually requiring you to input your conclusion directly into their portals.*

4) 10.2.6 Customer Complaints and Field Failure Tests Analysis (IATF16949)

(Requirement-paraphrase)

The organization shall perform analysis on customer complaints and field failures, including any returned parts, and shall initiate problem solving and corrective action to prevent recurrence. Where requested by the customer, this shall include analysis of the interaction of embedded software of the

organization's product within the system of the final customer's product. The organization shall communicate the results of testing/analysis to the customer and also within the organization.

(Highlights of the clause)

- (Ref to old Standards). There had been a similar clause, 8.5.2.4 Rejected Product Test/Analysis, in the previous version of ISO/TS16949.
- The old clause was dealing with rejected parts from customer plants, engineering facilities and dealerships. Organization shall minimize the cycle time of this process. Records of these analyses shall be kept
  and made available upon request. The organization shall perform analysis and initiate corrective action to prevent recurrence.
- The old requirements are all retained. The new clause has included customer complaint into the scope
- Another new area is: where requested, organization also need to analyse interaction with embedded software of the final product Reporting to customer and internal
- Although not specified, cycle time should be minimized, as it is a major concern of OEM customers.

(Compliance best practice)

10.2.6 Customer Complaints and Field Failure Tests Analysis
(Customer Complaints)

- *Customer complaint in general, means quality complaints. Commercial and delivery complaints are managed through other means e.g. score cards, or by their logistics with different documentations.*
- *For complaint handling, customers normally have their own methods, and organization must abide. Some of the important points are response time, handling methods, and complaint closure method.*
- *It is also good to have a generic process, where customer method is referenced. The method should be similar to the 10.2.3 See a specimen in* ***Exhibit 26-4.***

(Field Test Analysis)

- *Whether complaints or warranty claims, this clause (Field Test Analysis) will be applicable*
- *Field failure test analysis shall be carried out where applicable.*
- *Communicate results of testing/analysis to customer and within organization*

5) 8.5.5 Post-delivery activities (ISO9001)
This was already discussed in Chapter 19. Please refer.

6) SIs & FAQs

No SIs & FAQs for this Chapter

7) Supplementary Notes

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

Clause	Section	Clarification Subjects
9.1.2, 9.1.2.1	CBP	**SN26.1. Why is score cards from customer is better than customer satisfaction survey?**
9.1.2, 9.1.2.1	CBP	**SN26.2. Why is very detail customer satisfaction survey not preferred? We can analyse better than simple ones.**
9.1.2, 9.1.2.1	CBP	**SN26.3. Why and how do we acknowledge customer satisfaction survey returns?**
9.1.2, 9.1.2.1	CBP	**SN26.4. Why we should compile 2 different list of customer satisfaction survey results?**
9.1.2, 9.1.2.1	CBP	**SN26.5. Is it OK to come up with a final score of the QCDS (quality, cost, delivery, service) and use it as criteria of measure? Say passing mark is 80%.**
9.1.2, 9.1.2.1	CBP	**SN26.6. For negative returns on pricing, how do we handle?**
10.2.5	CBP	**SN26.7. If there are disagreement with customers on judgement of warranty validity, how should we handle?**
10.2.6	CBP	**SN26.8. Do we need to conduct field failure analysis for all warranty claims?**
10.2.6	CBP	**SN26.9. How do we share failure test analysis with internal departments?**

SN26.1. Why is score card from customer is better than customer satisfaction survey?

Customer scorecard is an official exercise of the customer and scoring is guided and transparent. Therefore it is reliable. You can also seek clarifications/try to resolve on doubtful areas. Customer Satisfaction Survey on the other hands are not so reliable. They are sometimes treated very lightly and answered by low ranking employees. I have seen a case where all survey forms for 10 companies in a group were told to be sent to a procurement office in Singapore. All the forms were subsequently replied by a junior clerk in Singapore, with 100% identical results for all 10 companies. This is a sheer waste of time and misleading. This admittedly is an extreme case of misapplication, the ratings of customer satisfaction are at best generalizations not supported with data, sometimes tainted with bias and prejudice.

SN26.2. Why is very detail CSS not preferred? We can analyse them better than simple ones.

People replying your survey are not your employees, they are your customers. They have no obligations whatsoever to help you complete your tasks. Moreover they could be busy. Simpler surveys will help them to help you. If it is too complicated, your request is just ignored. That is the reason why some organizations only get about 30-50% replies.

SN26.3. Why and how do we acknowledge customer satisfaction survey returns?

This is basic courtesy that people seem to have forget. A simple expression of appreciation by email is all that is necessary. If you don't' do that, don't blame your customers next time when they ignore your request.

SN26.4. Why we should compile 2 different list of customer satisfaction survey results?

Automotive and non-automotive customer have different expectations and targets. If you use average figures from a mixed pool for automotive audit, you will fail in many instances. For example: on-time delivery. Automotive customers expect 100% on-time, or very close to it. Results from a mix pool normally cannot achieve that and you will have a lot of explanations to do. If you only show the automotive list, you should be able to hit the target and no more questions asked.

SN26.5. Is it OK to come up with a final score of the QCDS (quality, cost, delivery, service) and use it as criteria of measure? Say passing mark is 80%.

It will be OK for non-automotive, but not automotive. In automotive, we look into the details. A score of 85% example, could hide poor delivery ratings, which is not good. But if the individual ratings are also shown, then the method is OK.

SN26.6. For negative returns on pricing, how do we handle?

Acknowledge the concern and promise to get back to the person. Then ask the marketing people to word the reply for you to send out. Any further development shall then be handled by the marketing people.

SN26.7. If there are disagreements with customers on judgement of warranty validity, how should we handle it?

You try to reason out with your counterpart. If no agreement can be reached, you escalate to a higher authority. We have seen such cases especially agreement can only be reached at a higher level.

SN26.8. Do we need to conduct field failure analysis for all warranty claims?

No, it is also not possible due to a few reasons.

a) usually you are required to visit OEM site to view the returns. In some instances, non-valid claims due to secondary causes can be rejected there and then, with customer acceptance. Those rejected ones do not need further analysis, which is a good thing.

b) sometimes customers do not get the returned parts, so there is nothing for you to analyse

c) customer has a policy of giving a certain percentage of returns for analysis. You only have a chance to analyse those that are returned

SN26.9. How do we share failure test analysis with internal departments?

You should have a report to conclude each case. Just share the reports with them.

8) Exhibits

Exhibit 26-1. Critical Customer Satisfaction Criteria

Critical Customer Satisfaction Criteria

Premium Freight outbound

	J	F	M	A	M	J	J	A	S	O	N	D
Event	0	2	0	0	0	1	1	0	0	0	0	0
RM		300				100	900					
Remark		A				B	C					

Remarks:

A: Due do customer change order quantity and increase. Need to arrange special delivery. Management approved

B: Same as above

C. Machine 3 broke down

Premium Freight inbound

	J	F	M	A	M	J	J	A	S	O	N	D
Event	0	2	0	0	0	1	0	0	0	0	0	0
RM		1000				200						
Remark		A				B						

Remarks:

A: due do customer increase order, shortage of material. Air freight. Customer agree to pay.

B. Material XXX ran short after deducting the off shelf-life items.

Customer Disruption (line down)

	J	F	M	A	M	J	J	A	S	O	N	D
Event	0	2	0	0	0	0	0	0	0	0	0	0
RM		15000										
Remark		A										

Remarks:

A: Due to customer A line down 15 minutes @RM1000/min. Some parts cannot fit

Special status notification (serious warning from customer e.g. no new bidding)

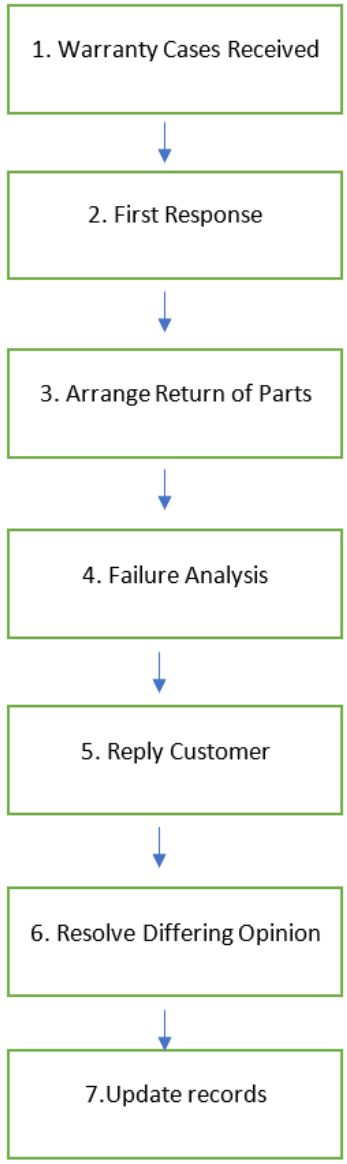
	J	F	M	A	M	J	J	A	S	O	N	D
Event	0	2	0	0	0	0	0	0	0	0	0	0
RM												
Remark		A										

A= From Customer B. Due to many rejects. Added pre-shipment quality gate.

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

- This is often omitted, and also not reported in Management Reviews
- Note that premium freight has 2 types, inbound (purchasing), outbound (delivery)

Exhibit 26-2. Warranty Procedure

Responsible	Flow Diagram	Description
QA		Point 1: • Customer will inform through portal, email etc Point 2: • First responder shall access the information e.g. from customer portal • The info shall be studied and background checked for possible clues Point 3: • Parts usually need to be collected from the customer. • Obvious unwarranted claims can usually be reject while collecting the returned parts • Most common rejections are based on secondary damaged-damaged occurred after delivery Point 4: • The analysis of failure shall then • Most analysis will first confirm failure by means of functional tests • In some cases, simulation needs to be done. Point 5: • The final analysis shall be feedback to customer, with full report Point 6: • If there are differing opinions that cannot be resolved at the normal level, the case shall be escalated to higher authority Point 7: • There should be a running log for warranty cases, and this should be update • The reports are sent to customer Including NTF cases (no-trouble found) • Relevant internal departments, including finance shall be informed via copies of the reports. • Where applicable, organization shall update customer portal directly

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

- This procedure is a requirement for documented process
- Actually, each customer has its own procedure, which you need to follow
- But you should try to maintain one procedure as far as possible, in order to avoid adding complexities to the clause

Warranty Cases Resolution

Date	Customer – case No	Description	Investigation Date	Report No	Failure Part Analysed?	Conclusion Valid/Not Valid	Follow up actions	Status
15/3/16	Omron- WCN-299	Casing detached	16-20 Mar 2016	WCI-17-12	Yes	Valid	Replaced part and carry out 8D problem solving	Resolved 17/3/16. 8D report 17-17

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

- This is a typical recording form for claims from the field. Each claim has to be recorded, even if it is not valid. This is particularly important, as OEM tend to deduct first and reimburse later, for non-valid cases.
- More and more OEM nowadays require you to input these data directly onto their portals
- Your reports need to be clear and convincing so you do not end up paying for fault not caused by you

Exhibit 26-4. Customer Complaint Procedure

Responsible	Flow Diagram	Key Points
Respondent / PIC	3-3(1) Complaint from customer	3-3(1) ▪ Customer complaint may be via an official NC format, email, or a phone call ▪ If complaint is by email, acknowledge and contact customer immediately ▪ Respondent shall note down all details, and specific customer requests ▪ Enter the complaint into the Complaint Master List
	3.3(2) Mitigation and Correction	3-3(2) ▪ If complaint is causing customer interruption, mitigation actions shall be taken immediately , e.g. send backup products by fastest method ▪ decisions shall be made, in consultation with customer, regarding disposition of defective products on customer's site e.g. return, onsite sorting et. ▪ Arrange for implementation of disposition method as agreed
	3-3(3) Investigate & Analysis	3-3(3) ▪ investigate validity and extend of problem or potential problem ▪ carry out Root Cause Analysis and decide on long-term solution ▪ if problem is due to product quality, take containment actions internally e.g. stop machine and delivery of similar product and quarantine 1 lot each, before and after, for verification ▪ For detail problem-solving, refer to QP3-1 ▪ If return is involved, refer to QP3-4
QMR/PIC	3-3(4) Reporting to Customer	3-3(4) ▪ Comply to customer requirements on complaint handling e.g. timeline and reporting ▪ In the absence of a customer specified method, internal CAR format shall be used to document problem-solving data and results
QMR/ Doc Controller QAQC	3-3(5) Closure/Tidy up	3-3(5) ▪ Closure shall comply to customer method e.g. 3 trouble-free shipment, or customer verification onsite etc. ▪ Disposition decisions shall be made on quarantined materials/products and implemented. ▪ All documentation concerning the complaint shall be filed for easy retrieval
	3-3(6) Documentation Updates	3-3(6) ▪ All other documentations are then checked through, and updated as needed. ▪ The documents are: process flow chart, FMEA, control Plan, WI, visual guides, Inspection Sheets, etc.
	End	

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

- This procedure is for handling of complaints. You can think of it as a subset of problem solving, because complaints are also nonconformity and handled the same way
- Customer complaint may also lead to recall or return of goods. If so, you should also have processes to deal with such eventualities

>> End of Chapter 26 <<

Chapter 27. Maintenance Related

Contents:

0) Introduction

There are only 2 applicable clauses in this chapter. The reason why a whole chapter is devoted to this is because the Clauses have new elements that are not commonly misunderstood and/or poorly catered for. Also there are 2 FAQ that are used to clarify some doubts. Many NCs have been written on this clause alone.

1) 8.5.1.5 Total Productive Maintenance (IATF16949)

(Clause Description-Paraphrase)

The organization shall develop, implement, and maintain a documented total productive maintenance system. At a minimum, the system shall include the following:

a) identification of process equipment necessary to produce conforming product at the required volume;
b) availability of replacement parts for the equipment identified in item a);
c) provision of resource for machine, equipment, and facility maintenance;
d) packaging and preservation of equipment, tooling, and gauging;
e) applicable customer-specific requirements;
f) documented maintenance objectives, for example: OEE (Overall Equipment Effectiveness), MTBF (Mean Time Between Failure), and MTTR (Mean Time To Repair), and Preventive Maintenance compliance metrics. Performance to the maintenance objectives shall form an input into management review (see ISO 9001, Section 9.3);
g) regular review of maintenance plan and objectives and a documented action plan to address corrective actions where objectives are not achieved;
h) use of preventive maintenance methods;
i) use of predictive maintenance methods, as applicable;
j) periodic overhaul.

(Highlights of the clause)

- *(Ref to old Standards). There had been a similar clause,* 7.5.1.4. Preventive and Predictive Maintenance, in the previous version of ISO/TS16949.
- Previous requirement was only a)-d). New requirements are from e) to j)
- Therefore the requirements had increase a lot.
- Notable changes are: f) maintenance objectives are needed, g) regular review of maintenance plan and objectives, and take actions when objectives are not met, g) predictive maintenance is no longer mandatory, j periodic overhaul: b) is now on replacement parts for all machines, not only key manufacturing equipment

- There are 2 FAQs. FAQ#26 explains why overhaul is required and available in any situation, FAQ#27 explains the true meaning of TPM.

(Compliance best practice)

8.5.1.5 Total Productive Maintenance

1. *A master list of equipment shall first be compiled. There are many ways to do this.* ***Exhibit 27-1*** *is one specimen.*
2. *Critical spare parts shall also be compiled, stating minimum quantities of the inventory required. See* ***Exhibit 27-2.***
3. *Preventive maintenance schedule shall be planned, with review dates. See* ***Exhibit 27-3.***
4. *Overhaul maintenance shall also be included in the plan. See* ***Exhibit 27-3****. Also see FAQ-26.*
5. *Set objectives that show effectiveness or efficiencies e.g. OEE, MTTR, MTBF etc. The previous common KPI of 100% on-time maintenance is not very acceptable.*
6. *Daily maintenance preferably should be conducted by the user department, not maintenance team (FAQ#27).* ***Exhibit 27-4*** *is a sample of daily maintenance checklist****.***
7. *Review objectives and performance as planned. If results are not satisfactory, take improvement actions.*

2) 8.5.1.6 Management of Production Tooling and Manufacturing, test, inspection tooling and equipment (IATF16949)

(Clause Description-Paraphrase)

The organization shall provide resources for tool and gauge design, fabrication, and verification activities for production and service materials and for bulk materials, as applicable. The organization shall establish and implement a system for production tooling management, whether owned by the organization or the customer, including:

a) maintenance and repair facilities and personnel;
b) storage and recovery;
c) set-up;
d) tool-change programmes for perishable tools;
e) tool design modification documentation, including engineering change level of the product;
f) tool modification and revision to documentation;
g) tool identification, such as serial or asset number; the status, such as production, repair or disposal; ownership; and location.

The organization shall verify that customer-owned tools, manufacturing equipment, and test/inspection equipment are permanently marked in a visible location so that the ownership and application of each item can be determined. The organization shall implement a system to monitor these activities if any work is outsourced

(Highlights of the clause)

- (Ref to old Standards). There had been 2 similar clause, 7.5.1.5 Management of Production Tooling, and 7.5.4.1, customer-owned production tooling, in the previous version of ISO/TS16949. Now they are into a common clause.
- All previous requirements of 7.5.1.5are retained and covered in opening, a)-f) and last paragraph is the former 7.5.1.4.
- The new clause clarified the scope includes manufacturing, test and inspecting tooling and equipment.

- Tool identification is a requirement, such as asset no, serial no. Ownership and location shall be indicated on the records
- If customer tooling, it needs ownership permanent marked in visible location.

(Compliance best practice)

8.5.1.6 Management of Production Tooling …

Tooling storage and marking.

1. *This refers to production tolling*
2. *Name of owner shall be clearly marked, and able to be seen from a distance.*

Documentation

3. *If customer owned, master list shall be available showing ID of the tooling, ownership, frequency for maintenance, total tool life. See* ***Exhibit 28-2***
4. *Individual file or card for each tooling with details of service and repairs, should be available*

Method of Preventive Maintenance

5. *Method of service shall be according to customer, example by 'shot count', that is after certain quantity of shots. You need a system to track the operations, and bring the tooling down for maintenance. See* ***Exhibit 27-5****.*
6. *Schedule according to calendar months, if used, need to be justified, or correlated to the method specified by customer*

Total Tool Life

7. *Forward warning to be given to tooling owner to replace tooling when near the total life. In practice do not wait till the total life is exceeded; but inform, say, when it reaches 80% of total life*

Other types of Tools

8. *Other forms of tools e.g. holding jigs and fixture also need maintenance but much less. It may be a thorough checking every 6-12 months. A schedule should also be prepared*
9. *Record shall be updated as maintenance is performed*

Repairs

10. *Repair is a separate item from preventive maintenance. However it should also be recorded and the pattern of breakdowns can provide more clues to the reliability of the machines, and further decisions can be made.*

3) SIs & FAQs

FAQ	IATF Clause	Questions and Answers
26	**8.5.1.5 Total Productive Maintenance**	**QUESTION** **What is the intent of including the term "periodic overhaul" in the requirements for Total Productive Maintenance?** **ANSWER** The intent of all the line items in section 8.5.1.5 is to include the minimum steps to maintain manufacturing equipment over a long period of usage so it can consistently produce product to specification. "Periodic overhaul" is rework of manufacturing tooling and equipment needed when regular maintenance steps are no longer enough to keep the tooling and equipment in a condition where it can continue to make product to specification, as detected using Mean Time Between Repairs or other similar metrics. Periodic overhaul is already defined in section 3 of the standard: "maintenance methodology to prevent a major unplanned breakdown where, based on fault or interruption history, a piece of equipment, or subsystem of the equipment, is proactively taken out of service and disassembled, repaired, parts replaced, reassembled, and then returned to service." Perhaps periodic overhaul is not applicable to some types of tooling and equipment. Perhaps some tooling is simply replaced with a new tool at the end of its useful life. However, all tooling and equipment does have a limited life based on usage, time or other known factors. The tooling and equipment manufacturer would be a good source to determine which factors and to estimate when such major work needs to be completed. Periodic overhaul or its appropriate equivalent (e.g. replacement) would need to be accounted for in the steps of the organization's maintenance plan.
27	**8.5.1.5 Total Productive Maintenance**	**QUESTION** **What is the intent of using the term "Total Productive Maintenance" for this clause, is there a connection to the industry term "Total Productive Maintenance"?** **ANSWER** The term "Total Productive Maintenance" (TPM) used in the IATF 16949 standard refers to various similar approaches that focus on proactive and preventive techniques for improving tooling and equipment reliability through the machines, equipment, processes and employees that add manufacturing value to an organization. For example, the industry approach for TPM places the responsibility for routine maintenance, such as cleaning, lubricating and inspection in the hands of the operators. Clause 8.5.1.5 of IATF 16949 has some requirements which align with some of the pillars of industry TPM. However, the individual requirements of 8.5.1.5 [a) through j)] are as stated in IATF 16949. The use of the term "Total Productive Maintenance" in IATF 16949 gives organizations an opportunity to adopt the underlying principles of industry Total Productive Maintenance while meeting the listed requirements of 8.5.1.5 in IATF 16949.

4) Supplementary Notes

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

Clause	Section	Clarification Subjects
8.5.1.5	CBP	**SN27.1. Is a machinery & equipment master list required? What is the purpose?**
8.5.1.5	CBP	**SN27.2. Why are we still taking about critical spare parts, when the clause now asks for replacement parts for all machines on the master list?**
8.5.1.5	CBP	**SN27.3. Can I set maintenance objectives such as a) 100% ontime maintenance as an objective? Or b) below certain amount of expenditure per year?**
8.5.1.5	CBP	**SN27.4. Are we allowed to outsource maintenance?**
8.5.1.5	CBP	**SN27.5. If we are practicing preventive maintenance but still having frequent breakdowns, is it a finding?**
8.5.1.5	CBP	**SN27.6. If I can't stop machine for preventive maintenance, due to heavy demand by production, how should I do it?**
8.5.1.5	CBP	**SN27.7. If we don't need to do overhaul, so how do we comply?**
8.5.1.5	CBP	**SN27.8 What does preservation means in this maintenance context?**
8.5.1.5	CBP	**SN27.9. How do we plan the review for objectives? What do we review?**
8.5.1.5	CBP	**SN27.10. Do we need a report as the records?**
8.5.1.6	CBP	**SN27.11. How to I schedule tooling maintenance, by calendar month?**
8.5.1.6	CBP	**SN27.12. Can I use external for maintenance?**
8.5.1.6	CBP	**SN27.13. How is permanent marking done on tooling. What if the customers do not allow engraving on their tooling?**.
8.5.1.6	CBP	**SN27.14. For other types of tools e.g. holding jigs and inspection jig, what is the method to show regular maintain?**
8.5.1.5	CBP	**SN27.15. Some spares are critical but too costly to keep, such as, PLC, air compressors, what can we do?**

SN27.1. Is a machinery & equipment master list required? What is the purpose?

That is a requirement. It is to show total and types of machines and equipment are available. It is part of infrastructure planning. Also you need this to plan Master Preventive Maintenance Schedule, to guide on maintenance.

SN27.2. Why are we still taking about critical spare parts, when the clause now asks for replacement parts for all machines on the master list?

It will be perfect if the new requirements can be provided. However it may be too much to change over within a short period. Providing spare parts for critical equipment will largely meet the needs, if criticality is defined as time taken for procurement. In this case, you will not run of stock resulting in unplanned outage.

SN27.3. Can I set maintenance objectives such as a) 100% on-time maintenance? Or b) below certain amount of expenditure per year?

No. They can be maintained as additional objectives. What IATF wants to see is something that indicate effectiveness or efficiency such as OEE, MTBF, MTTR, MTTF etc

SN27.4. Are we allowed to outsource maintenance?

Yes. Most organizations do that for specialized equipment e.g. air compressors. You can delegate the work, not the whole responsibility. You must still be tracking the timing and operational reliability.

SN27.5. If we are practicing preventive maintenance but still having frequent breakdowns, is it a finding?

It should be. Preventive maintenance is supposed to prevent breakdowns. If breakdowns are frequent, it means your preventive program is not effective; and something should have been done, instead of allowing the breakdowns to go on.

SN27.6. If I can't stop machine for preventive maintenance, due to heavy demand by production, how should I do it?

You need to step up your in-process inspection, for the extended period, to make sure quality is OK. Stop at the first opportunity for maintenance. Better still, if you know of the heavy use upfront, service the machine ahead of the schedule, so the machine operations would not be interrupted.

SN27.7. If we don't need to do overhaul, so how do we comply?

See FAQ-26 for the answer. Unless we are referring to consumable type of tools e.g. drilling and cutting bits, which are simply replaced when they are no longer functional. All other equipment should require overhaul to extend total life, or to overcome frequent, nagging problems.

SN27.8 What does preservation mean in this maintenance context?

When some machines are not used for a long time, it will deteriorate e.g. gathering of dust, rusting, moving parts getting jammed etc. Preservation means step taken to protect the equipment while not in use e.g. apply antirust, plastic wrap the equipment to keep out the dust, use desiccants to prevent moisture etc.

SN27.9. How do we plan the review for objectives? What do we review?

You can base your priority on problematic equipment or critical equipment. For review, you should look into the achievement of objectives, breakdown frequencies and impact on production, for the preceding period/year. You can then decide if the maintenance frequencies, checking items, and methods are adequate or suitable.

SN27.10. Do we need a report as the records?

Records are definitely needed. The format is not prescribed by ISO or IATF. You can use one that suits your circumstances.

SN27.11. How to I schedule tooling maintenance, by calendar month?

Most customer would want the preventive maintenance to be based on actual usage. For production tooling, for example, maintenance by shot-count is usual. Once decided, say 50000 shots for service, you track the shot-count to bring down the tooling for maintenance. You also need to follow a checklist to conduct the preventive maintenance. There is also a common practice to have minor and major maintenance, using different checklists. Calendar month-based is acceptable, so long calendar months can correlate to the specified shot-count. This is tedious, and you have a lot to prove during audit.

SN27.12. Can I use external for maintenance?

Yes, it is practiced, although in rare cases. But most organizations would manage the whole process with their own employee, for better flexibilities. If you have to use outsourced contractors, you must still be responsible to track the work timing and ensure work quality.

SN27.13. How is permanent marking done on tooling. What if the customer does not allow us to engrave on their tooling?

Engraving is one way. If you are not allowed to do that, you can consider having dedicated areas for each customer's tooling. Color-coding for different customers' tooling is another method. Customer names can be placed on the dedicated racks, if cannot be engraved. A matrix can also be used to show tooling serial number against owners, and prominent displayed. On top of that, the tooling itself must have some identification e.g. serial no etc.

SN27.14. For other types of tools e.g. holding jigs and inspection jig, what is the method to show regular maintenance?

You need to check on damage and deformation on the tools regularly. Common frequencies seen are once a year, but it depends on usage rates.

SN27.15. Some spares are critical but too costly to keep, such as, PLC, air compressors, what can we do?

You may work out some arrangement with your local supplier to keep the spare part on your behalf. Anyway they have other customers who are also in the same situation, and could already be providing this service. If you can produce some evidence that such an agreement is on, it would be acceptable. Better still you can visit them once a year to see if they keep their promises. If there is no local supplier, then you would have to keep the spare part, or take the risks. You can reduce the risk by keeping tight surveillance on the machines for signs of malfunctioning, and order the part at the earliest possible time.

Equipment Master List

Key: H=High, M= Medium, L= Low

No.	Description	Model/Serial No.	Location	Usage (H.M.L)	Maintenance every			
					30 days	3 Months	6-monthS	12 months

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

- This is an example of an equipment master list. The majority of the organization I have seen, had skipped this and prepare a master schedule instead. (Exhibit 27-3)
- It is also acceptable to proceed direct to the schedule (Exhibit 27-3), except the basis of preventive maintenance should be seen

Exhibit 27-2. Spare Part List

Critical Spare Parts Control

No.	Spare Part	Machine	Reasons for keeping Stock	Min quantity	Remarks
1	V-belt 200X	TRE 200	Consumable and common for many machines	5 pc	
2	Syntex H XED	OYR optical machine	Consumable, 2 machines, part is from Germany. Lead time 2 months	5pc	
3	Reducing valve. BN-3R01 15°	TRE 300	Have life span. Common for 4 machines	3	
4	PLC xxx	Press	Can break down without warning. Common for 5 machines. Lead time 2 weeks air freight	0	Too expensive. Will monitor carefully for signals of problems
5	Air compressor	Whole plant	Only 1 unit working. The smaller ones are all spoilt	0	Agreement with rental company to loan if spoilt. 2 days to install.

Remarks given in this section explain on the Exhibit. Do not include them as part of your working document

- The list is fictitious and the purpose is to show how to fill the form
- There is another stock card normally to be used in tandem, see below
- Item 4 and item 5 are interesting. They are not technically correct but frequently practiced. The organizations would not keep spares but adopt alternative measures with good reasons.
- Item 4, PLC is not advisable to keep as it can get spoilt on long-holding; and when discovered, the warranty is over. Again there may be excess machines so the situation is not so critical
- For air compressor's case, it is not a big issue as rental units are available at very short notice.

Stock Card

Spare Parts	Std Packing	Shell Life	Min Stock	Max Stock	Lead Time
V-belt 200X	10 pc/ box	3 years	5 pc	15 pc	1 month

Date	Description/Document	Qty In	Qty Out	Balance	Remarks
1/3	Carried down	15			
5/4	GRN-0118/19		2	13	
7/5	GRN-0320/10		5	8	Order for 10
9/5	GRN- 350/19		3	5	
15/5	GRN- 358/19		1	4	
1/6	Receive	10		14	

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

- Stock control is by each type of spare part.
- There are many ways to keep track of stock movement: Stock card as above, bin card at the storage area, or an excel page in the computer etc.
- Good stock control takes into consideration of lead time, historical consumption, and trends

Machine Maintenance Schedule (2019)

No.	Tasks	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	M/C to Review	Status	Report Ref
1	NC Turning 1	x			x			x			x					
		12/1			14/4											
2	NC Turning 2		x			x			x			⊗				
			1/2													
3	NC Turning 3			x			x			x			x	x		
				1/4												
4	CNC Milling 1	x			x			x			x					
		2/2			4/4											
5	CNC Milling 2		x			x			x			x				
			15/2													
6	Press 1			x			x			x			x	x		
				13/3												
7	Press 2	x			x			x			x					
		8/1			18/4											

⊗ = Overhaul

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

- Crosses at the yellow zone, are planning for performance review. This is done besides KPI such as MTBF, MTTR, downtime etc.
- Review should include: comparison on breakdowns, frequencies of maintenance, maintenance costs, production hour losses etc. Appropriate recommendations should be made to management if current method is OK, or machine should be replaced etc.
- Reviews are usually done at year end after completing 12 months, and records of review available

Daily Maintenance Check List

Equipment	No/Identification	Person Responsible	Months-Year

Place "√" for good situations and "X" for bad situations on each column respectively. Inform supervisor immediately on problems or symptoms. Denote 'S' for Sundays under relevant dates.

No.	Service/Task/Checking	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
	Checker's Initials																
	Superior's random checks																

No.	Service/Task/Checking	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
	Checker's Initials																
	Superior's random checks																

ecord actions taken for 'X':

Remarks given in this section explain on the Exhibit. Do not include them as part of your working document

- This is an example of daily maintenance checklist. It should be pinned up near the machine, and it is OK for it to get soiled
- The recording is in 2 layers in the above example. However if there are many checking items, you might have to use 2 sheets for 1 month
- The job of daily checking is best done by the operators, and not technicians, for creating sense of ownership. See FAQ 27.

Exhibit 27-5. Tooling Shot Count Tracking

Tooling Shot Count

CUSTOMER	:		MOULD MAKER	:
PART NAME	:		NUMBER OF CAVITY	:
PART NUMBER	:		Shots for PM	: Say 50000

PRODUCTION RECORDER :

PRODUCTION DATE	QUANTITY (SHOT)	ACCUMULATIVE SHOT	REMARK

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

- This is an example of production tooling shot-count control. The shot-count for maintenance is fixed at certain shots, at the start of maintenance program
- The quantity data is taken from production or planner and tracked daily
- When the shot count reaches the shot-limit or thereof, preventive maintenance is to take place

>> End of Chapter 27 <<

Chapter 28. Identification and Traceability, Property Belonging to External Parties

Contents:

0) Introduction

Identification and traceability, and properties belonging to external parties are actually 2 different topics. They are lumped in a chapter, otherwise the 2 chapters are too short each. Also these 2 topics are generally well-managed and there are not many problems and complaints from customers expected.

1) 8.5.2 Identification and traceability (ISO9001)

(Clause Description-Paraphrase)

The organization shall identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision. The organization shall control the unique identification of the outputs when traceability is a requirement, and shall retain the documented information necessary to enable traceability.

NOTE (16949) Inspection and test status is not indicated by the location of product in the production flow unless inherently obvious, such as material in an automated production transfer process. Alternatives are permitted if the status is clearly identified, documented, and achieves the designated purpose.

(Highlights of the Clause)

- (Ref to old Standards).There had been a similar clause, 7.5.3 of the same title, in the old version of ISo9001. All requirements of the previous clause are retained
- This clause only applies when traceability is a requirement. In automotive, this clause is a requirement.
- The requirement is identify the output with respect to monitoring and measurement throughout production and service cycle, and retain the documented information for traceability
- IATF added a NOTE here. That if identification and test status cannot be indicated by location of the product, alternatives are permitted if designated purpose can be achieved

(Compliance Best Practice)

8.5.2 Identification and traceability

1. *In automotive, traceability is a requirement. Therefore there is no exemption for traceability*
2. *Identification for traceability is primarily on status of monitoring & measuring (M&M). Examples, 'waiting for inspection',' QC pass', 'on-hold', 'MRB decision', 'scrap' etc.*
3. *Method used for identification of M&M status can be tagging, or special place allocated with signages, barcode etc*

2) 8.5.2.1 Identification and traceability-supplemental (IATF16949)

(Clause Description-Paraphrase)

The purpose of traceability is to support identification of clear start and stop points for product received by the customer or in the field that may contain quality and/or safety-related nonconformities. Therefore, the organization shall implement identification and traceability processes as described below.

The organization shall conduct an analysis of internal, customer, and regulatory traceability requirements for all automotive products, including developing and documenting traceability plans, based on the levels of risk or failure severity for employees, customers, and consumers. These plans shall define the appropriate traceability systems, processes, and methods by product, process, and manufacturing location that:

a) enable the organization to identify nonconforming and/or suspect product;
b) enable the organization to segregate nonconforming and/or suspect product;
c) ensure the ability to meet the customer and/or regulatory response time requirements;
d) ensure documented information is retained in the format (electronic, hardcopy, archive) that enables the organization to meet the response time requirements;
e) ensure serialized identification of individual products, if specified by the customer or regulatory standards;
f) ensure the identification and traceability requirements are extended to externally provided products with safety/regulatory characteristics

(Highlights of the clause)

- (Ref to old Standards). There was a similar clause, 7.5.3.1 of the same tile, in the previous version of ISO/TS16949. It used to only said that dentification & Traceability cannot be exempted.
- Now the new clause is expanded as below:
- Organization shall determine the requirements from internal, customer, and regulatory perspective, including a developing a traceability plan, based on risk and failure severity
- Traceability plan shall include requirements stated as a) to f) of the clause
- Control shall include externally provided products with safety and regulatory requirements

(Compliance best practice)

8.5.2.1 Identification and traceability-supplemental

1. *This clause adds to the normal requirement for M&M. It focusses on traceability of data for handling of emergency and problem solving*
2. *To be of value, risks of the product on operators, customer and consumer need to be studied and considered in this particular emergency response plan*
3. *A traceability plan is needed for each product or product line found to be high risk. See* ***Exhibit 28-1*** *for a specimen.*

3) 8.5.3 Property belong to customers and external providers (ISO9001)

(Requirement-paraphrase)

The organization shall:

a) exercise care with property belonging to customers or external providers while it is under the organization's control or being used by the organization.

b) The organization shall identify, verify, protect and safeguard customers' or external providers' property provided for use or incorporation into the products and services.

c) When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer or external provider and retain documented information on what has occurred.

NOTE A customer's or external provider's property can include materials, components, tools and equipment, premises, intellectual property and personal data.

(Highlights of the clause)

- (Ref to old Standards). There had been a similar clause, 7.5.4 Customer Property, in the previous version of ISO/TS16949.
- All requirements remain and the total requirement is short, as given a) to c) in the clause description above
- Note the major change of supplier properties also under control and external parties is included in the clause.
- The Note also list out more items considered external properties,

(Compliance best practice)

8.5.3 Property belong to customers and external providers

1. *This clause is about managing properties belong to external parties. It used to be only customer properties involved, but in this new version, properties from suppliers shall also be treated the same way*
2. *Establish a procedure covering all external properties and how they are managed and reported. There are generally 2 methods:*
   a) *For equipment, each equipment shall have an asset card to keep records of transaction and communications See* ***Exhibit 28-2.***
   b) *For consumables such as raw parts, packaging materials and labels etc, the method shall follow agreement with customers. Generally speaking, this is managed by logistics or warehouse dept. The original D/O from customer, delivery order of finished goods, scrap control, and current stock levels will be used for reconciliation. See* ***Exhibit 28-2***

4) SIs & FAQs

No SIs & FAQs for this Chapter

5) Supplementary Notes

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

Clause	Section	Clarification Subjects

8.5.2	CBP	**SN28.1 Where are the usual problem occurring in the production line on Identification and traceability?**
8.5.2	CBP	**SN28.2. Can we use temporary, handwritten labels for WIP?**
8.5.2 8.5.2.1	CBP	**SN28.3. If traceability plan is provided by customer, do we still need our own internal method?**
8.5.1.3	CBP	**SN28.4. Is it possible that external providers can loan equipment to an organization? Can you give an example?**
8.5.1.3	CBP	**SN28.5. How are the consumables type of customer properties being managed? Which department should be responsible?**
8.5.1.3	CBP	**SN28.6. How are the tooling best managed, who should be responsible?**

SN28.1 Where are the usual problem occurring in the production line, on Identification and traceability?

A few places:

a) WIP from one point to another, quite often there is no tagging/labelling.

b) at work stations, inspected and not-inspected parts got mixed up , or Ok and NG got mixed up

c) FG warehouse, when changing from temporary to permanent labels, wrong use of labels can happen.

SN28.2. Can we use temporary, handwritten labels for WIP?

Yes, but make sure they are correctly written, and handwriting legible.

SN28.3. If traceability method is provided by customer, do we still need our own internal method?

If you have only one customer, you probably won't need another internal method. However, if you have several customers, it is unlikely all of them will provide you with a traceability method. Then you should have an organization-specific method, and reference to customer method, if applicable.

SN28.4. Is it possible that external providers can loan equipment to an organization? Can you give an example?

Yes. it is possible, though rare. I have seen an organization needed to test the window motor (purchased part) before delivering the car door liner to customer. Supplier was happy to loan a tester to the organization, plus the attendant training, to help reduce claims from the OEM.

SN28.5. How are the consumables type of customer properties being managed? Which department should be responsible?

Materials such as paper cartons, labels are best managed by the warehouse. A reconciliation report is needed after a period, say every 3 months to the customer. The report should show total receipt – consumed quantity – damaged = balance. The balance data shall be attached. Customer may check onsite to verify the report.

SN28.6. How are the tooling best managed, who should be responsible?

Production Tooling belongs to customer is best managed by the toolroom. Master list shall be available with individual tooling file/cards. For communications, use email and correspondence printed out for records, also kept by toolroom. Design/Project department can keep a copy of email, as they are most likely the window to customer.

6) Exhibits

Exhibit 28-1. Traceability chart

Responsible	Process Flow	Records for Traceability
Store/ IQC	Note 1 Incoming materials	Note 1: • Supplier D/O with Lot No • COA/Mil Cert • IQC report • RoHS (once a year)
Welding Supervisor	Note 2 MIG Welding	Note 2: • Traveller /Lot No • Program selection record • First piece chisel test records • X-Ray penetration test (monthly) • Machine maintenance records
Assembly Supervisor	Note 3 Accessories & Insert	Note 3: • Traveller /Lot No • First piece/IPQC inspection records • Machine/spot weld tips/ fixture/measuring jigs maintenance records
Store / IQC	Note 4 ED Coating (Outsourced)	Note 4: • Consignment and return ID & traceability agreement • Consignment D/O and return from supplier • Report on thickness, cross cut results by supplier • Second party audit report
Painting section	Note 5 Painting	Note 5: • Traveller /Lot No • Paint thickness, cross cut
QC	Note 6 QC	Note 6: • FQC report on color, appearance, dimension
Store	Note 7 Packing/Storage	Note 7: • OQC checks on packing, labelling
Store	Note 8 Delivery	Note 8: • Delivery note to customer • COA/ Mil Cert

Responding to Complaint

Responsible	Requirement	Standard Practice
QC, store	To identify NCP and suspect	• From prelim info, explore possible causes
QC/Production	To identify and segregate NCP and suspect	• Customer to quarantine and segregate NCP & Suspect • Organization to quarantine and segregate NCP & Suspect (plus 1 lot before and 1 lot after)
QC	Within Respond time	• AS instructed by customer, to avoid line down
QC, Purchasing	Documentation on forward and backward traceability	• Trace forward to other customers, and put outgoing on hold, or alert customer • Trace backward to supplier for more data

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

- This is an example how to construct a traceability chart. There are 2 portions: a) is a flowchart of your operations, b) how you respond to complaints (which also satisfy the clause requirement)
- For the first portion, you list down the various stages where ID&T is required, and identify the records available. Pay special attention to interfaces, where changing of hands occur, as there should be some documentation. If not, that is an omission that needs to be corrected
- The second portion is the guideline to trace the records and clause requirement.

Exhibit 28-2. External Property Management

External Property Management

Type: Equipment

Property	Owner	Date Received
Model/Serial No etc	Dept Responsible/PIC	Date Returned

B. Incidents/Communications

Date/Time	Incident reported	Owner Rep	Agreement	Status
14/6/18 2:30 pm	Tooling XXX accidentally dropped and damaged	Zakaria, Purchasing	Org will repair the tooling at its own cost before Aug 2018. Send verification result to customer	1/9/18: Tooling was repaired and trial run. OK. Results send to customer

Type: Consumables

Property	Owner	Date Received (By Consignment D/O)
Model/Serial No etc	Dept Responsible/PIC	Date Returned (By D/O of Finished Parts + Inventory in store)

Date	Consignment D/O	Qty	FG D/O	Qty	Balance
1/11	BHS 15987	1000			1000
3/11	BHS 16705	1000			1000
5/11			JTC0981	1500	500

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

- The IATF V2016 has included supplier-provided property into the control. This kind of external property is rare, but relevant in some situations.
- The usual understanding of external properties means tooling and measuring equipment, which is not fully correct in the new version. External property also includes consigned materials, packaging materials, labels, drawings, technical specs, persona data etc provided by an external party.
- The first table above is only suitable for tooling and measuring equipment.
- Consigned materials and packaging materials, labels are fast-turnover items and not practical to be controlled in the first table. The second table is more suitable.
- Drawing and technical data are maintained as document or record control, usually by Doc Controller or Engineering dept. Normal receiving, revision and distribution data are sufficient for controls.

>> End of Chapter 28 <<

Chapter 29. Storage and Delivery

Contents:

0) Introduction

There are 2 primary related clauses on preservation in this chapter. The reason why a whole chapter is devoted to this is because the clauses have quite a fair bit of changes. They are not fully understood and/or poorly catered for.

1) 8.5.4 Preservation (ISO9001)

(Clause Description-Paraphrase)

The organization shall preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements. NOTE Preservation can include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection.

(Highlights of the clause)

- (Ref to old Standards). There had been a similar clause, 7.5.5 Preservation of product, in the previous version of ISO/TS16949.
- The old clause requires the organization to:
- preserve the conformity of product during internal processing and delivery to the intended destination.
- preservation shall include identification, handling, packaging, storage and protection.
- The main functions dealing with preservation are therefore warehouse and logistics

(Compliance Best Practice)

8.5.4 Preservation

1. *This is only the ISO9001 portion of preservation*
2. *See 8.5.4.1 for a combined discussion*

2) 8.5.4.1 Preservation-supplemental (IATF16949)

(Clause Description-Paraphrase)

Preservation shall include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection. Preservation shall apply to materials and components from external and/or internal providers from receipt through processing, including shipment and until delivery to/acceptance by the customer. In order to detect deterioration, the organization shall assess at appropriate planned intervals the condition of product in stock, the place/type of storage container, and the storage environment. The organization shall use an inventory management system to optimize inventory turns over time and ensure stock rotation, such as "first-in-first-out" (FIFO). The

organization shall ensure that obsolete product is controlled in a manner similar to that of nonconforming product. Organizations shall comply with preservation, packaging, shipping, and labelling requirements as provided by their customers.

(Highlights of the clause)

- There had been a similar clause, 7.5.5.1 Storage and inventory, in the previous version of ISO/TS16949.
- The old clause read: In order to detect deterioration, the condition of product in stock shall be assessed at appropriate planned intervals. The organization shall use an inventory management system to optimize inventory turns over time and assure stock rotation, such as "first-in-first-out" (FIFO). Obsolete product shall be controlled in a similar manner to nonconforming product.
- The old requirements are all retained and appear at the second paragraph.
- The new requirement include controls of: i) storage containers, and storage environment, ii) definition of preservation added include contamination control, transmission or transportation, iii) abide all preservation, packaging, shipping, and labelling requirements as provided by their customers

(Compliance Best Practice)

8.5.4.1 Preservation-supplemental

Inventory Rotation & Shelf Life Control

1. *Establish a preservation system such as FIFO with colour coding, which is acceptable to the customers*
2. *Shelf-life control should be introduced, especially for sensitive materials such as glue, chemicals, paints and solvent. A shelf-life guide and methods of preservations e.g. cold room needed, humidity control only etc, should be prepared for reference, better still, displayed. See* ***Exhibit 29-1.***

Packing Standard

3. *Packing standard shall be approved by customer*

Shipment Control

4. *Compliance to delivery schedules shall be demonstrated: how the customer call-in is managed to ensure delivery to customer's place on time, or ready to be picked up by 'milk-runs'*

Inventory reliability

5. *Stock check every month is usually practiced. It should, at the same time, check on expiry dates, conditions of the material/products, and storage conditions, with reference to item 2 above*

3) SIs & FAQs

No SIs & FAQs for this Chapter

4) Supplementary Notes

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

Clause	Section	Clarification Subjects

8.5.4, 8.5.4.1	CBP	**SN29.1. Is color-coding the only system for FIFO? Are there others?**
8.5.4, 8.5.4.1	CBP	**SN29.2.Any pit fall of the various methods?**
8.5.4, 8.5.4.1	CBP	**SN29.3.Is shelf life checking only for finished goods?**
8.5.4, 8.5.4.1	CBP	**SN29.4.How to control expired materials?**
8.5.4, 8.5.4.1	CBP	**SN29.5.Shelf life control requires manufacturing dates, if no manufacturing dates are provided, what do we do?**
8.5.4, 8.5.4.1	CBP	**SN29.6.Where else identification can be lost besides warehouse?**
8.5.4, 8.5.4.1	CBP	**SN29.7.Is training to delivery man important?**
8.5.4, 8.5.4.1	CBP	**SN29.8. How to conduct expired material re-inspection and how to judge if is OK?**
8.5.4, 8.5.4.1	CBP	**SN29.9.How do we handle expired materials and finished goods.**
8.5.4, 8.5.4.1	CBP	**SN29.10. Old stocks not disposed but kept in the warehouse, how to prevent unintended use?** **.**

SN29.1. Is colour-coding the only system for FIFO? Are there others?

Colour-coding is a very common and well accepted system, but it is not the only method. Another method is to line product or material physically up in sequence, and the top of the line is the first to arrive and used. Feeding to the line is at the back. Another method is to use the stock card to control the issue of material first-in-first out.

SN29.1. Any pit fall of the various methods?

- Colour codes: normal number of colours used is 6. The Jan and Jul will share the same colour, Feb and Aug the same colour and so on. Any old stock from Jan can mix up with July
- Physical sequence: need to move the goods physically, which can be heavy and exhausting
- Stock card. If some incoming lots are not recorded, FIFO will be disrupted

SN-29.2. Is shelf life checking only for finished goods?

No. Shelf life for materials is equally important. Expired materials used will lead to quality problem and normally escape detection at FQC. When finally detected in the field, it is too late and can be costly.

SN-29.3. How to control expired materials?

Use a system of expiry date monitoring. Expiry dates are usually expressed as number of months from the manufacturing dates. A list should be prepared as the shelf-life guide. By looking at current date and manufacturing date on the label, expiry can be easily calculated using the shelf-life guide. You can check any material/FG at any time, or once a month during stock-take.

SN-29.4. Shelf life control requires manufacturing dates, if no manufacturing dates are given, what can we do?

You can use the receiving date. A world-class Japanese company would deduct 6 months from the expiry date based on shelf-life. Example, If a chemical has an expiry date of 12 months from date of manufacturing, the expiry date based on receiving date will now be 6 months only (12-6 months). Not very accurate, but practical and safe.

SN-29.5.Where else identification can be lost besides warehouse?

Half-use materials kept at production floor. You can lose the label from the pallet or material bags. This is common. Identification and traceability needs to extend to this place.

SN-29.6. Is training to delivery people important?

Yes, some materials are sensitive to moisture or heat. Delivery people should be trained to deal with the changing weather conditions. Securing of the cargoes is also important to avoid damage. We have seen many of such incidents, where the parts arrived damaged, at the customers' premises. Additionally, they should also abide by delivery time, safety and environment, while at customer's premises, according to customer operations or instructions.

SN-29.7. How to conduct expired material re-inspection and how to judge if it is OK?

Many of the expiry dates are just caution dates. The material or FG may still be usable, but need verification of the quality, including functional tests. This can be conducted by QC based on the original specs, provided there are suitable testing facilities available.

SN-29.8.How do we handle expired materials and finished goods. Can we downgrade for other uses? Sell to after-market?

Selling expired materials or finished goods to undisclosed buyers and after-market is not permitted by any customer. To downgrade for other users may be acceptable, but customer should be informed.

SN-29.9. Old stocks not disposed but kept in the warehouse, how to prevent unintended use?

This is also common because many management want to keep them "just in case they are needed later". They take up space, and creating a lot of inconveniences. The best way is to get rid of them as soon as possible. If the materials are still to be kept, they should be kept in a place far away from the active operation areas, and clearly marked obsolete.

5) Exhibits

Exhibit 28-1. Preservation Control

Preservation Control

No	Item	Shelf Life	Caution Period	Storage Conditions	Reaction Plan	Key determination
1	Resin ABC	-	3 years	Dry, ambient temp	Re-verification by QA	Color & first piece inspection
2	Steel coil XZY	-	1 year	Dry , ambient temp	Re-verification by QA	Rust
3	Glue XXXX	6 months	-	<10C (freezer)	Scrap	Expiry Date
4	Paint	6 months	-	Dry, ambient	Return to vendor under agreement	Expiry date. SDS data

Remarks given in this section explain on the Exhibit. Do not include them as part of your working document

- This is an example of preservation control guide
- Copies are displayed in the warehouses to guide on compliance. It is also useful to guide stock-take, to spot any deterioration and incorrect storage method etc.
- Note that there are 2 areas of concern a) shelf life, b) caution period. There is a difference.
- Shelf-life is generally recognized and observed by the organization, or manufacturer. Once exceeded, the material or product is scrapped. Glue, paints and some chemicals are of this category.
- Caution period is not shelf-life per se. Resins is typical case. They shelf-life is not stated by manufacturers and also not expected to deteriorate over 5 years. A caution period of 3 years is assigned in the above case, for safety purpose. When 3 years is reached, the material is re-verified by QA, to ascertain if it is still usable. If so, it can be used and re-assigned a caution date (usually shorter this time). The re-verification method is important, See Best Practice for more explanation.

>> End of Chapter 29 <<

Chapter 30. QAQC Activities

Contents:

0) Introduction

There are many applicable clauses in this chapter. There is only one ISO9001 clause and the rest are all IATF clauses. Many of the clauses are not well catered for. Some areas are neglected or taken for granted. Many NCs have been written on this clause alone.

1) 8.6 Release of products and services (ISO9001)

(Clause Description-Paraphrase)

The organization shall implement planned arrangements, at appropriate stages, to verify that the product and service requirements have been met. The release of products and services to the customer shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer. The organization shall retain documented information on the release of products and services. The documented information shall include: a) evidence of conformity with the acceptance criteria; b) traceability to the person(s) authorizing the release.

(Highlights of the clause)

- (Ref to old Standards). There had been similar clauses, 8.2.4 Monitoring and measuring of products, in the previous version of ISO9001. *It is almost a word*-for-word re-production of the old clause. Note the change of title.
- Although the word release is used, it is meant cover all inspections, “at appropriate stages”, which can be confusing
- This is an important clause, the following must be complied to:
    a. Release of products can only take place when all inspections are done and passed, unless otherwise approved by a relevant authority and, as applicable, by the customer.
    b. The organization shall retain documented information on the release of products and services. The documented information shall include: a) evidence of conformity with the acceptance criteria; b) traceability to the person(s) authorizing the release.

(Compliance best practice)

8.6 Release of products and services

1. *You should have an inspection plan showing the planned inspections and record the results produced*
2. *On the inspection sheet, the person performing the inspections, and any special person signing for waivers and disposition decisions, shall be recorded*

2) 8.6.1 Release of products and services-supplemental (IATF16949)

(Clause Description-Paraphrase)

The organization shall ensure that the planned arrangements to verify that the product and service requirements have been met encompass the control plan and are documented as specified in the control plan (see Annex C). The organization shall ensure that the planned arrangements for initial release of products and services encompass product or service approval. The organization shall ensure that product or service approval is accomplished after changes following initial release, according to ISO 9001, Section 8.5.6

(Highlights of the clause)

- (Ref to old Standards). This is a totally new clause
- besides the requirements of 8.6, control plan now has a part to play in the release
- the inspection plan must agree with the control plan
- the method of initial release shall be described on the control plan
- if changes occur after initial release, the product needs to be re-inspected and approved again

(Compliance best practice)

8.6.1 Release of products and services-supplemental

1. *To comply with this clause, the control plan shall be made available to the production department*
2. *The inspection plan shall be periodically compared with the control plan. Quite commonly, the two documents do not agree with one another*
3. *The method of initial release (first-piece) shall be described on the control plan* ***Exhibit 21-9.***

3) 8.6.2 Layout inspection and functional testing (IATF16949)

(Clause Description-Paraphrase)

A layout inspection and a functional verification to applicable customer engineering material and performance standards shall be performed for each product as specified in the control plans. Results shall be available for customer review.

NOTE 1 Layout inspection is the complete measurement of all product dimensions shown on the design record(s). NOTE 2 The frequency of layout inspection is determined by the customer.

(Highlights of the clause)

- (Ref to old Standards). There had been a similar clause, 8.2.4.1 of same title, in the previous version of ISO/TS16949.
- The old clause read: A layout inspection and a functional verification to applicable customer engineering material and performance standards shall be performed for each product as specified in the control plans. Results shall be available for customer review. NOTE Layout inspection is the complete measurement of all product dimensions shown on the design records.
- The new clause is therefore almost a word-for-word, reproduction of the old clause."
- There is a FAQ#21, that clarifies that layout inspection is not the same as re-approval.

(Compliance best practice)

8.6.2 Layout inspection and functional testing

1. *The layout inspection and functional verification shall be shown In the control plan. See **Exhibit 30-1**. This is hardly done in most organizations.*
2. *When you are adding in the first-piece buy-off, use actual data, and do not refer to another document. See **Exhibit 30-1.***

4) 8.6.3 Appearance items (IATF16949)

(Requirement-paraphrase)

For organizations manufacturing parts designated by the customer as "appearance items," the organization shall provide the following:

a) appropriate resources, including lighting, for evaluation;

b) masters for colour, grain, gloss, metallic brilliance, texture, distinctness of image (DOI), and haptic technology, as appropriate;

c) maintenance and control of appearance masters and evaluation equipment;

d) verification that personnel making appearance evaluations are competent and qualified

(Highlights of the clause)

- (Ref to old Standards). There had been a similar clause 8.2.4.2, with same title. in the older version of ISO/TS16949. The new clause is a word-for-word reproduction of the old clause

(Compliance best practice)

8.6.3 Appearance items

3. *In most cases, lightings must be adequate for inspection. Ensure sufficient light intensity, especially for night time*
4. *Provide masters to guide on checking e.g. Life samples, colour photos, quality alerts, training*
5. *People make appearance evaluations shall be competent and qualified. You need to do the Attribute GR&R on these people as evidence.*

5) 8.6.4 Verification and acceptance of conformity of externally provided products and services (IATF16949)

(Requirement-paraphrase)

The organization shall have a process to ensure the quality of externally provided processes, products, and services utilizing one or more of the following methods:
a) receipt and evaluation of statistical data provided by the supplier to the organization;
b) receiving inspection and/or testing, such as sampling based on performance;
c) second-party or third-party assessments or audits of supplier sites when coupled with records of acceptable delivered product conformance to requirements;
d) part evaluation by a designated laboratory;
e) another method agreed with the customer.

(Highlights of the clause)

- (Ref to old Standards). There had been similar clauses, 7.4.3.1. Incoming product conformity to requirements, in the previous version of ISO/TS16949. *There was n*o change. The new clause is almost a word-for-word re-production of the old clause
- The clause is on incoming quality control. It spells out the various acceptable methods for incoming QC. The most common being incoming inspections, or based on certificate of compliance from suppliers.

(Compliance best practice)

8.6.4 Verification and acceptance of conformity of externally provided products and services

1. *Incoming inspection shall be pre-planned, follow quality agreement from customer.*
2. *If COA is used, the data shall be studied for conformance. For acceptance criteria e.g. chemical specs, IQC shall base the judgement on internally approved criteria, not what is printed on supplier's reports.*

6) 8.6.5.Statutory and regulatory conformity (IATF16949)

(Requirement-paraphrase)
Prior to release of externally provided products into its production flow, the organization shall confirm and be able to provide evidence that externally provided processes, products, and services conform to the latest applicable statutory, regulatory, and other requirements in the countries where they are manufactured and in the customer-identified countries of destination, if provided.

(Highlights of the clause)

- (Ref to old Standards). There had been a similar clause, 7.4.1.1 of the same tile, in the previous version of ISO/TS16949.
- Now it has more requirement, including externally provided products. These products must be ensure of compliance to the latest applicable statutory, regulatory and other requirements in the countries they are manufactured, and countries of destination (See FAQ#24)
- Evidence of compliance is required that verification has been carried out.
- This is link on from 8.4.2.2. First you define what are needed and then to check and ensure compliance

(Compliance best practice)

8.6.5.Statutory and regulatory conformity

1. *Verification for statutory and regulatory compliance is an important requirement. Some of these requirements are verifiable at FQC/ OQC. Some compliances however, are based on documents to be furnished by the office e.g. RoHS/SOD.*
2. *The same method is also applicable to externally-provided products, but the documentation will be prepared by the external providers. You may want a copy in the file, just in case customer requires the evidence.*

7) 8.6.6 Acceptance criteria (IATF16949)

(Clause Description-Paraphrase)

Acceptance criteria shall be defined by the organization and, where appropriate or required, approved by the customer. For attribute data sampling, the acceptance level shall be zero defects (see Section 9.1.1.1).

(Highlights of the clause)

- (Ref to old Standards).There had been a similar clause, 7.1.2 of same title, in the previous version of ISO/TS16949. The new clause is a word-for-word reproduction of the old clause
- Need to define the acceptance criteria; e.g. 0.4, 0.65 etc, to be approved by customer, if applicable. For attribute, C= 0 shall be the criteria.

(Compliance Best Practice)

8.6.6 Acceptance criteria

1. *Acceptance criteria; e.g. 0.4, 0.65 etc, shall be listed on the control plan, to be approved by customer, if applicable. For attribute, C= 0 shall be the criteria.*
2. *Provide training to relevant people, I have seen in too many places where QC people do not know about acceptance criteria. It is good to display the chart.*

8) SIs & FAQs

FAQ	IATF Clause	Questions and Answers
21	**8.6.2 Layout inspection and functional testing**	**QUESTION:** **Is a layout inspection different from a product requalification or functional testing?** **ANSWER:** Yes, as stated in Note 1 of 8.6.2 of IATF 16949, [Layout inspection is the complete measurement of all product dimensions shown on the design record(s)]; layout inspection is limited to dimensional measurement and requirements. Performance or materials measurements are not included in a layout inspection. Product requalification would normally imply full validation to all product approval requirements (e.g. PPAP or PPA) and therefore exceeds the scope of a layout inspection. Functional testing/verification would normally be limited to performance and material measurements such as durability or tensile strength and would not include dimensional measurements. Where frequency is not defined by the customer, the organization is responsible to define the frequency of layout inspection. Layout inspection is a part of product requalification, if product requalification is required by the customer. On-going layout inspection and functional testing requirements are defined in the control plan. If customer-specific requirements exist, then those requirements (including layout inspection and functional testing requirements) are also included in the control plan.

9) Supplementary Notes

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

S/N	Reference	Clarification Subjects
8.6 8.6.1	CBP	**SN30.1. What is the confusion of 'release' and 'all stages' about?**
8.6 8.6.1	CBP	**SN30.2. What are the correct way to record the person releasing a production lot?**
8.6 8.6.1	CBP	**SN30.3. Can we make reference to the first-piece buy off recording sheet, instead of listing down the first piece and specs on control plan?**
8.6.2	CBP	**SN30.4. *What is layout inspection? Is* re-approval and layout inspection the same?**
8.6.3	CBP	**SN30.5. *Must photo used for master appearance guide be colored?***
8.6.4	CBP	**SN30.6. *For COC (certificate of conformance) provided by supplier, why can't the criteria given on the report be followed?***
8.6.6	CBP	**SN30.7. What are the pitfall for the implementation of AQL?**

SN30.1. What is the confusion of 'release' and 'all stages' about?

In the last version, ISO has clarified that release means the last inspection point, before sending to customer. All other inspection points are not referred as release. In the new clause, 'all stages' is still mentioned in a heading 'release'. That is the confusion.

SN30.2. What are the correct way to record the person releasing a production lot?

The person responsible for releasing can be recorded by signature, a personalized rubber stamp, or the employee no. But signature (or initial) should be clear and traceable.

SN30.3. Can we make reference to the first-piece buy-off recording sheet, instead of listing down the first piece and specs on control plan?

No. The first piece characteristics data are very important and must be recorded on the control plan to signified they have been approved. Inspection sheets can be subject to unauthorized changes. Reference for other types of documents such as WI is acceptable, because they are normally too wordy.

SN30.4. What is layout inspection? Is re-approval and layout inspection the same?

See FAQ-21 for explanations

SN30.5. Must photo used for master appearance guide be coloured?

Photos are used for judgement on colour and other details. Black and white photos are not suitable for colour reference for sure. Some other details can be seen better in colour photos but not black and white, especially those produced by lower quality photocopier.

SN30.6. For COC (certificate of conformance) provided by supplier, why can't the criteria given on the report be followed?

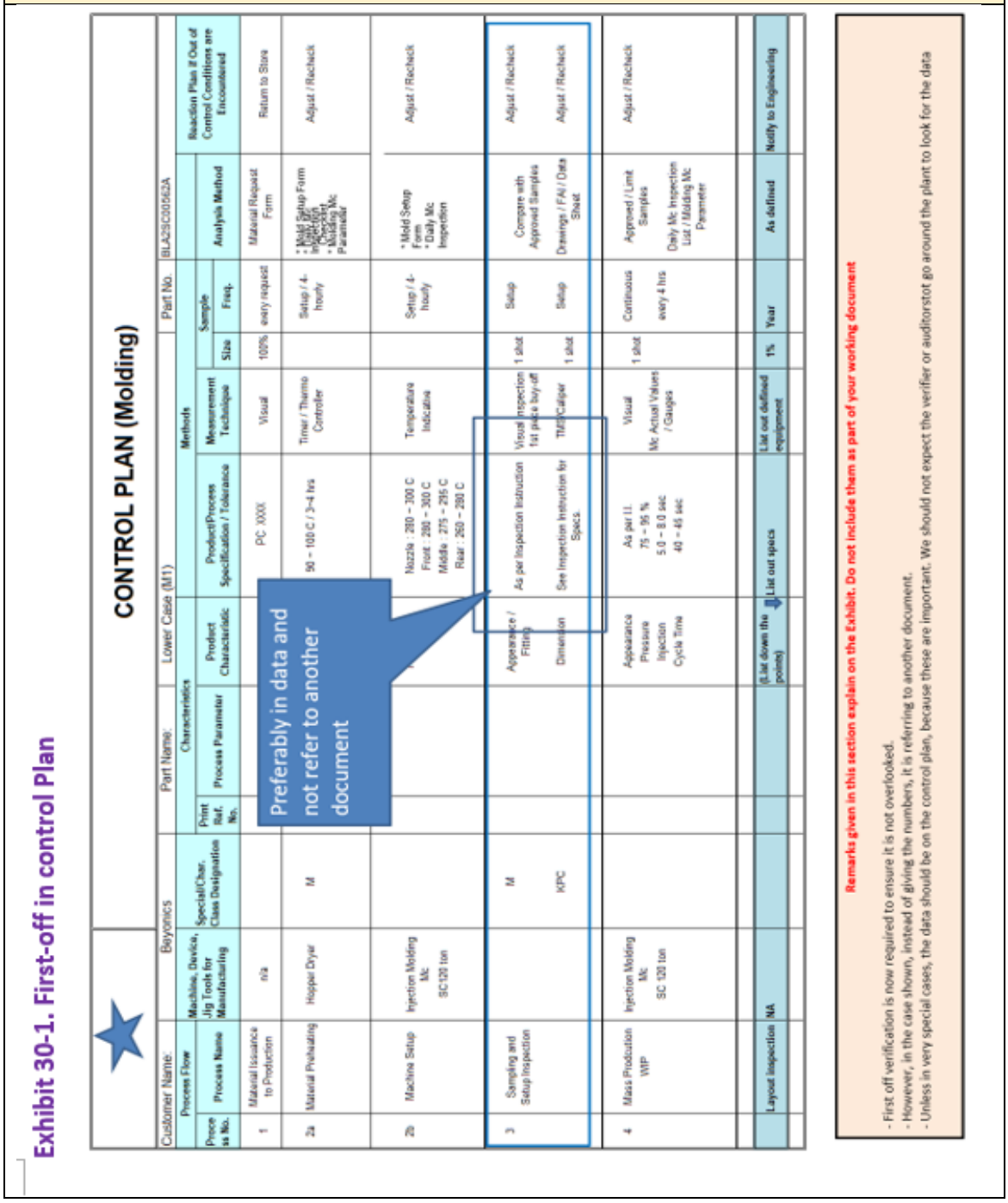
A supplier has many customers with different requirements and specs. The criteria listed on the COC may be a generic set, and not suitable for you. You should use your own defined list of specs.

SN30.7. What are the pitfall for the implementation of AQL?

Quite commonly, QC people do not inspect all the samples specified by the AQL. The reason given is customer only wanted the results of 5-10 samples and there is only enough space on the report for the results of 5-10 pc. This is incorrect. They need to inspect all the full sample size according to the AQL specified. From there you pick the data to the customer.

10) Exhibits

Exhibit 30-1 First off in Control Plan



>> End of Chapter <<

Chapter 31. Nonconformity, Corrective Action & Preventive Action

Contents:

0) Introduction

There are a few applicable clauses in this chapter. Clause 10.2.3 is almost a repeat of 10.2. Preventive is not required in ISO9001, but it is still required by IATF. The reason why a whole chapter is devoted to this is because there had been some subtle changes, which is not commonly aware and/or poorly catered for. Surprisingly after 30 years of ISO, closing methods are not well understood by many organizations. Many NCs have been written on this clause alone.

1) 10.2, 10.2.1 Nonconformity and Corrective action (ISO9001)

(Clause Description-Paraphrase)

When a nonconformity occurs, including any arising from complaints, the organization shall:

a) react to the nonconformity and, as applicable:
1) take action to control and correct it;
2) deal with the consequences;
b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:
1) reviewing and analysing the nonconformity;
2) determining the causes of the nonconformity;
3) determining if similar nonconformities exist, or could potentially occur;
c) implement any action needed;
d) review the effectiveness of any corrective action taken;
e) update risks and opportunities determined during planning, if necessary;
f) make changes to the quality management system, if necessary. Corrective actions shall be appropriate to the effects of the nonconformities encountered.

(Highlights of the clause)

- (Ref to old Standards*). There had been similar clauses,* 8.5.2 Corrective Actions, in the previous version of ISO9001.
- All requirements in the previous clause are retained and included in second half of new clause.
- New requirements added are: a(2), b (containment), & b(2), c(e) & c(f)
- b(3) is seldom adopted, although not new to most people. It is about similar problem or potential problem exist, elsewhere in the organization or process etc. If so, the corrective actions can be extended (horizontal application) to these areas.

(Compliance best practice)

10.2, 10.2.1 Nonconformity and Corrective action

1. *This clause and 10.2.3 are very similar and discussed together here*
2. *The procedure on corrective actions to include the new requirements, i.e. a(2), b (containment), b(2), c(e) & c(f).*
3. *Provide a flowchart in the procedure to guide handling of nonconformity. See* ***Exhibit 31-1.***
4. *Containment shall be included as first response, if it has not been part of your corrective action procedure*
5. *The method used (why-why, fish-bone, Pareto etc) should be defined*
6. *Updating of process documents should follow, as a result of the changes (10.2.3 requirement)*
7. *Horizontal replication to similar or potential problems needs to be an added step. This is best deal with using another form, due to space constraint.* ***Exhibit 31-2.*** *Also see* ***SN-31.3 to SN-31.5*** *for explanations.*

2) 10.2.2 (Retain documented information) (ISO9001)

(Clause Description-Paraphrase)

The organization shall retain documented information as evidence of:

a) the nature of the nonconformities and any subsequent actions taken;

b) the results of any corrective action

(Highlights of the clause)

- (Ref to old Standards).This is a totally new requirement.
- It is just about the need for record, which is not a problem in most organizations

(Compliance best practice)

10.2.2 (Retain documented information)

1. *The clause required records to be retained*
2. *This is generally not an issue, as record keeping is a well-establish practice in ISO and manufacturing context*

3) 10.2.3 Problem Solving (IATF16949)

(Clause Description-Paraphrase)

The organization shall have a documented process(es) for problem solving including:

a) defined approaches for various types and scale of problems (e.g., new product development, current manufacturing issues, field failures, audit findings);

b) containment, interim actions, and related activities necessary for control of nonconforming outputs (see ISO 9001, Section 8.7);

c) root cause analysis, methodology used, analysis, and results;

d) implementation of systemic corrective actions, including consideration of the impact on similar processes and products;

e) verification of the effectiveness of implemented corrective actions;

f) reviewing and, where necessary, updating the appropriate documented information (e.g., PFMEA, control plan). Where the customer has specific prescribed processes, tools, or systems for

problem solving, the organization shall use those processes, tools, or systems unless otherwise approved by the customer.

(Highlights of the clause)

- (Ref to old Standards). There had been a similar clause, 8.5.2.1 of the same title, in the previous version of ISO/TS16949.
- The old clause was a very simple statement : "The organization shall have a defined process for problem solving leading to root cause identification and Elimination"
- Point d) used to be 8.5.2.3 Corrective action impact
- The new clause is rewritten as a step-wise listing of requirements. Only real addition is is to revised document after problem solving e.g. FMEA, Control Plan etc. Revise of control plan is also mentioned in 8.5.1.1.

(Compliance best practice)

10.2.3 Problem Solving

The extra requirements here has been added to Best Practice of 10.2.1. Please refer.

4) 6.1.2.2 Preventive Actions (IATF16949)

(Clause Description-Paraphrase)

Potential nonconformities need to be determined and prevented. A process shall be established to lessen the impact of negative effects of risk including the following: (a) determining potential nonconformities and their causes; (b) evaluating the need for action; (c) determining and implementing action needed; (d) documented information of action taken; e) reviewing the effectiveness; f) utilizing lessons learned to prevent recurrence in similar processes. Preventive actions shall be appropriate to the severity of the potential issues.

(Highlights of the clause)

- (Ref to old Standards).There has been a similar clause (8.5.3) of the same title in the old version of ISO/TS16949.
- Preventive action in ISO9001, however, is no longer required.
- Method quite similar to NCR. See a) to f). notable: eval need, doc info. Action appro to severity, lessons learned

(Compliance best practice)

6.1.2.2 Preventive Actions

1. *To comply, a process shall be established (not necessarily documented), or design a form for processing such cases.*
2. *The form is quite similar to a CAR/NCR, except there is step of preliminary decision whether to take action or otherwise. See* ***Exhibit 31-3.***
3. *External happenings elsewhere can be a trigger for preventive actions. Example, if a similar organization having problem with a new material that you are also using, preventive action should kick in*
4. *You horizontal replication step in the problem-solving model (see* ***Exhibit 31-1)****, is a preventive action, but the trigger is within the organization.*

5) SIs & FAQs

No SIs & FAQs for this Chapter

6) Supplementary Notes

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

Clause	Section	Clarification Subjects
10.2.1	CBP	**SN31.1. Are there any other methods for root cause analysis besides the 3 types mentioned e.g. brain storming?**
10.2.1	CBP	**SN31.2. Horizontal application can be very wide in scanning area, how far should we go or stop?**
10.2.1	CBP	**SN31.3. Do we apply horizontal application this to internal audit? Our NCR format does not have a column for this record.**
10.2.1	CBP	**SN31.4. Do we apply application to customer audit/ customer complaint handling? The customer format does not have this column.**
10.2.1	CBP	**SN31.5. Do we apply application to CB audit? The CB format does not have this column.**
10.2.1	CBP	**SN31.6. Do we apply application every time a piece of reject occurs in the production floor?**
6.1.2.2	CBP	**SN31.7. Isn't corrective actions preventive in nature? Is it not the same as preventive action?**
6.1.2.2	CBP	**SN31.8. Instead of a new form, can I use a CA form, add the extra column needed on prelim decision?**
6.1.2.2	CBP	**SN31.9. Why Preventive action not required in ISO9001, as it looks useful?**

SN31.1. Are there any other methods for root cause analysis besides the 3 types mentioned e.g. brain storming?

The most common and accepted methods are the 3 types given. They are well understood and do not required much explanations. Any other method can be used, so long you can demonstrate that they lead logically to the root cause. And also your own people understand and know how to use the method.

SN31.2. Horizontal replication can go very wide, how far should we go or stop?

Pragmatism has to come in here. We are not into academic research but doing practical work that is keeping the organization going. Stick close to what is important and relevant, and don't wonder off too far. You should know where and when to stop. If in doubt, seek some opinion within your organization.

SN31.3. Do we apply horizontal replication to internal audit? Our NCR format does not have a column for this record.

Yes, it applies to internal audit as well. Modify your format to comply.

SN31.4. Do we apply horizontal replication to customer audit/ customer complaint handling? The customer format does not have this column.

Yes, it applies to customer audit and complaint handling. You cannot modify customer format but there is a way to comply. You can do the closing first on your own internal format, and then transfer what customer needs onto their format.

SN31.5. Do we apply application to CB audit? The CB format does not have this column.
Answer same as customer audit, please refer.

SN31.6. Do we apply horizontal replication every time a piece of reject occurs in the production floor?
No. You don't raise an NCR for a single nonconformity, unless it is a safety issue and/or expensive. You probably wait for a week or a month to review trends and the gravity of the various types of rejects, to issue an NCR. And if you do, you will complete the task right up to horizontal replication. Then you are in compliance.

SN31.7. Isn't corrective actions preventive in nature? Is it not the same as preventive action?
They are both preventive in nature, with a difference:

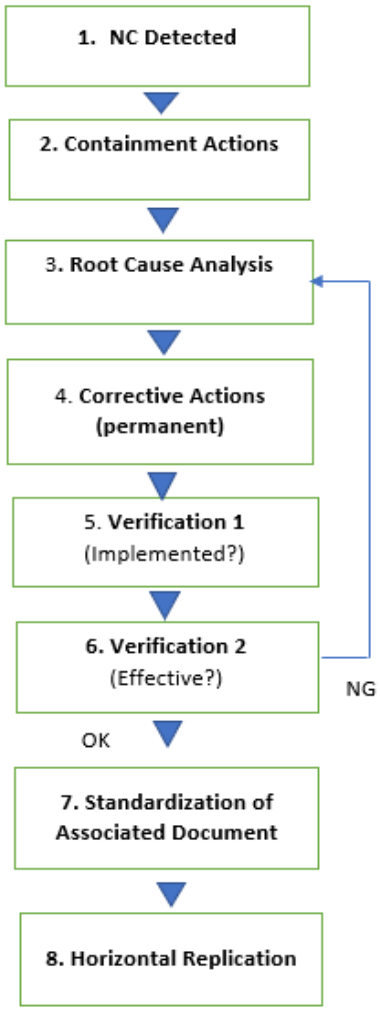
- Corrective Action is prevention of recurrence- problem has happened and we want to prevent it from happening again
- Preventive Action is prevention of occurrence. It may have happened elsewhere, or suspected to happen, and actions taken to prevent it. The horizontal replication is a preventive action

SN-31.8. Instead of a new preventive action form, can I use a CA format, by adding the extra column on preliminary decision?
For most cases of horizontal replication, it is the last part of the corrective action format; or as a continuation sheet (**Exhibit 35-2).**
The preventive action format (**Exhibit 35-3),** is potential nonconformity, never happened in the organization before. You take proactive action to prevent it. You need a new format. But you can use a NCR/with some modifications.

SN31.9. Why Preventive action is not required in ISO9001, as it looks useful?
The reason given by ISO is risk management analysis have fundamentally replace the need for another set of risk management analysis. IATF16949 thinks otherwise and retains the preventive actions.

7) Exhibits

Exhibit 31-1. NC, CA & Problem Solving

Responsibility	Flow Diagram	Description
Receiver of notification Person-in-charge Applicable process owner		Note 1 • When a nonconformance is detected. This can be detected by organization itself, or via a customer alert Note 2 • Containment shall first be taken • It is also called temporary corrective actions, or correction. An example is: If rejects produced-Stop machine, Deal with consequences Note 3 • After taking the containment, root cause analysis then begins • 3 types of analytical tools can be used: a) Why-why analysis, b)Fish bone and c Pareto Analysis. Note 4 • The corrective actions must be link to the root cause, otherwise is it not effective Note 5 • First verification is if the actions have been implemented correctly. Note 6 • Next verification is if the effects are good. If not, go back to root cause analysis Note 7 • After the NC is effectively solved, document shall be standardized • They may include PFC, FMEA, CP, WI etc Note 8 • Branch out to verify if there is similar situation or potential situations affected by same problem • If yes, actions should be taken to apply the same concept to solve the problem

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

- In the past, both ISO and IATF were not rigid on handling methods for nonconformities
- This new revision however spelt the methods very clearly, in 10.2.1, 10.2.2 (ISO) and 10.2.3 (IATF).
- Step 8 in the flowchart above is now a requirement. In IATF it used to be called Corrective Action Impact (8.5.2.3 of the old IATF version). In Japan it is referred to as 'Yokoten'.
- It is best to use a different form to show Step 8 (Horizontal Replication) due to space constraint

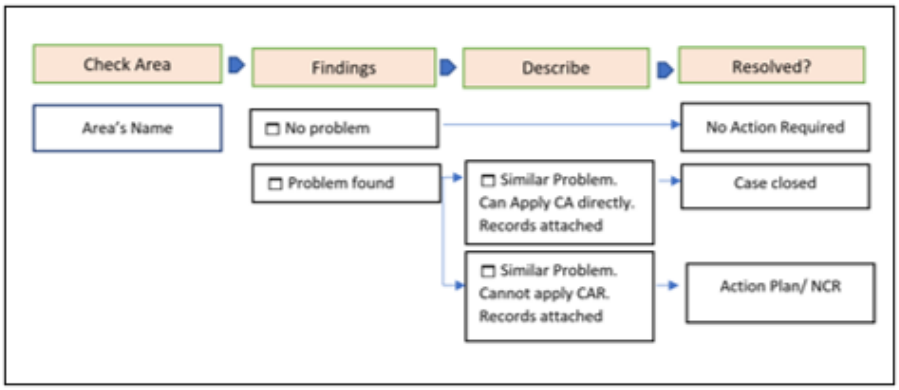
Exhibit 31-2. NC Horizontal Replication

NC Horizontal Replication

A) Nonconformance

Source of NC External Audit (Surv 1)	Date 20 Feb 2018	NCHR 2018/QMS-7	Date of NCHR 25 Mar 2018
NC Background • A new process of spray painting has been added but there is no training for the new skill required for Store control. • NC resolved, but no evidence of horizontal replication			Clause: 10.2.3. Problem Solving

A. Horizontal Replication Guide



B. Actual Checking

No	Check Area	Findings	If Finding, Describe	Resolution
1	Purchasing	Similar problem of no training	Can apply CA directly. Provided training. Implemented (3/328)	Resolved
2	Production	No problem-training provided by supplier	NA	No Action Needed
3	QAQC	No problem-requirement given by customer	NA	No Action Needed
4	Environment	Similar problem of no training	Hazardous waste PIC not inform and not taught how to handle paint wastes. Inform EMR	NCR. EMS-017/19

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

- This is only a specimen on how to complete horizontal replication. This method is simple, but effective and sufficient to comply to the requirement.
- We have seen organization putting 2 tick boxes, yes or no, (if horizontal replication done?). And they always tick yes, but without evidence. This is not acceptable.
- We have also seen very complicated methods, which are technically good, but avail no added benefits.

Exhibit 31-3. Preventive Action Request (PAR)

Preventive Action Request (PAR)

Event	Date	PAR No.
Market information	2 Nov 2018	PAR/01/2018

Potential Problem/Non-conformance Noticed

Potential Problem Description	Impact description
Heard next-door company was using a new material XYZ. End part turns yellowish after a week, and rejected by customer. Material is direct buy by customer. We have also started using the material. Our customer also same.	We may also have same problem Risk: ( ) Low ( ) Mid (x) High Actions required: (x) Yes ( ) No

(Root Cause Analysis)

Possible Root Cause	Possibility Yes/No
Wrong method (Temperature etc?) Checked SDS and verified OK	No
Environment (Wrong storage?) Material and finished parts kept under shade and inside store. Store is cooling	No
Material Problem (Inherent material problem) (No other causes detectable in our place)	Yes

(Action)

No	Actions	Due	Actual
1	Notify customer	2/11	2/11
2	Check on methods and environment of storage	3/11	2/11
3	Send confirmatory results to customer and request further advise	3/11	3/11
4	Stop production until customer provides answer	3/11	3/11
5	Purchased the old material	4/11	4/11
6	Resume production	5/11	7/11

Notes:

1. Customer advise to go back to old material, on 3/11
2. Ordered new materials and resume production
3. New agreement reached on delivery due to lost of time by 1 week

Results Verification

Results Of Action Taken is Effective? (x) Yes ( ) No

Disposition of PAR: (x) Closed out ( ) Repeat ( ) No Further Actions Needed

QMR/Date	Top Management Approval/Date

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

- This is a sample of preventive action request. You can also use the normal CAR, but make a slight change, on need for action (red circle area)
- This PAR is equivalent to horizontal replication, therefore there is no need to do horizontal replication, after closing of the PAR

>> End of Chapter 31 <<

Chapter 32. Nonconforming Outputs

Contents:

0) Introduction

There are several closely-related clauses in this chapter, on defective products and their handling. They make a very suitable cluster for discussion. Many of these clauses are new, and some not fully misunderstood and/or poorly catered for. Many NCs have been written on this clause alone. Some attention should be given.

1) 8.7, 8.7.1. Control of nonconforming outputs (ISO9001)

(Clause Description-Paraphrase)

The organization shall ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery. The organization shall take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This shall also apply to nonconforming products and services detected after delivery of products, during or after the provision of services. The organization shall deal with nonconforming outputs in one or more of the following ways:

a) correction;
b) segregation, containment, return or suspension of provision of products and services;
c) informing the customer;
d) obtaining authorization for acceptance under concession. Conformity to the requirements shall be verified when nonconforming outputs are corrected.

(Highlights of the clause)

- (Ref to old Standards). There had been a similar clause, 8.3 Control of Nonconforming Product, in the previous version of ISO9001.
- The old clause aims at preventing their unintended use or delivery of nonconforming outputs via a) eliminate the nonconformity, b) apply concession, c) stop the original intended use.
- Records: handling of the NC, including concession. Corrected NC subject to re-inspection.
- If detected after delivery or use has started, work on appropriate actions appropriate to the effects, potential effects

- New clause keeps all the previous requirement and reworded for clarity. Some new additions are similar as 10.2.1. correction; segregation, containment, return or suspension of provision, c) informing the customer; d) obtaining authorization for acceptance under concession. Conformity to the requirements shall be re-verified when ok after rework
- Note that the formal NCP (nonconforming product), is now called NCO (nonconforming output)

(Compliance best practice)

8.7, 8.7.1. Control of nonconforming outputs

1. *This applies to the nonconforming output (NCO) detected. Any decision to use the NCO (UAI or rework) has to be approved by the customer.*
2. *If answer is negative, the NCO shall be scrapped*
3. *If the NCO can still be used, apply for concession from the customer. There is usually a customer procedure on how such applications shall be processed. Approvals should specify the quantities allowed, and temporary specs to follow.*
4. *Sometimes concession is only given for rework, and the rework method and specs shall be approved or agreed by the customer*
5. *This requires a procedure, if applicable, but many organizations do not seem to have it. See* ***Exhibit 32-1***

2) 8.7.1.1 Customer Authorization for Concession (IATF16949)

(Clause Description-Paraphrase)

The organization shall obtain customer authorization prior to further processing for "use as is" and rework (SI-9) for repair ~~dispositions~~ of nonconforming product. If sub-components are reused in the manufacturing process, that sub-component reuse shall be clearly communicated to the customer in the concession or deviation permit. The organization shall maintain a record of the expiration date or quantity authorized under concession. The organization shall also ensure compliance with the original or superseding specifications and requirements when the authorization expires. Material shipped under concession shall be properly identified on each shipping container (this applies equally to purchased product). The organization shall approve any requests from suppliers before submission to the customer.

The organization shall obtain a customer concession or deviation permit prior to further processing whenever the product or manufacturing process is different from that which is currently approved. The organization shall obtain customer authorization prior to further processing for "use as is" and rework dispositions of nonconforming product. If sub-components are reused in the manufacturing process, that sub-component reuse shall be clearly communicated to the customer in the concession or deviation permit. The organization shall maintain a record of the expiration date or quantity authorized under concession. The organization shall also ensure compliance with the original or superseding specifications and requirements when the authorization expires. Material shipped under concession shall be properly identified on each shipping container (this applies equally to purchased product). The organization shall approve any requests from suppliers before submission to the customer.

(Highlights of the clause)

- (Ref to old Standards). There had been a similar clause, 8.7.1.1 Customer Authorization for Concession, in the old version of ISO/TS16949.
- The old clause is expanding on concessions.
  i) It requires organization to obtain customer concession or deviation permit before delivery whether a) use as is, b) rework, c) reuse of subcomponents,
  ii) Organization shall maintain record on expiration date or quantity authorized,
  iii) Organization must go back to original specs when concession expires,
  iv) Material shipped shall be properly identified on each shipping container,
  v) Purchased products also treated same way. Where suppliers are involve, organization must check the compliance before submission to customer.
- The new clause is just a rewording, for better clarity, and no material change in the content,
- There are a minor change on the new clause via SI-9, more on correcting grammatical errors.

(Compliance best practice)

8.7.1.1 Customer Authorization for Concession

1. *Develop a process/procedure (not mandatory) for concession management. See* ***Exhibit 32-1***
2. *Concession Records should be in customer format. If there is no customer format, use your own. See* ***Exhibit 32-5****. The records are mandatory.*

3) 8.7.1.2 Control of nonconforming product-customer-specified process (IATF16949)

(Clause Description-Paraphrase)

The organization shall comply with applicable customer-specified controls for nonconforming product(s)

(Highlights of the clause)

- (Ref to old Standards). This is a totally new requirement
- If customer has a specified process on control of certain nonconformity, you need to followed.

(Compliance best practice)

8.7.1.2 Control of nonconforming product-customer-specified process

1. *This refers to special cases, specialty in nature, or repair or rework procedures developed by the customer.*
2. *When preparing a repair and a rework procedure, this clause shall be included. See* ***Exhibit 32-2***

4) 8.7.1.3 Control of Suspect Product (IATF16949)

(Clause Description-Paraphrase) The organization shall ensure that product with unidentified or suspect status is classified and controlled as nonconforming product. The organization shall ensure that all appropriate manufacturing personnel receive training for containment of suspect and nonconforming product.

(Highlights of the clause)

- (Ref to old Standards). This is a totally new clause.

- Unidentified or suspect status is classified as nonconformities
- Relevant people shall be trained for containment of suspect and nonconforming product

(Compliance best practice)

8.7.1.3 Control of Suspect Product

1. *Material, WIP and Finished Product that have lost their labels or identifications need to be controlled as suspect. No assumption shall be taken*
2. *Onhold tags or equivalent can be used to identify the suspect. See* ***Exhibit 32-3***
3. *Sometimes the rectification is simple, consisting of tracing only, while sometimes re-inspection is needed, much depends on the case at hand.*
4. *Approval is needed from the appropriate authority to revert status of conforming from suspect.*

5) 8.7.1.4 Control of Rework Product (IATF16949)

(Clause Description-Paraphrase)

The organization shall utilize risk analysis (such as FMEA) methodology to assess risks in the rework process prior to a decision to rework the product. If required by the customer, the organization shall obtain approval from the customer prior to commencing rework of the product. The organization shall have a documented process for rework confirmation in accordance with the control plan or other relevant documented information to verify compliance. Instructions for disassembly or rework, including re-inspection and traceability requirements, shall be accessible to and utilized by the appropriate personnel. The organization shall retain documented information on the disposition of reworked product including quantity, disposition, disposition date, and applicable traceability information.

(Highlights of the clause)

- (Ref to old Standards). There had been similar clauses, 8.3.2 of the same title.
- The old clause was very simple: “Instructions for rework, including re-inspection requirements, shall be accessible to and utilized by the appropriate personnel”.
- A lot new requirements added in the new clause :
    i. utilize risk analysis (such as FMEA) methodology to assess risks in the rework process prior to implementation
    ii. if required by the customer, the organization shall obtain prior approval from the customer
    iii. have a documented process for rework confirmation in accordance with the control plan or other relevant documented information to verify compliance.
    iv. Instructions for disassembly or rework, including re-inspection and traceability requirements,
    v. retain documented information on the disposition of reworked product, including quantity, disposition, disposition date, and applicable traceability information.

(Compliance best practice)

8.7.1.4 Control of Rework Product

1. *A document process is needed for this activity*
2. *There are generally 2 types of rework: a) minor touch-up e.g. on appearance, slight over-dimension problem etc., b) uncommon and rework that needs elaborated work*
3. *Type a) is usually a common occurrence, and procedure well-established. The control is the re-inspection to original specs, including functional*
4. *Type b) would need ad-hoc preparation of the rework procedure. This needs to be careful as it is more complicated than Type a). A multidisciplinary team should be used to develop the procedure and inspections.*
5. *Inspection is generally reference to control plan or other guiding document. WI for disassembly, refitting etc, and shall be prepared and made accessible to operators. Records shall be maintained.*
6. *Before implementation, risk analysis is required. Risk analysis can be carried out on a FMEA format. The risk shall be mainly on impact on the product, operations, customer's operations and operator safety.*
7. *Apply approval from customer if applicable.*

6) 8.7.1.5 Control of repair product (IATF16949)

(Clause Description-Paraphrase)

The organization shall utilize risk analysis (such as FMEA) methodology to assess risks in the repair process prior to a decision to repair the product. The organization shall obtain approval from the customer before commencing repair of the product. The organization shall have a documented process for repair confirmation in accordance with the control plan or other relevant documented information. Instructions for disassembly or repair, including re-inspection and traceability requirements, shall be accessible to and utilized by the appropriate personnel. The organization shall obtain a documented customer authorization for concession for the product to be repaired. The organization shall retain documented information on the disposition of repaired product including quantity, disposition, disposition date, and applicable traceability information.

(Highlights of the clause)

- (Ref to old Standards).This is a totally requirement
- Requirement is same as rework.
- Rework and repair has a fundamental difference.
- Rework is slight deviation from the planned processes, resulting in specs not being met, but can be corrected by minor touch up or rework activities. Reference document is still based on control plan, work instruction. Some additional WI to guide on the rework. Scope of work is normally small. The work is still carried out off-line with proper tools and facilities.
- Repair generally means working to restore original specs due to damage from mishandling, wrong usage, long usage or physically damage. The scope of work varies, WI could be totally different. Inspection is on the objective of the repair. This kind of work is rare in a manufacturing organization.

(Compliance best practice)

8.7.1.5 Control of repair product

This is similar to Type b) rework in Clause 8.7.1.4. Please refer.

7) 8.7.1.6 Customer Notification (IATF16949)

(Clause Description-Paraphrase)

The organization shall immediately notify the customer(s) in the event that nonconforming product has been shipped. Initial communication shall be followed with detailed documentation of the event.

(Highlights of the clause)

- (Ref to old Standards). There had been a similar clause, 8.3.3 Customer Information, in the old version of ISO001/IATF16949. It was only a 1-liner: "Customers shall be informed promptly in the event that nonconforming product has been shipped"
- Now there is a new requirement to Initial communication shall be followed with detailed documentation of the event.

(Compliance best practice)

8.7.1.6 Customer Notification

1. *This should be a CSR and stated in SQM.*
2. *Even there is no SQM, customers must be informed promptly in the event that nonconforming product has been delivered*
3. *Initial notification shall be followed with detailed documentation of the event.*

8) 8.7.1.7 Nonconforming product disposition (IATF16949)

(Clause Description-Paraphrase)

The organization shall have a documented process for disposition of nonconforming product not subject to rework or repair. For product not meeting requirements, the organization shall verify that the product to be scrapped is rendered unusable prior to disposal. The organization shall not divert nonconforming product to service or other use without prior customer approval.

(Highlights of the clause)

- (Ref to old Standards). There had been similar clauses, 8.7.1.7 of the same title, in the old version of ISO/TS16949. The new clause is essentially a word-for-word reproduction of the old clause.
- Documented procedure is required but seldom seen being provided.
- Important to note, that product to be scrapped is rendered unusable, to avoid diversion to other use or service part
- Organization shall verify and keep evidence

(Compliance best practice)

8.7.1.7 Nonconforming product disposition

1. *Handling of scrap disposition is a documented process. Most organizations do not have this procedure.*
2. *Due to its straightforward nature, the requirements (point 2 and 3 below) are printed on the Disposition of Scrap Form, in the case shown. See* ***Exhibit 32-5.***
3. *Organization needs to render the scrap NCO unusable before disposing. Records shall show verification of the conditions of the scrap. See* ***Exhibit 32-5***
4. *Organization shall not divert nonconforming product to service or other use without prior customer approval.*

9) 8.7.2 (relevant documented information) (ISO9001)

(Clause Description-Paraphrase)

The organization shall retain documented information that: a) describes the nonconformity; b) describes the actions taken; c) describes any concessions obtained; d) identifies the authority deciding the action in respect of the nonconformity.

(Highlights of the clause)

- (Ref to old Standards). There had been similar clauses, also 8.7.2 of exact content, in the previous version of ISO9001.
- The requirement is to retain records of nonconformity, actions taken, concession and identify the authority deciding on the actions in respect of the nonconformity
- The records needed are found in 10.2.2, and 8.7.1.1

(Compliance best practice)

8.7.2 (relevant documented information)

1. *This is a repeat of 10.2.2 and 8.7.1.1, about the need to retain records*
2. *Therefore in practice, there is no special efforts to keep these records, as they are already practiced. You just need to know where to find them.*

10) SIs & FAQs

SI Nbr	IATF Clause	Description
9	**8.7.1.1 Customer authorization for concession**	The organization shall obtain a customer concession or deviation permit prior to further processing whenever the product or manufacturing process is different from that which is currently approved. The organization shall obtain customer authorization prior to further processing for "use as is" and ~~**rework**~~ **for repair (see 8.7.1.5)** ~~**dispositions**~~ of nonconforming product. If sub-components are reused in the manufacturing process, that sub-component reuse shall be clearly communicated to the customer in the concession or deviation permit. ***Rationale for change:*** *Clarify requirements and eliminate contradiction in relation to customer approval associated with rework.*

FAQ	IATF Clause	Questions and Answers
11	**8.7.1.7 Nonconforming product disposition**	**QUESTION 1:** **What is the intent and requirements for "rendering unusable" prior to disposal? When and where does the "rendering unusable" of product need to occur?** **ANSWER 1:** The intent is to ensure that the product cannot find its way into the unofficial aftermarket, onto a road vehicle, or accidentally shipped to the customer. The process of rendering nonconforming product unusable, does not have to occur in the manufacturing area as long as the product is rendered unusable prior to final disposal.
11 (cont.)	**8.7.1.7 Nonconforming product disposition**	**QUESTION 2:** **How does the organization control this?** **ANSWER 2:** The organization is responsible to develop and implement a nonconforming product disposition process and verify its effectiveness. **QUESTION 3:** **Can the organization use a service provider to render the product unusable?** **ANSWER 3:** Yes, it is acceptable to contract the process of rendering the product unusable to a service provider. If a service provider is used, the organization needs to approve, and periodically verify, how the supplier is rendering the product unusable.
11 (cont.)	**8.7.1.7 Nonconforming product disposition**	**QUESTION 4:** **Does nonconforming product disposition apply only to final product or does it also apply to component/interim sub-assembly?** **ANSWER 4:** This requirement applies to the product that has gone through the part approval process and that the organization is shipping to the customer. **QUESTION 5:** **For rendering unusable, how much damage needs to be done to the nonconforming product?** **ANSWER 5:** The nonconforming product needs to be rendered unusable and unrepairable. There is no requirement for crushing or pulverizing the product into many pieces.

11) Supplementary Notes

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

Clause	Section	Clarification Subjects
8.7.1.2	CBP	**SN32.1. What is corrective action specified by customer? Can give an example?**
8.7.1.3	CBP	**SN32.2. What are suspect ? What can be the consequences? And how to handle?**
8.7.1.4 8.7.1.5	CBP	**SN32.3. *Can we have a combined procedure for rework and repair?***
8.7.1.4 8.7.1.5	CBP	**SN32.4. *What is reuse of components?***
8.7.1.7	CBP	**SN32.5. *Why and how to render a scrap unusuable?***
8.7.1.7	CBP	**SN32.6. *Can we divert to service or other use?***
8.7.1.7	CBP	**SN32.7. *Do we need to lock the scrap area?***

SN32.1. What is corrective action specified by customer? Can give an example?

Example: A process that originally done by the customer, but outsourced later to a supplier. Equipment, material. procedure and QAQC system are all transferred from the customer. If there is a problem, supplier goes back to the customer and supplier provides them a solution. That is customer-prescribed corrective action. And the supplier is expected to followed.

SN32.2. What are suspect ? What can be the consequences? And how to handle?

Most common one is labels missing, either fell off or a missed step by operators. Tendency is the operators will put back the label they think is correct, by looking at the shape of the material. This may suffice in reality, but it carries a major risk. The correct way is the suspects shall be first tagged on-hold, as suspect product. The follow-up actions are: a) trail backwards to identify the correct part No, b) inspect the final characteristics again to verify, c) seek approval by the relevant authority to add back the labels. If the identity cannot be established, the suspects shall be scrapped.

SN32.3. Can we have a combined procedure for rework and repair?

Yes. More so if the 2 types are quite similar. But if they are vastly different, a combined procedure can be confusing and can lead to errors. Then it would not be advisable to do so. **Exhibit 32-2** is a combined Rework & Repair Procedure.

SN32.4. What is re-use of components? Can give an example?

In some casting or moulding processes, there are the metal components used as the brackets, or conduit etc. in the article. The finished part could be rejected due to defects on casting or mouding and scrapped. But the metal part can be salvaged for re-use. They may or may not be acceptable and tests need to be done for verification. Customer would definitely need to be informed or for approval.

SN32.5. Why and how to render a scrap un-usable?

You destroy the part to the extent that it cannot be re-sold or re-used by unscrupulous parties, in particular as imitation products. Depending on the nature of the product, you may have to hack and break them to the point it cannot be used anymore.

SN32.6. Can we divert to service or other use?

Only if approved by customer. Diverting to secondary market is absolutely not permitted.

SN32.7. Do we need to lock the scrap area?

You can decide on that, as there is no requirement. For other types of industry such as medical and food, scrap rooms are under lock and key. You might want to do that to ‘wow’ your customers

12) Exhibits

Exhibit 32-1. Customer Concession Management

Responsibility	Flow Diagram	Description
QA	Note 1 Deviation detected ↓ Note 2 Apply for Concession (If applicable) ↓ Note 3 Reuse of subcomponent to be inform ↓ Note 4 Establishing Records Required ↓ Note 5 When Concession Ended ↓ Note 6 Shipping Procedure	Note 1 • Deviation detected • If deviation comes from suppliers, organization shall ensure this procedure is followed by the supplier Note 2 • If the deviation is slight and there is provision from customer to grant concession, organization shall apply for concession • Comply to customer procedure as required • Concession may be for 'Used As Is' or rework or repair • Rework and repair refer to procedure XXX • This procedure is on 'Used As Is' Note 3 • If applicable, this step will be complied to • Any subcomponents recovered for re-used shall be notified to customer Note 4 • Establish the records customer required and start recording as shipment takes places Note 5 • When concession ends, the original or superseded specs shall be followed Note 6 • Customer requirements on shipping method to be complied e.g. identified on each shipping container • Purchased product shall be handled the same way
QA/ Logistics		

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

- Documentation process for concession is a requirement and this is an example. Customers normally have some procedures of their own, and you need to abide
- It is also common that no concession is allowed for some customers or product lines

Exhibit 32-2. Rework and Repair Procedure

Responsibility	Flow Diagram	Description
QA Core team Production/ QA QA	Note 1 Defects for Repair or Repair ↓ Note 2 Develop Rework or Repair Procedure ↓ Note 3 Risk Analysis ↓ Note 4 Implementation & (re) Inspections ↓ Note 6 Documentation	Note 1 • When there is rework or repair is required • Inform customer for approval, where required Note 2 • Prelim rework/repair method is developed. If there is a method provided by customer, it shall be complied • WI shall also be developed e.g. for disassembly, refit, inspection etc. • These WI shall be accessible to persons doing the rework or inspections • Special identification and traceability shall also be decided before implementation Note 3 • For rework, risk analysis shall be to ensure the reworked product shall meet original specs • For repair, risk analysis shall be to ensure the repaired product conformed to control plan, and relevant WI as required • For both rework and repair, the risk analysis shall also include the impact on the operations, customer's operations and operator safety Note 4 • If approved by customer, implementation the plan • For rework, the final product shall be re-inspected to original specs • For repair, inspection shall be conducted against relevant guiding document • Delivery shall be according to customer instructions, including identification and pre-approval before delivery Note 5 • Full records shall be retained and reported to customer • Such records shall be min: quantity, disposition, disposition rate, traceability system in use etc

Remarks given in this section explain on the Exhibit. Do not include them as part of your document

- Documented process is a requirement for rework and repair
- This is a sample that can accommodate both rework and repair

Exhibit 32-3 Onhold Label

On-hold Tag

No:	Date:
Process/ Area Found	
Discrepancy/Problem: ☐ Suspect -Missing Identification ☐ Dimension out of specs ☐ Visual inspection out of specs ☐ Functional Test Fail Raised by :	**DISPOSITION** ☐ Rework/Repair ☐ Return to Vendor ☐ Return to Customer ☐ Used As Is ☐ Scrap **Corrected by:** Special Approval by (UAI, Scarp, Etc) Remarks

Remarks given in this section explain on the Exhibit. Do not include them as part of your working document

- This is a sample on an onhold tag. It is normally using colored paper e.g. yellow or pink
- Details are written under the relevant discrepancy. Disposition is the decision arrived on the nonconformities
- Approval authority is required for traceability. The tag is retained as records and for traceability

Concession Record

Products

Approval Ref:

Date	Defects	Expiry Date	Quantify Granted	Special ID required	Quantity shipped	Cumulative Qty	Remark

Remarks given in this section explain on the Exhibit. Do not include them as part of your working document

- Concession record is a requirement and this is a example of the recording form
- This record might be required to accompany each shipment for customer to track controls

Exhibit 32-5 Disposition of scrap Form

Nonconforming Product Disposition

Customer:

IMPORTANT REMINDRS:

- For product not meeting requirements, the organization shall verify that the product to be scrapped is rendered unusable prior to disposal.
- The organization shall not divert nonconforming product to service or other use without prior customer approval

Date	Parts Name	Qty/ Weight If applicable)	D/O No/Contractor	Verification of Disposal		
				Qty/Weight	Un-usability confirmed	Verifier

Remarks given in this section explain on the Exhibit. Do not include them as part of your document

- The uppermost box is the documented process required by the standard. As it is only 2 sentences involved, there is no necessity to create a separate document but park them here on the form itself
- Details of disposition is recorded here. The auditor will check is whether the scrapped have been rendered unusable, and is internally verified.

>> End of Chapter 32 <<

Chapter 33. Internal Audit

Contents:

0) Introduction

There are several closely-related clauses in this chapter, relating on the various types of internal audits. They make a very suitable cluster for discussion. Many of these clauses are new, and some not fully misunderstood and/or poorly catered for. Many NCs have been written on this clause alone. Some attention should be given.

1) 9.2.1. Internal Audit (Scope) (ISO9001)

(Clause Description-Paraphrase)

The organization shall conduct internal audits at planned intervals to provide information on whether the quality management system:

a) conforms to:

1) the organization's own requirements for its quality management system;

2) the requirements of this International Standard;

b) is effectively implemented and maintained.

(Highlights of the clause)

- (Ref to old Standards).There had been a similar clause, 8.2.2 of the same title, in the old version of ISO9001. The old clause was rather long. Para 2 onwards became another clause in the new standard as 9.2.2.
- The new clause is almost identical to first para of the old clause, except a slight change of words-from' to determine', to 'provide' info.
- Key ideas still same ,to ensure the Standards and own QMS and effectively implemented
- The new clause basically has the same requirements

(Compliance best practice)

9.2.1. Internal Audit (Scope)

1. *Scope of internal audit is to assess the effectiveness of the QMS, in meeting the requirements of:*
   - *ISO9001/IATF16949 standards*

- *Organization's own QMS*

2. *This is the same as before and not seen as an issue so far*

2) 9.2.2 Internal Audit (Activities) (ISO9001)

(Clause Description-Paraphrase)

The organization shall:

a) plan, establish, implement and maintain an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits;

b) define the audit criteria and scope for each audit;

c) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;

d) ensure that the results of the audits are reported to relevant management;

e) take appropriate correction and corrective actions without undue delay;

f) retain documented information as evidence of the implementation of the audit programme and the audit results. <mandatory procedure status remain in 9.2.2.1

NOTE See ISO 19011 for guidance.

NOTE See ISO 10011-1, ISO 10011-2 and ISO 10011-3 for guidance.

(Highlights of the clause)

- (Ref to old Standards). This new clause was the back end the old 8.2.2, in the previous version of ISO9001.
- The new clause is a reworded version to be more readable, with some redundant sentences removed.
- The new requirements are: a) frequencies of audit shall also consider changes to the process, b) ensure that the results of the audits are reported to relevant management
- The total requirements are given in a) to f).

(Compliance best practice)

9.2.2 Internal Audit (Activities)

1. *A documented process is required. (see 9.1.1.1). The procedure in your former ISO/TS16949 can be used. But make sure the 3 types of audits are mentioned inside. I used to see only the QMS system audit being mentioned in the earlier days of transition*
2. *Results should show effectiveness, and generally expressed as findings*
3. *For negative findings, issue NCR in accordance to the method defined*
4. *The audit report shall be submitted to Management, without undue delay. Submission is when the audit is done and concluded. (not to wait for the NC to close out)*
5. *Follow-up actions shall be taken to close up the NC and OFI/Observations issued.*

3) 9.2.2.1 Internal Audit Program (IATF16949)

(Clause Description-Paraphrase)

The organization shall have a documented internal audit process. The process shall include:

a) the development and implementation of an internal audit programme that covers the entire quality management system including quality management system audits, manufacturing process audits, and product audits.

b) The audit programme shall be prioritized based upon risk, internal and external performance trends, and criticality of the process(es).
c) Where the organization is responsible for software development, the organization shall include software development capability assessments in their internal audit programme.
d) The frequency of audits shall be reviewed and, where appropriate, adjusted based on occurrence of process changes, internal and external nonconformities, and/or customer complaints.
e) The effectiveness of the audit programme shall be reviewed as a part of management review.

(Highlights of the clause)

- (Ref to old Standards). There had been a similar clause, 8.2.2.4 Internal Audit Plan, in the old version of ISO/TS16949.
- The old clause was a friendly, one-liner: " Internal audits shall cover all quality management related processes, activities and shifts, and shall be scheduled according to an annual plan".
- The new clause has some new requirements a) to e)
- The type of internal audits mentioned as QMS, manufacturing process, product
- Notable change is the frequency of audits shall be reviewed and, where appropriate, adjusted based on occurrence of process changes, internal and external nonconformities, and/or customer complaints.
- Another notable change is Where the organization is responsible for software development, the organization shall include software development capability assessments in their internal audit programme.
- Another notable change is the clause title change from " internal audit plans" to 'internal audit program'

(Compliance best practice)

9.2.2.1 Internal Audit Program

1. *All audit programs for the implementation types of audits need to be prepared and documented*
2. *The programs can be documented separately, or on the same document. See* ***Exhibit 33-1*** *for a combined program.*
3. *Shifts audit is now applicable to Manufacturing Process Audit and no long QMS system. See clause 9.2.2.3.*
4. *All your types of audit can be carried out in rotation over 3 years (see Clauses 9.2.2.2, 9.2.2.3, 9.2.2.4)*

4) 9.2.2.2 QMS System Audit (IATF16949)

(Clause Description-Paraphrase)

The organization shall audit all quality management system processes over each a three-year audit cycle. calendar period, according to an annual programme, using the process approach to verify compliance with this Automotive QMS Standard. Integrated with these audits, the organization shall sample customer-specific quality management system requirements for effective implementation.

(Highlights of the clause)

- (Ref to old Standards). There had been a similar clause, 8.2.2.1 of same the title, in the old version of ISO/TS16949.

- The old clause was a friendly one-liner: “The organization shall audit its quality management system to verify compliance with this Technical Specification and any additional quality management system requirements”
- There is an SI (SI-14) modifying the original clause content.
- A 3-year rotation is allowed. Process approach. Frequency may be adjusted all processes be sampled though out 3-year cycle, all applicable 9K, IATF clauses + CSR
- Notable changes are:
  i. that shift audit is no longer here, but MPA
  ii. CSR shall be sampled during the QMS audit

(Compliance best practice)

9.2.2.2 QMS System Audit

1. *You are allowed to audit all the QMS processes over a 3-year period. My recommendation is that you continue to audit all processes every year..*
2. *If rotation is still preferred, you have to prepare the 3-year program first. See* ***Exhibit 33-2.***
3. *Note that rotation does not mean total processes divided equally by 3. Some critical COP e.g. design, production and customer satisfaction still need to be audited every year. Other minor processes can be alternated over the next 2 years.* For initial or *recertifications, you must audit all processes.*
4. *From the program, you must still prepare an audit plan, with more details. See* ***Exhibit 33-3.***
5. *QMS system audit shall be based on automotive process approach. This is not well implemented in most cases seen. Most organizations are still using procedures for auditing and this is not adequate. This can be improved by using an additional list to cover the missing elements. See* ***Exhibit 33-4.***
6. *CSR of customers are to be sampled during QMS (system) audit. You can also elect to conduct CSR on separate occasions. See* ***Exhibit 6-2.***

5) 9.2.2.3. Manufacturing Process Audit (IATF16949)

(Clause Description-Paraphrase)

The organization shall audit all manufacturing processes over each three-year calendar period to determine their effectiveness and efficiency using customer-specific required approaches for process audits. Where not defined by the customer, the organization shall determine the approach' to be used. Within each individual audit plan, each manufacturing process shall be audited on all shifts where it occurs, including the appropriate sampling of the shift handover. The manufacturing process audit shall include an audit of the effective implementation of the process risk analysis (such as PFMEA), control plan, and associated documents.

(Highlights of the clause)

- (Ref to old Standards). There had been a similar clause, 8.2.2.2 of same title, in the old version of ISO/TS16949. The old clause was a friendly, 1-line: The organization shall audit each manufacturing process to determine its effectiveness.”
- The new clause is much expanded. Notable changes are: a) 3-year rotation allowed, b) customer specified approach to be used e.g. VDA6.3, c) All shifts to be audited, d) process risk analysis, by auditing the implementation of the various process document.

(Compliance best practice)

9.2.2.3. Manufacturing Process Audit

1. *Manufacturing Process Audit (MPA) audit also needs its own program for the year. The program can be a standalone, or combined with others. See **Exhibit 33-1.***
2. *For 3-year rotation for MPA is also allowed. If elect to do so, the 3-year rotation need to be shown. See **Exhibit 33-2.***
3. *For the immediate audit, prepare a separate audit plan to show more information, including shift auditing and changeover sampling. See **Exhibit 33-3.***
4. *If customer specifies a particular method be used, you need to comply. For example, if a German OEM specifies VDA6.3 for process audit, you must comply. Furthermore your MPA auditors must be qualified according to the VDA's requirement.*
5. *A specimen of MPA audit checklist is provided here. See **Exhibit 33-5***
6. *On the question of Process risk, it is considered OK if you conduct the audit using control plan, FMEA and WI during the audit.*

6) 9.2.2.4 Product Audit (IATF16949)

(Clause Description-Paraphrase)

The organization shall audit products using customer-specific required approaches at appropriate stages of production and delivery to verify conformity to specified requirements. Where not defined by the customer, the organization shall define the approach to be used.

(Highlights of the clause)

- (Ref to old Standards). There had been a similar clause, 8.2.2.3 of the same title, in the previous version of ISO/TS16949.
- The old clause was a friendly, -liner: The organization shall audit products at appropriate stages of production and delivery to verify conformity to all specified requirements, such as product dimensions, functionality, packaging and labelling, at a defined frequency.
- The new clause is much expanded. Notable changes are: a) 3-year rotation allowed, b) customer specified approach to be used e.g. VDA6.5, c) audit points are at appropriate stages of production and delivery to verify conformity to specified requirements

(Compliance best practice)

9*.2.2.4 Product Audit*

1. *Product Audit (PDA) also needs its own audit program for the year. It can be a standalone, or combined with others. See **Exhibit 33-1.***
2. *3-year rotation for PDA is also allowed. If elect to do so, use another table to show the rotation. See **Exhibit 33-2.***
3. *For the immediate audit, prepare a separate audit plan to show more information, including timing and auditors. See **Exhibit 33-3.***
4. *Choice of parts to be audited are generally based on: a) customer requirement, b) criticality, and c) performance*
5. *If customer specifies a particular method be used, e.g. VDA6.5, you have to comply. If there is no customer requirement, you can use your own format for the audit.*
6. *A specimen of PDA checklist is provided here. See **Exhibit 33-6***

7) 7.2.3. Internal Auditor Competency (IATF16949)

(Clause Description-Paraphrase)

The organization shall have a documented process to verify the internal auditors are competent, taking into account any customer-specific requirements on this area. Organization shall maintain a list of qualified internal auditors.

System auditors shall have the following competencies

a) Understanding the automotive process approach for auditing, including risk-based thinking
b) Understanding of applicable customer-specific requirements
c) Understanding of ISO9001 and IATF16949 requirements
d) Understanding of applicable core tool requirements
e) Understanding how to plan, conduct, report and close out audit findings

(SI-4 has modified the clause that the requirements a)-e) apply only for QMS System Auditor)

Manufacturing Process Auditor ~~further~~ (SI-4) shall have:

f) understanding of the relevant manufacturing process (es) to be audited, including
g) process risk analysis (such as FMEA) and control plan)

Product Auditor ~~further~~ (SI-4) shall have

h) understanding of product requirements
i) use of relevant measuring and test equipment to verify product conformity

Others:

j) If the organization's personnel provide the training to achieve competency, the trainer shall be competent with evidence. (Refer to internal trainers only -SI-4)
k) minimum number of audits a year as defined by organization (No longer applied SI-4)
i) maintain knowledge of relevant requirements base on changes internally or externally. Internal changes may be process technology, product technology; External changes may concern changes in requirements of ISO9001, IATF16949, core tools and CSR
m) if there is special customer requirement e.g.VDA6.3 audit, then the MPA auditor must be process auditor qualification which requires formal training, work experiences and auditing experiences

(Highlights of the clause)

- (Ref to old Standards). There had been a similar clause, 8.2.2.5 Internal Auditor Qualification, in the old version of ISO/TS16949.
- *In the last versions, it was only 1 liner that says,, "*The organization shall have internal auditors who are qualified to audit the requirements of this Technical Specification(see 6.2.2.2)"
- The new requirement is much expanded. Subsequently SI-I had modify the competency requirements to be more logical. Competencies for the 3 types of internal auditors are made clearer. See clause content above

(Compliance best practice)

7.2.3. Internal Auditor Competency

1. *Internal auditors need to be qualified. Clauses 7.2.3 specified the qualifications for the various types of auditors. SI-4 amended some of the rules.*
2. *Clause 7.2.4 also spelt out qualifications for second-party auditors*
3. *IATF auditors will check on the current list of internal auditors. Therefore it shall be made available. The qualifications adopted shall also be available for audit. You can also place both the qualifications and current auditor list separately or together.* ***Exhibit 33-7*** *is a 2-in-1 list.*

4. *Internal auditors should be ranked. The model given here has 3 types ranking, support, full and trainer auditors. See **SN33-14.***
5. *Auditor list shall be updated every year.*

8) SIs & FAQs

SI Nbr	IATF Clause	Description
4	**7.2.3 Internal auditor competency**	The organization shall have a documented process(es) to verify that internal auditors are competent, taking into account any **requirements defined by the organization and/or** customer-specific requirements. For additional guidance on auditor competencies, refer to ISO 19011. The organization shall maintain a list of qualified internal auditors. Quality management system auditors**~~, manufacturing process auditors, and product auditors~~** shall **~~all~~** be able to demonstrate the following minimum competencies: a) understanding of the automotive process approach for auditing, including risk-based thinking; b) understanding of applicable customer-specific requirements; c) understanding of applicable ISO 9001 and IATF 16949 requirements related to the scope of the audit; d) understanding of applicable core tool requirements related to the scope of the audit; e) understanding how to plan, conduct, report, and close out audit findings. **~~Additionally,~~ At a minimum,** manufacturing process auditors shall demonstrate technical understanding of the relevant manufacturing process(es) to be audited, including process risk analysis (such as PFMEA) and control plan. **At a minimum,** product auditors shall demonstrate competence in understanding product requirements and use of relevant measuring and test equipment to verify product conformity. **~~Where training is provided~~ If the organization's personnel provide the training** to achieve competency, documented information shall be retained to demonstrate the trainer's competency with the above requirements.
4 (cont.)	**7.2.3 Internal auditor competency**	***Rationale for change:*** *Distinguish competency requirements for quality management system auditors, manufacturing process auditors, and product auditors. Clarified the trainer competency expectations for internally provided training.*
14	**9.2.2.2 Quality management system audit**	The organization shall audit all quality management system processes over **~~each~~ a** three-year **audit cycle ~~calendar period~~**, according to an annual programme, using the process approach to verify compliance with this Automotive QMS Standard. Integrated with these audits, the organization shall sample customer-specific quality management system requirements for effective implementation. **The complete audit cycle remains three years in length. The quality management system audit frequency for individual processes, audited within the three-year audit cycle, shall be based upon internal and external performance and risk. Organizations shall maintain justification for the assigned audit frequency of their processes. All processes are required to be sampled throughout the three-year audit cycle and audited to all applicable requirements in the IATF 16949 standard, including ISO 9001 base requirements, and any customer-specific requirements.** ***Rationale for change:*** *Clarified that the audit cycle remains three years in length. Deleted IATF 16949 FAQ 18 and put former FAQ 18 2nd paragraph requirements into SI 14. Clarified that all processes are to be audited during the three-year audit cycle.*

18 ***deleted***	**Quality management system audit** **9.2.2.2**	**See SI 14, issued November 2018, effective January 2019.**
19	**9.2.2.3** **Manufacturing process audit**	**QUESTION:** **For each manufacturing process audit do all shifts have to be covered?** **ANSWER:** Each audit does not have to cover all shifts in **one** audit (for example an audit of the pressing process could be done on shift 1 and 2, sampling shift changeover in year 1, and then in year 2 or 3 an audit undertaken on the third shift for pressing). However, **all** manufacturing processes must be audited on **all shifts** over a three-year cycle, the frequency depending on risk, performance, changes etc.
20	**9.2.2.4** **Product audit**	**QUESTION:** **Why is there no defined audit frequency for Product audit?** **ANSWER:** The audit frequency must be determined based on the risk and product complexity (See ISO 9001, Section 9.2.2). If an organization has high risk and high product complexity, it is recommended that product audit frequency be increased.

22	**9.2.2.4** **Product audit**	**QUESTION:** **How does a product audit differ from a layout inspection?** **ANSWER:** As defined in section 3 of IATF 16949, the term product is used to represent "…any intended output…" of the manufacturing process. Products typically have dimensional, performance (functional) and material requirements, therefore, product audits may contain verification of dimensional, performance (functional), or material requirements. As stated in the FAQ 21 above, a layout inspection is limited to dimensional requirements. Product audits can be carried out on finished or partially finished product, following customer specified approaches (e.g. VDA 6.5 Product Audit), if applicable. Product audits may include packaging and labelling requirements. A product audit, like other audit types, is an independent verification of compliance to requirements. As such, the product audit has a defined frequency and scope specified within the audit programme and is based on risk.

FAQ	IATF Clause	Questions and Answers
28	**9.2.2.3** **Manufacturing process audit**	**QUESTION** **What is intended frequency and coverage of Manufacturing Process Audits?** **ANSWER** Effective assessment of each manufacturing process is vital to ensure continued manufacturing of product meeting customer, statutory and regulatory requirements. However, aligned with the risk approach of ISO 9001 and IATF 16949, some manufacturing processes or aspects of manufacturing processes may need higher frequency of assessment than others. The organization determines the audit frequency, if not defined by the customer, by using the appropriate risk management approach, including consideration of new technologies and customer measured performance. Manufacturing processes demonstrated to be low risk by the organization may be audited less frequently than high risk processes; however, all manufacturing processes are audited within the 3-year audit cycle. Evidence for risk analysis includes continued compliance with all relevant requirements, (for example: statutory and regulatory, customer, process, and internal requirements). If any one of the relevant requirements is not met, the manufacturing processes is audited at a higher frequency than every 3 years. The 3-year frequency as per clause 9.2.2.3 is a minimum requirement intended for low risk and fully compliant manufacturing processes.

9) Supplementary Notes

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

Clause	Section	Clarification Subjects
9.2.2, 9.2.2.1	CBP	**SN33.1 All 3 types of audits now allow for a 3- year rotation. Should we accept the offer?**
9.2.2, 9.2.2.1	CBP	**SN33.2 How to show 3 year's rotation for QMS, when the audit program is only for finished year?**
9.2.2, 9.2.2.1	CBP	**SN33.3 How to show MPA and PDA rotation for the years?**
9.2.2.2	CBP	**SN33.4 QMS audit how to adjust frequency due to NC from audits and complaints from customers? What do we check during the re-audit?**
9.2.2.2	CBP	**SN33.5 We do verification after closing. Isn't this same as your suggested?**
9.2.2.2	CBP	**SN33.6 For QMS audit, how do we sample for CSR implementation?**
9.2.2.2	CBP	**SN33.7 How to audit Management Processes as QMR the most qualified audit, is a part owner of the process?**
9.2.2.2	CBP	**SN33.8 How to audit Internal audit and Management Review ? Internal audit is generally in progress, and management review is only after internal audit.**
9.2.2.2	CBP	**SN33.9 What are some of the frequent problem with QMS Audit?**
9.2.2.3	CBP	**SN33.10 What are some of the frequent problem with MPA?**
		SN33.11 What are some of the frequent problem with PDA?
7.2.3	CBP	**SN33.12 Why criteria and the current list of internal auditors need to be done separately?**
7.2.3	CBP	**SN33.13 How to define qualification of an internal trainer for internal audit?**
7.2.3	Exhibit 33-7	**SN33.14 The specimen Exhibit 33-7 you gave on auditor qualification, you categorize auditors into a few types of auditors. What is the purpose?**

SN33.1 All 3 types of audits now allow for a 3- year rotation. Should we accept the offer?

It is your choice, as you are allowed to do so. My opinion is no, don't do it.
QMS: From field experience, even after many cycles of audits, many organizations still have a lot of NC and weaknesses. You can imagine what will happen if you reduce the audits to once in 3 years?
MPA. New customers and new processes will make your rotation plan unsuitable.
PDA. New products will invalidate your rotation plan.

SN33.2 How to show 3 year's rotation for QMS, when the audit program is only for one year ?

Have a supplementary list to show the rotation over 3 years. See **Exhibit 33-2.**

SN33.3 How to show MPA and PDA rotation for the 3 years?

In SN-33.1, I have suggested you don't do it. But you must, then do a supplementary list to show 3 year rotation for MPA and PDA. See **Exhibit 33-2.**

SN33.4 QMS audit how to adjust frequency due to NC from audits and complaints from customers? What do we check during the re-audit?

Whenever NC (from internal or external audits), or customer complaint complaints occur, additional audit is required. This is recommended to take place within 6 months. When re-auditing, focus on the NC and check for any potentials for repeat, and horizontal replication. Don't waste time checking on closing evidences, as they had been checked earlier.

SN33.5 We always do verification after closing. Isn't this same as your suggested?

Your verification is still part of the original audit. The original intent is you re-audit the whole process or the affected clauses again. That will be very time consuming with no extra benefits w. The suggested method saves you time, and focus on something really useful, a) no potential for repeat, b) apply horizontal application.

SN33.6 For QMS audit, how do we sample for CSR implementation?

There are 2 ways you can do this: a) you audit the full list, on a separate occasion, b) distribute the duties among the QMS auditors to do the audit, during system audit. See Chapter 4. For more details

SN33.7 How to audit Management Processes as QMR, the most qualified auditor, is a part owner of the process?

Ask another senior auditor of the organization can be the auditor. QMR to be present as co-auditee in this process. This way, the process can be a learning process for top management too. Alternatively, use the services of an external consultant, or another senior member from a sister company.

SN33.8 How to audit Internal audit and Management Review ? Internal audit is generally still in progress, and management review is only after internal audit.

This is a cyclic problem and there is no perfect answer for this. One common way is to audit a mixture of current year's prep work and last year's records, and interview the persons in charge. There should be enough facts and data to deduce the effectiveness.

SN33.9 What are some of the frequent problem with QMS Audit?

a) Some organizations are still on procedure auditing, not checking on the other elements of the turtle,
b) some are just auditing the turtle diagram itself, with not much digging on the methods,
c) untrained, or inexperienced auditor are used to audit, resulting in zero or very few findings.

SN33.10 What are some of the frequent problem with MPA?

a) MPA audit is cramped in within the internal audit period, very hasty work with shoddy conclusions, b) not separately audited but consider production process (QMS system) as MPA, c) some processes are left out of the audit, d) no audit notes or checklist used, e) no NCR issued for findings

SN33.11 What are some of the frequent problem with PDA?

a) PDA audit is cramped in within the internal audit period, very hasty work with shoddy conclusions, b) very minimum product audited, e.g. only 1 part out of 20. c) method is not correct-auditors are duplicating the QC inspector's work, instead of auditing, d) no NCR issued for findings

SN33.12 Why criteria is needed to define the qualifications of internal auditors? Isn't the current list of internal auditors self-explanatory?

The list that normally seen is just data. What is the criteria for judgement? Exactly same as 7.2.3? If so, it has to be stated. Additionally, the list normally show only the training attended. Does it mean a person attended training is automatically qualified to audit? The least you can do is to list out all the

requirement according to 7.2.3, and also add on some practical training to be convincing. You can combine both information on the same sheet. See **Exhibit 33-6** for a specimen.

SN33.13 How to define the qualifications of an internal trainer, for internal audit?

Qualified internal trainers must have received training of the latest version of the subject, and have sufficient experience. A fresh graduate just passing an internal audit training is therefore not considered qualified. According to the specimen case, the most senior auditors with certain no of audits can be appointed. **Exhibit 33-6**

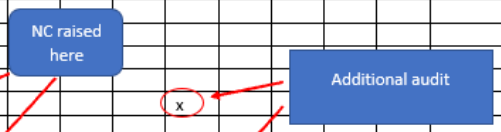
SN33.14 The specimen Exhibit 33-7 you gave on auditor qualification, you categorize auditors into a few grades. What is the purpose?

First, it gives chance to more people to participate in internal audit. New employees also can join as trainee auditor to learn, semi-trained ones can learn further from the leading seniors. The senior can become internal trainer, with the defined number of years. Most of all, quality of internal audit will improve, and load shared out.

10) Exhibits

Exhibit 33-1. 1 Year Internal Audit Program

No	A. QMS Audit- Processes	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Auditors
1	Management Planning/Review		X											
2	Internal Audit		X											
3	Handling of RFQ		X											
4	Manufacturing Process Design		X											
5	Order Processing/ Production Planning		X											
6	Purchasing		X											
7	Production- Casting		X											
8	Production- secondary processes			X										
9	Production- Machining													
10	Production-Assembly			X										
11	QAQC			X										
12	Infrastructure maintenance			X										
13	Machine preventive maintenance			X										
14	Tooling maintenance			X					x					
15	Storage & Delivery			X										
16	Customer feedback and complaint			X										
17	HR & Training			X										
18	Documentation			X										
19	Payment Collection			X					x					
20	Information Systems			X										



No	B. Other types of audit	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Auditors
1	**Manufacturing process audit (once /2 months)**		X (M1)		X (M2)		X (M3)		X (M4)		X (M5)		X (M6)	XXXX, YYY
2	**Product Audit (Once every 2 months)**			X (P1)		X (P2)		X (P3)		X (P4)		X (P5)		XXX, ZZZ

	C. Additional Audits		Plan	Actual	Judgement	Audit Notes
	Customer complaints					
1	NWB 1/18. Missing hole in Part No xxx. Date 16 Feb 2017		2/9	2/9	Effective	Closed out in Apr 2017. Re-audited on 2/9. The corrective actions still in place. No new incident on this part or other parts
2	PTNN. Model PPXX has plating peeling off, issue		3/9	2/9	Effective	Closed out in May 2017. Re-audited on 2/9. The corrective actions still in place. No new incident on this part or other parts
	NC from CB					(sustained, application on new cases
1	Risk and oppor not effective		27/8	27/8	Effective	Risk and opportunity had been updated. Seen one case, QAQC has increase 1 more item on measurement
2	CSR not audited		17/8	27/8	Effective	CSR to process matrix done. Sample some at production and find them in compliance. (checklist on production)
3	Reponse to customer feedback not effectve		27/8	27/8	Effective	Check feedback this time. AKIM's low rating on delivery has been worked on at high level, involving customer and the ED supplier
4	Proces control not effecitve- force meter not calibrated		27/8	27/8	Effective	Seen re-calibrated, WI in place, records well maintained
	Internal NC					
1	Purchasing ASL not updated		27/8	28/8	Effective	Seen even the latest appointed supplier Vendex has been included
	MPA					
1	M2. Step 13. N=3 not followed		27/8	28/8	Effective	Seen records of last 2 months and found n=3 observed
	PDA					
1	P3. Functional test-pull force not tested		27/9	28/9	Effective	Check OQC report to Nissan. Sampled 2 from each month. Pull force done.
2	P1. Salt pray on plating no results		27/10	28/10	Effective	Check OQC report to Denso, Send 3 months of records, every delivery. Salt spray test done.

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

- It is best to put all the audit programs on 1 page. This is particularly good for overall planning (timing and duration)
- QMS System audit is normally done in 1 compressed period e.g. 1-2 months. The case shown above is for 2 months
- MPA (manufacturing process audit) and PDA (product audits), are usually carried out over the entire year. Frequency and sampling depends on customer and internal requirements
- Clause 9.2.2.1 requires NC and complaints to be given additional audits. You can decide when to do that so long it is before the next internal audit. However, when conducted within 3-6 months is most effective.
- For additional audits, It should focus on continued effectiveness and any evidence of horizontal replication. There are also organizations that prefers to repeat audit of the clause, or even the entire department, but I think it is not necessary.

Exhibit 33-2. 3-year Rotation Internal Audit Program

3-Year Rotation Internal audit Program

No	A. QMS Audit- Processes	2018	2019	2020
1	Management Planning/Review	X		X
2	Internal Audit	X		X
3	Handling of RFQ	X	X	X
4	Manufacturing Process Design	X	X	X
5	Order Processing/ Production Planning	X	X	
6	Purchasing	X	X	
7	Production- Casting	X	X	X
8	Production- secondary processes	X	X	X
9	Production- Machining	X	X	X
10	Production-Assembly	X	X	X
11	QAQC	X		X
12	Infrastructure maintenance	X		X
13	Machine preventive maintenance	X		X
14	Tooling maintenance	X		X
15	Storage & Delivery	X		X
16	Customer feedback and complaint	X	X	X
17	HR & Training	X	X	
18	Documentation	X	X	
19	Payment Collection	X		X
20	Information Systems	X		X

No	B. Manufacturing Process Audit	2018	2019	2020
1	Manufacturing process audit (No customer requirement	Moulding	Turning	SMT. Cust-A
		Secondary Processes	Assembly Process/Packing	SMT. Cust B
		Assembly Process/Packing	Turning	SMT. Cust C
No	**B .Product Audit**	**2018**	**2019**	**2020**
2	Product Audit (No customer requirement	MM Series	NN Series	PP Series

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

- This is a specimen how to do rotation for all 3 types of internal audits. (I personally think this is not effective. It might be OK for IATF auditors because they are professionals, and specialized in this line of work).
- You will notice in QMS System Audit, the rotation does not mean you take all the 20 processes and split over 3 years. The important COP are still to be audited every year e.g. production and customer feedback. This is what IATF auditors also do, so that the critical processes do not get overlooked and risk slips in on the critical areas.
- For Manufacturing Process and Product Audits, the various types of audit targets are spread out too far apart and cannot be effective. You might as well decide year-to-year, according to priorities

Exhibit 33-3. Single Year Audit Plan

Internal audit Plan (2019)

No	A. QMS Audit- Processes	2019	Date	Time	Internal Auditors
1	Management Planning/Review				
2	Internal Audit				
3	Handling of RFQ	X	16 Jan	9:00-10:00	FLA: John
4	Manufacturing Process Design	X	16 Jan	10:00-12:00	FLA: John
5	Order Processing/ Production Planning	X	16 Jan	13:00-15:00	FLA: John
6	Purchasing	X	16 Jan	15:00-17:00	FLA: John
7	Production- Casting	X	18 Jan	9:00-10:00	TRA: Larry
8	Production- secondary processes	X	18 Jan	10:00-11:00	TRA: Larry
9	Production- Machining	X	18 Jan	11:00-12:00	TRA: Larry
10	Production-Assembly	X	18 Jan	13:00-14:00	TRA: Larry
11	QAQC				
12	Infrastructure maintenance				
13	Machine preventive maintenance				
14	Tooling maintenance				
15	Storage & Delivery				
16	Customer feedback and complaint	X	17 Jan	9:00-10:00	FLA: John
17	HR & Training	X	17 Jan	10:00-12:00	FLA: John
18	Documentation	X	17 Jan	13:00-15:00	FLA: John
19	Payment Collection				
20	Information Systems				

No	B. Manufacturing Process	2019	Date	Time	Auditor
1	Manufacturing process audit (No customer requirement	Turning, Assembly Process, Packing	15 Mar	Shift A	FLA. Lily
				Shift B Shift change witness here	FLA . Lily
				Shift C	FLA. Bexter

No	C. Product	2019	Date	Time	Auditor
2	Product Audit (No customer requirement	NN Series	20 Mar	2:00-5:00	FLA. Bexter

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

- A program is for a longer term, say over a year or 3 years. An audit plan is for audit for the immediate use. More data should be available for information to all concerned
- Only lead auditors are shown here. You can also list down the other members of the team

Process Approach Additional Checklists

Process Audited: Date:

No	Process Elements	Check Items	Findings
1	KPI	• Are the KPI achieved? • If consecutively more than 3 months of non-achievement without taking corrective/ improvement actions, it is an NC • If there are signs of losing control, internal auditors should have to trace the source, by going through the following in detail • If KPI are achieved, the following can be checked by sampling at the auditor's discretion	
2	Output	• Check every item/sampling items by requesting to view evidence • Take a cursory look to see if things are in order	
3	Input	• Check every item/sampling items by requesting to view evidence • Take a cursory look to see if things are in order	
4	Tool/Equipment	• Sampling on the tool/equipment needed to perform the job • See the item, or request to see how it is used, to deduce it is functioning good enough to produce the desire result. For measurement equipment, check on calibration to see it is still within the calibration period	
5	Competency	• Know who are the people in the dept • Select the new or newer staff to see their competencies • If there is enough time, interview the persons based on some reference e.g. SOP/QP, WI, latest training etc • If there is not enough time, view the training records	
6	Method	• Check the Procedure in greater details	

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

- Surprisingly, many IATF-certified companies, are still auditing based on procedures. The other elements of the process are often neglected,
- Some companies try to use turtle diagrams for the QMS system audit, but tend to be audited too shallowly for procedures (methods)
- Internal auditors can carry on auditing the procedures first, and finished off by auditing the above list. The 2 list add together, will make the process approach audit complete

Manufacturing Process Audit Record

Process Name: Cutting **Part No Running:** **Date Audited** **Time Audited**

A. Checklist

Process No	(Sub) Process	Machine, device etc	Characteristics		Class (SC)	Method					Reaction Plan
			Product	Process		Specs	Eval Technique	Sample		Control Method	
								Size	Freq		
Process 30	Cutting										
Step 30.1	Setup					F1					
30.2	Loading material		F2								
30.3	First Off checking							F3			
30.4	IPQC										

B. Audit Conclusion

Finding No	Finding Type	Ref No (NC only)	Findings Description	Containment Requirement	Closing date agreed
F1	Minor NC	IANC/MPA/19-01	Length set up was wrong. Seen as 250mm. Should be 200 mm	Yes	1 week
F2	OFI		The type of material should be recorded, or label retained	No	Dept's discretion
F3	Minor NC	IANC/MPA/19-02	N=1. In control plan it is stated n=3.	Yes	1 week

Lead Auditor: Auditee Rep:

Date Date:

Remarks given in this section explain on the Exhibit. Do not include them as part of your document

- For MPA, you need to follow customer requirement e.g. to use VDA6.3. Customer may also specify frequencies and which stages to audit
- For this specimen, there is no customer format specified and the organization uses the control plan as checklist. This recording form patterns after the control plan format, so the findings can be placed at the corresponding slots. Later the findings are expanded in conclusion heading.
- With this method, you can audit all the processes within the control plan at one go, or by subprocesses, or on different days, especially if the processes cannot be completed on the same day.
- You can also take a photocopy of the control plan as checklist and make notes on it, and summarize into a conclusion sheet, like the above.

Exhibit 33-6 Product Audit Checklist

Product Audit Checklist

Customer/Product TBN-099-10101-OC	Process OQC	Lot No
Auditor	Auditee	Date

No	Checking Areas	Specification	Results		Judgment OK/NG
			From record	Auditor Testing (Optional)	
A	**Dimensions**				
	Inspection Point A	1.10.2-10.3mm	15-10.2mm Sampling Jan, Mar 2108	No need	OK
	XXX				
B	**Appearance**				
	Scratch mark	Scratch-free	Seen full year. OK	Sampled by auditor. OK	OK
	XXX	XXX	XXX	XXX	
	XXX				
C	**Labelling & Packaging**				
		Follow WIXXX	OQC report full year seen. OK	Auditor checked on Lot No 5334. ROHS found not on label	NC
D	**Functioning.**				
	e.g. salt spray test	96 hours no rust	See OQC report for fully year. OK	Auditor seen the Lot No XXX, see part no rust. OK	OK

Others/ Remarks

Other Observation/Comments:
See demo by inspector XXX doing the 250mm measurement using calipers. Method OK. See here training record, she is competent for FQC. OK. Calipers calibration external. Seen Report No , Calibrated by Labcare, SAMM No 234 (IATF certified).
Storage area for this part is seen, no factors that can be affect product are checked and everything is functioning and OK.

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

- Product audit has some similar requirements with MPA. You need to follow customer requirement, e.g. they may specify VDA6.5. Or which products to audit and at what frequencies.
- Product audit generally looks into dimension, appearance, functional and packaging. But you can look into more areas like in the case above, under 'Observation/Comments'. You can also report on inspector competency, testing method, equipment calibration status, storage conditions etc., that can affect product quality, or reliability of the QC results.
- There is a frequent question on how many stages should we be checking for this audit. The answer is based on criticality. The most important is the final point FQC or OQC area. You can include upstream inspection area where is important e.g. problem-prone, or where there is a hand-off involved.
- I have noted in many companies, the PDA auditor is not really doing product audit, but merely duplicating the FQC inspector to check the products. See Best Practice for more information.

Exhibit 33-7. Internal and Supplier Auditors List

QMS System AUDITOR LIST

No	Name	Mandatory Training			Extra Training					Audit Experience			Grades		
		A) ISO9001:2015 Std	B) TIATF16949 Std	C) Audit Course	D) PQP/PPAP	E) Control Plan	F) FMEA	G) MSA	H) SPC	0-2 Audits	3-10 Audits	>10 Audits	Support Auditor SPA	Full Auditor FLA	Trainer Auditor TRA
1	ABC	x	x	x	x	x	x	x	x	x		x			x
2	DEF	x	x	x						x			x		
3	GHI	x	x	x	x	x	x				x		x		
4	JKL	x	x	x				x	x		x			x	
5	MNO	x	x	x	x	x	x	x	x	x	x			x	

Qualification Criteria:

- All auditors must pass all mandatory training A, B & C) . Otherwise the candidate is a trainee, who can observe but cannot officially audit
- 'Extra' training (D to H) is not mandatory for everyone. Only those auditing technical processes will need them e.g. design, QA, production. Even so, only relevant tools need to be trained. Example, MSA training is only needed for auditing QAQC. This rule applies to all grades of auditors
- The classification is then based on the audit experience. Support auditor can only audit under supervision. Full and trainer auditor can audit independently. Trainer auditor is also qualified to train.

MANUFACATURING AUDITOR LIST

No	Name	Mandatory Training						Others		Audit Experience			Grades		
		A) PQP/PPAP	B) Control Plan	C) FMEA	D) MSA	E) SPC	F) Audit Course	G) Min 1 year exp in manufacturing		0-2 Audits	3-10 Audits	>10 Audits	Support Auditor SPA	Full Auditor FLA	Trainer Auditor TRA
1	ABC	x	x	x	x	x	x	x				x			x
2	DEF	x	x	x	x	x	x				x		NA	NA	NA
3	GHI	x	x	x	x	x	x	x		x			x		
4	JKL	x	x	x	x	x	x						NA	NA	NA

Qualification Criteria:

- All MPA auditors must pass all mandatory training (A, B, F). Otherwise the candidate is a trainee, who can observe but cannot officially audit. In this case, 1 Year experience (G) in manufacturing is also mandatory. Failing which the person is still a trainee, until qualified by trainer auditor
- In the case above, DEF and JKL' s names should not have appeared on the auditor list, as they are not qualified yet as auditor. They are still trainees.
- The classification is based on the audit experience. Support auditor can only audit under supervision. Full and trainer auditor can audit independently. Trainer auditor is also qualified to train.
- If there is a customer-specified method, the auditor qualifications specified shall be complied

Exhibit 33-7. Page 2

PRODUCT AUDITOR LIST

No	Name	Mandatory Training					Others				Audit Experience			Grades		
		A) Training on M& M Equipment	B) Control Plan	C) Audit Course	D) MSA	E) SPC	F) Min 1 year Exp as QA supervisor				0-2 Audits	3-10 Audits	>10 Audits	Support Auditor SPA	Full Auditor FLA	Trainer Auditor TRA
1	ABC	x	x	x	x	x	x						x			x
2	DEF	x	x	x	x	x					x			NA	NA	NA
3	GHI	x	x	x	x	x	x					x			x	
4	JKL	x	x	x	x	x	x				x			x		

Qualification Criteria:

- All Product auditors must pass all mandatory training (A, B, C). Otherwise the candidate is a trainee, who can observe but cannot officially audit. In this case, 1 Year experience in QA is also mandatory (F). Otherwise the person is still a trainee, until qualified by trainer auditor
- In the case above, DEF's names should not have appeared on auditor list, as he/she is not qualified yet
- The classification is based on the audit experience. Support auditor can only audit under supervision
  Full and trainer auditor can audit independently. Trainer auditor is also qualified to train.
- If there is a customer-specified method, the auditor qualifications specified shall be complied

SECOND PARTY AUDITOR LIST

No	Name	A) Automotive process audit methods (IATF internal audit training)	B) Applicable CSR of org and customers (CSR and org SQM)	C) Applicable product safety and statutory & regulatory requirement	D) Applicable ISO9001/ IATF16949 clauses (ISO/IATF standards training)	E) Applicable manufacturing processes, including FMEA and CP (experience with the type of Ind & as required)	F) Applicable core tools (Core Tool Training-**As required**)	Audit Experience			Grades		
								0-2 Audits	3-10 Audits	>10 Audits	Support Auditor. SPA	Full Auditor. FLA	Trainer Auditor. TRA
1	ABC	x	x		x	x	x			x			x
2	DEF	x	x		x	x	x		x			x	
3	GHI	x	x		x			x			x		

Qualification Criteria:

- All Product auditors must pass all mandatory training (A, B, C). Otherwise the candidate is a trainee, who can observe but cannot officially audit. Item D, E and F are as required. Hence the auditor without these 2 competencies can audit non-manufacturing e.g. warehouse, purchasing etc. This case applies to Auditor GHI
- The classification is based on the audit experience. Support auditor can only audit under supervision.
  Full and trainer auditor can audit independently. Trainer auditor is also qualified to train.

Remarks given in this section explain on the Exhibit. Do not include them as part of your document

- Normally only one list is used to cover all types of internal auditors, which is incorrect, as the qualifications for all the 4 types of auditors are different.
- It is also assumed that an internal auditor, after attended a training course, is considered qualified. This is also not acceptable. Some practical work is needed. In the above examples, the number of audits is used for this purpose, to ensure auditors have the required experience.
- The auditors are best classified into a few grades. In this case they are: a) support, b) full and c) trainer auditors. Trainer auditors can be used to do internal training and qualification of junior auditors, so that more auditors can be trained up, to relieve the load on a few auditors.

>> End of Chapter 33 <<

Chapter 34. Business Planning & Management Review

0) Introduction

There are several closely-related applicable clauses in this chapter. At first glance, discussing business planning towards the end seems odd. There is a good reason-it is a natural pair with management review. Business planning is the front end of operations (planning), and review is the back end (results). It is therefore apt to discuss them as a pair, to see the cause and effect.

1) 6.2.2.1 Quality Objectives and planning to achieve them-supplemental (IATF16949)

(Clause Description-Paraphrase)

Top management shall ensure that quality objectives to meet customer requirements are defined, established, and maintained for relevant functions, processes, and levels throughout the organization. The results of the organization's review regarding interested parties and their relevant requirements shall be considered when the organization establishes its annual (at a minimum) quality objectives and related performance targets (internal and external).

(Highlights of the clause)

- (Ref to old Standards). There had been a similar clause, 6.2.2 of the same title, in the old version of ISO9001. Contents of both the new and old are rather similar.
- The requirement is to set Objectives for relevant functions, processes, and levels
- Notable change is bjectives setting is minimum annually
- Another notable the requirements of interested parties shall be considered as objectives

(Compliance best practice)

6.2.2.1 Quality objectives and planning to achieve them-supplemental

1. *The clause is discussed here for business planning*
2. *Set minimum one (1) KPI for a process. Some processes such as production, QAQC, and Sales should have more KPI due to the importance*
3. *If customers specified some KPI, they shall be included in your KPI list.*
4. *Evidence of approval by Top Management is required, either by signing on a list, or attached to the Business Planning report.*

2) 6.3. Planning of Changes (ISO9001)

This clause is already discussed in Chapter 12. Please refer.

3) 9.3, 9.3.1 Management Review (ISO9001)

(Clause Description-Paraphrase)

Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organization

(Highlights of the clause)

- (Ref to old Standards). There had been similar clauses, 5.6, 5.6.1 of the same titles, in the old version of ISO9001.
- The old clause reads: Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives."
- The new clause is a reworded version of the old one, with the second sentence removed, probably it is repeated at the input.

(Compliance best practice)

9.3, 9.3.1 Management Review

1. *This is only the ISO9001 portion of management review*
2. *See 9.3.1.1 for combined discussion*

4) 9.3.1.1 Management Review-supplemental (IATF16949)

(Clause Description-Paraphrase)

Management review shall be conducted at least annually. The frequency of management review(s) shall be increased based on risk to compliance with customer requirements resulting from internal or external changes impacting the quality management system and performance-related issues.

(Highlights of the clause)

(Ref to old Standards). This is a totally new requirement. The requirements are:

Frequency of Management Review (MRM) is subject to change, but minimum is once a year.

- Frequency depends on a) risk to compliance with customer requirements, b) changes in internal or external context, c) performance etc
- Frequency to increase when there are nonconformities raised (internal and external), customer complaints etc. (Ref 9.2.2.1)

(Compliance best practice)

9.3.1.1 Management Review-supplemental

1. *The entire management review has a lot areas to cover, therefore a documented process is recommended*
2. *This should be available from the ISO/TS16949 days, or provided by your consultant.*

5) 9.3.2 Management Review Inputs (ISO9001)

(Clause Description-Paraphrase)
The management review shall be planned and carried out taking into consideration:
a) the status of actions from previous management reviews;
b) changes in external and internal issues that are relevant to the quality management system;
c) information on the performance and effectiveness of the quality management system, including trends in:
1) customer satisfaction and feedback from relevant interested parties;
2) the extent to which quality objectives have been met;
3) process performance and conformity of products and services;
4) nonconformities and corrective actions;
5) monitoring and measurement results;
6) audit results;
7) the performance of external providers;
d) the adequacy of resources;
e) the effectiveness of actions taken to address risks and opportunities (see 6.1);
f) opportunities for improvement.

(Old version)
a) results of audits,
b) customer feedback,
c) process performance and product conformity,
d) status of preventive and corrective actions,
e) follow-up actions from previous management reviews,
f) changes that could affect the quality management system, and
g) recommendations for improvement.

(Highlights of the clause)
- (Ref to old Standards). There had been a similar clause, 5.6.2 of same title, in the old version of ISO9001. The agenda items have increased from the old to the new.
- Old requirement are given in a), b), c), c1, c3, c6. Item d) and f) have been removed
- The total requirement is now a) to g)
- Notable change is: i) feedback from interested parties, ii) the effectiveness of actions taken to address risks and opportunities

(Compliance best practice)

9.3.2 Management Review Inputs
1. *This is only the ISO9001 portion of management review*
2. *See 9.3.2.1 for combined discussion*

6) 9.3.2.1 Management Review Inputs-supplemental (IATF16949)
(Clause Description-Paraphrase)
Input to management review shall include:
a) cost of poor quality (cost of internal and external nonconformance);
b) measures of process effectiveness; <repeated in ISO9001?>
c) measures of process efficiency; ; <repeated in ISO9001?> for product realization processes, as applicable <not normal QMS efficiency>

d) product conformance; <repeated in ISO9001?>
e) assessments of manufacturing feasibility made for changes to existing operations and for new facilities or new product (see Section 7.1.3.1);
f) customer satisfaction (see ISO 9001, Section 9.1.2);
g) review of performance against maintenance objectives; Still need to add and comment
h) warranty performance (where applicable);
i) review of customer scorecards (where applicable);
j) identification of potential field failures identified through risk analysis (such as FMEA);
k) actual field failures and their impact on safety or the environment.

(Highlights of the clause)

- (Ref to old Standards). There had been a similar clause, 5.6.2.1 Review input-Supplemental, It was only 1 sentence: input to management review shall include an analysis of actual and potential field-failures and their impact on quality, safety or the environment.
- Total new requirement is very long from a) to k), with many new requirements
- Notable changes: i) field failure had become 2 discussion items, actual and potential, ii) for actual field failure, only safety and environmental impact required, quality has been removed, iii) there are some repeated items with 9.3.2.e.g b), c) d), f) and g).
- 2 SI added to this clause. SI-13: Process efficiency for product realization and SI-16 summary results of measurements at specified stages during the design and development of products and processes, as applicable.

(Compliance best practice)

9.3.2.1 Management Review Inputs-supplemental

1. *The agenda is quite confusing at certain parts, with repetition between ISO9001 and IATF16949.*
2. *A consolidated and streamlined agenda is proposed, to avoid hopping around and back tracking. See* ***Exhibit 34-1***
3. *Some items are poorly catered for and specimens given here as:*
   (i) COPQ. See ***Exhibit 34-2.***
   (ii) the 3 critical controls on customer satisfaction. See ***Exhibit 26-1.***
   (iii) Process Efficiencies ***(Exhibit 23-3)***
   (iv) Actual field failure and impact on safety and environment. See ***Exhibit 34-3.***

7) 9.3.3 Management Review Outputs (ISO9001)

(Clause Description-Paraphrase)

The outputs of the management review shall include decisions and actions related to:

a) opportunities for improvement;
b) any need for changes to the quality management system;
c) resource needs.

The organization shall retain documented information as evidence of the results of management reviews.

(Highlights of the clause)

- (Ref to old Standards). There had been a similar clause, 5.6.2 Review Input.
- Requirements of the new and old are similar, with the new one broader in scope.
- Total requirement see a) to c)

(Compliance best practice)

9.3.3 Management Review Outputs

1. *Input means presentations, discussions, proposals. arguments and suggestions.*
2. *Output in this clause technically means the conclusion. And they are resolutions, consensus, and decisions. Generally there will be many of them in a meeting.*
3. *To be practical, only take those with follow-up actions to be 'output', and list them in the Management Review output. Tabulate them in a table to show the actions needed, due dates, PIC etc. See* ***Exhibit 34-1***

8) 9.3.3.1 Management Review Outputs-supplemental (IATF16949)

(Clause Description-Paraphrase)

Top management shall document and implement an action plan when customer performance targets are not met.

(Highlights of the clause)

- (Ref to old Standards). This is a totally new clause
- The requirement is to document and implement an action pan when customer performance targets are not met

(Compliance best practice)

9.3.3.1 Management Review Outputs-supplemental

1. *This is about cases of customer performance targets not met. IATF wants this to be highlight and followed up.*
2. *List them in another sub-header under output. See* ***Exhibit 34-1***

Continuing

9) SIs & FAQs

SI Nbr	IATF Clause	Description
13	**9.3.2.1 Management review inputs – supplemental**	Input to management review shall include: a) cost of poor quality (cost of internal and external nonconformance); b) measures of process effectiveness; c) measures of process efficiency **for product realization processes, as applicable**; d) product conformance; e) assessments of manufacturing feasibility made for changes to existing operations and for new facilities or new product (see Section 7.1.3.1); f) customer satisfaction (see ISO 9001, Section 9.1.2); g) review of performance against maintenance objectives; h) warranty performance (where applicable); i) review of customer scorecards (where applicable); j) identification of potential field failures identified through risk analysis (such as FMEA); k) actual field failures and their impact on safety or the environment. ***Rationale for change:*** *Clarified that not every process requires an efficiency measure. The organization needs to determine which processes require efficiency measures within their quality management system.*
16	**9.3.2.1 Management review inputs – supplemental**	Input to management review shall include: a) cost of poor quality (cost of internal and external nonconformance); b) measures of process effectiveness; c) measures of process efficiency for product realization processes, as applicable; d) product conformance; e) assessments of manufacturing feasibility made for changes to existing operations and for new facilities or new product (see Section 7.1.3.1); f) customer satisfaction (see ISO 9001, Section 9.1.2); g) review of performance against maintenance objectives; h) warranty performance (where applicable); i) review of customer scorecards (where applicable); j) identification of potential field failures identified through risk analysis (such as FMEA); k) actual field failures and their impact on safety or the environment; **l) summary results of measurements at specified stages during the design and development of products and processes, as applicable.** ***Rationale for change:*** *In the section "8.3.4.1 Monitoring" the summary results of measurements at specified stages during the design and development of products and processes was required as an input to management review; however, it was not displayed in the section 9.3.2.1. Measurements may consider, for example: timing, costs, or feasibility.*

10) Supplementary Notes

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

Clause	Section	Clarification Subjects
6.2.2.1	CBP	**SN34.1. Why is Clauses 4.1, 4.2, 6.1, part of Business Planning? Is so, should top management be handling this task?**
6.2.2.1	CBP	**SN34.2. Can you give some example of customer objectives?**
6.3	CBP	**SN34.3. Why is Management of Change included here?**
9.3.2 9.3.2.1	CBP	**SN34.4. Where can we get some explanations of the exact meaning of the various agenda items?**
9.3, 9.3.1	CBP	**SN34.5. What is the normal time taken for a good management review meeting?.**
9.3, 9.3.1	CBP	**SN34.6. How to run a management review meeting ?**
9.3, 9.3.1	CBP	**SN-34.7. How long should the Minutes take to prepare?**

9.3, 9.3.1	CBP	**SN34.8. Must Top Management be present in Management Review meeting?**
9.3, 9.3.1	CBP	**SN34.9. Can QMR chair the management review meeting?**
9.3.2, 9.3.2.1	CBP	**SN34.10. Should data pertaining to the report be attached, or directly printed on the report?**
9.3, 9.3.1	CBP	**SN34.11. Can IATF management review be combined with ISO14001 or ISO45001**?
9.3, 9.3.1	CBP	**SN34.12. For far-away plants that cannot attend Group Management Reviews in person, what can be done?**
9.3, 9.3.1	CBP	**SN34.13. Can the minutes be in Powerpoints, or must be in full text?**
9.3, 9.3.1	CBP	**SN34.14. What are some of the usual problems of management review meetings?**
9.3, 9.3.1	CBP	**SN34.15. Your example for management review minutes is very complicated and difficult to write. Can we reduce the content?**
9.3.3,	CBP	**SN34.16. If we put some comments to everything we discussed, can that be considered as output?**

SN34.1. Why are Clauses 4.1, 4.2, 6.1, consider as part of Business Planning? If so, should top management be handling this task?

Top Management is definitely involved in business planning, because it is a high level activity. The QMS team will also be actively involved to assist to provide data and information.

SN34.2. Can you give some example of customer objectives?

Example 1. A Malaysian OEM car plant requires its suppliers to score min AB in manufacturing process audit, and achieve an internal reject <30ppm. Suppliers are required to take them up as KPIs, monitored and reported. Example 2. A plant in China is required by its Israeli customer to achieved <2000ppm of internal reject rate, and include this as a KPI in the organization's QMS.

SN34.3. Why include Management of Change here (Management Process)?

This is where the responsibility belongs. By nature, this type of change is a bigger and needs funding and resources. One good time to do this is during business planning where budget can be requested.

SN34.4. Where can we get some explanation of the exact meaning of the various agenda items?

Exhibit 34-1 is a full management review report. From the content, you should be able to understand the meaning of each item of management review input and output. Please refer.

SN34.5. What is the normal time taken for a good management review meeting?

4 hours should be good enough. However, the participants should come prepared, otherwise the 4 hours cannot achieve much.

SN34.6. How to run a management review meeting ?

Process owners should come prepared and make presentations of graphs and Powerpoints, relating to their process/dept. They should later request input on certain issues such as pending problems and resources required. The other participants should be given time to ask questions, share opinions and give suggestions. Decision can be made through consensus, show of hands, or on management directive.

SN34.7. How long should Minutes take to prepare?

1 week is a fair time frame to write a management review. Action items, however, can be sent out immediately as a prelim report, so participants can start to work on them.

SN34.8. Must Top Management be present in Management Review meeting?

Yes, to show commitment. But if he/she really cannot, then QMR to run briefings for him/her later. with minutes draft. Input form management is then incorporated into the minutes. The final minutes shall be signed by top management. Continuous absence of top management will not be acceptable.

SN34.9. Can QMR chair the management review meeting?

It is common due to QMR being more familiar with the QMS. However, it is conducted under delegation from top management. Top Management is usually present at the meeting. Besides the QMR, any other senior member may also be appointed to perform this task under delegation.

SN34.10. Should data pertaining to the report be attached, or directly printed on the report?

Either way is acceptable. In the case of attachment, the copies of attachments should be physically tagged here, for easy retrieval.

SN34.11. Is combine meeting with ISO14001 or ISO45001 acceptable?

Yes, management reviews can be combined. But you have to think of effectiveness. Would the participants get confused? Also time availability is important. Do you have time to run, say, for 6 hours at a stretch, for example?

SN34.12. For far-away sites that cannot attend Group Management Review in person, what can be done?

Video conference is acceptable. Take a photo of the attendees with the monitor screen as the background for evidence.

SN34.13. Can the minutes be in Powerpoints, or must be in full text?

Powerpoints are good for presentation. But Management Review is an official document not only used for IATF, but often read by Board of Directors. It is official and should be written in full length.

SN34.14. What are some of the usual problems of management review meetings?

a) incomplete discussion items, against requirements given in the standards, b) wrong answers to agenda items due to misunderstanding , c) KPI achievement claims not supported by raw data, c) output not available, or vaguely stated.

SN34.15. Your example for management review minutes is very detail and difficult to prepare. Can we reduce the content?

You should take the specimen as a maximum target. You can start off by providing less fact and data, so long it meets the requirement. You may to gradually build up to a level of your choice, over the years.

SN34.16. If we put some comments to everything we discussed, can it be considered output?

Yes it can. However, that method would generally end up with a lot of action items, that you can't possibly cope with. It is to your advantage you to trim down the list, and repeat them at the end of the report. See **Exhibit 34-1.**

11) Exhibits

Exhibit 34-1. Management Review Minutes

Management Review

Meeting Description	Date/Time	Venue
Management Review. ISO9001:2015 & IATF16949:2016.	12 Nov 2019. 2-5 pm	Company Conference Room
Participants: Chair: Wilson Tan (MD) Participants: XXX, XXXX,		

1. Status of actions from previous Management Reviews

There were 3 follow-up items from last year's management review, they are all acted upon successfully as follows:

No	Improvement items	Due Date	PIC	Status as at Management Review
1	Refresher Training on Internal Audit	Sep 2019	QMR	Training conducted on 1-2 Jun 2019. Skills used for this year's internal audit effectively
2	Roof of material warehouse to repair-now leaking	June 2019	Maintenance	Roof leaking was repaired in Jun 2019, as plan. Now OK
3	Need new operators for CNC section and one crane operator	June 2019	HR/ Production	New operators required have been recruited in July, trained and now working

2. Changes in external and internal issues that are relevant to the QMS

No	Doc Info	Reviewed on	Conclusion
a)	Internal Analysis	16 Aug 2019	No major changes, and no mitigation or corrective actions needed
b)	External Analysis	18 Aug 2019	No major changes, and no mitigation or corrective actions needed
c)	Interested Parties	20 Aug 2019	No major changes, and no mitigation or corrective actions needed
d)	Scope of QMS	21 Aug 2019	No major changes, and no mitigation or corrective actions needed
e)	Contingency Plan	21 Aug 2019	No major changes, and no mitigation or corrective actions needed
f)	Organization Knowledge	25 Aug 2019	No major changes, and no mitigation or corrective actions needed
e) and f) are included due to their strategic nature and importance in QMS			

3. Information on the performance and effectiveness of the QMS, including trends

A) MP1. Management Planning, M2 Management Review

S/N	Discussion Item	Target/Expected	Actual	Actions Needed
a	KPI-1	Management Review 3 weeks before external audit	Review 12 Nov 2019 External Audit scheduled 15 Dec 2019. OK	NA
b	KPI-2	Business Planning/ budget submit before end of Jan of year	Submit to BOD on 25 Dec last year and approved. OK	NA
c	Safety & Environment	No incident, no near miss. No env breaches	No incident, no near miss. No env breaches. OK	NA
d	Resources	Sufficient resources to support the operations	Sufficient resources. OK	NA

Exhibit 34-1. Page 2

e	Changes that can affect process, or even the organization	Report the changes	New product lines next year on CJX Line.	Later during project launch
f	Risks and Opportunities changes in this area	Report the changes	Some changes, see SP-4 for details	See SP-4 for details
g	Opportunity for Improvement	Suggest any improvement that can improve the operations	None	NA
h	Other remarks	NA		

B) MP2. Internal Audits

S/N	Discussion Item	Target/Expected	Actual	Actions Needed
a	KPI-1	5 days to reply NC raised in internal audits	Average 4.6 days. OK	NA
b	Safety & Environment	No incident, no near miss. No env breaches	No incident, no near miss. No env breaches. OK	NA
c	Changes that can affect process, or even the organization	Report the changes	No changes	NA
d	Risks and Opportunities changes in this area	Report the changes	No changes	NA
e	Resources	Sufficient resources to support the operations	A little short on internal auditors	NA
f	Opportunity for Improvement	Any improvement that can improve the operations	We have lost some internal auditors due to resignation. Need to train up some more.	HR to apply for budget to run an inhouse training by external trainer
g	Other remarks	NA		

C) MP3. Continual Improvement

S/N	Discussion Item	Target/Expected	Actual	Actions Needed
a	KPI-1	Min 5 projects a year	Last year 8 projects. OK	NA
b	Safety & Environment	No incident, no near miss. No env breaches	No incident, no near miss. No env breaches. OK	NA
c	Resources	Sufficient resources to support the operations	Sufficient resources. OK	NA
	Changes that can affect process, or even the organization	Report the changes	No changes	NA
	Risks and Opportunities changes in this area	Report the changes	No changes	NA
d	Opportunity for Improvement	Any improvement that can improve the operations	Have been improving on quality of the projects.	Consider some incentives for good projects
e	Other remarks	NA		

D) COP-1. RFQ Handling

S/N	Discussion Item	Target/Expected	Actual	Actions Needed
a	KPI-1	Submission of Quotation on time	2 submissions, all on time. OK	NA
b	Safety & Environment	No incident, no near miss. No env breaches	No incident, no near miss. No env breaches. OK	NA
c	Resources	Sufficient resources to support the operations	Resources sufficient. OK	NA

Exhibit 34-1. Page 3

8. Audit Results

(internal Audit)
Internal audits were carried out between 13 Sep to 5 Oct 2019. 16 NC and 20 OFI had been raised. NCs were all closed out at time of Management Review.

(Customer Audit)
No customer audit last year

(3rd Party Audit)
IATF::2016 had been audited by XXX on 3 June 2019, with 2 minor NC.

9. Monitoring and measurement results

- KPI measurement and performance see 3A- 3K above
- Measurement and monitoring on products and processes are conducted daily mainly on site. No major issues noticed throughout the year

10. Performance of external providers

Please refer 3O above

11. Adequacy of resources

Please refer 3A- 3K above

12. The effectiveness of actions taken to address risk and opportunities

Please refer 3R above

13. Opportunities for improvement

Please refer 3A- 3K above

(IATF)

14. Cost of Poor Quality
Please refer 3R above

15. Measures of Effectiveness.
Effectiveness is monitored by the various KPI of all the processes.
Please refer 3A- 3K above

16. Measures of Process Efficiency Process efficiency, for product realization processes, as applicable <SI-13>
Conducted a process study of the blow moulding machine LX80. The output is achieved. OK. See Special Report attached.

17. Product conformance
Please refer 3P above. Generally no major issues

18. Assessment of manufacturing feasibility made for changes to existing operation and for new facilities or new product

No new facilities or new product last year. Also no changes to existing operations.

19. Review of performance against maintenance objectives
Objectives set as KPI, which are reviewed every month. If objectives not met, actions will be taken. More details, please refer 3Q.

20. Warranty performance
NA. No warranty in contractual agreement

21. Review of customer scorecards
Only XXX and YYY have scorecards. They are sent in every month. For last 12 months, the feedback has been good, scoring A for both customers

Exhibit 34-1. Page 4

22. Identification of potential field failures identified through risk analysis (such as FMEA)
This year some risks have been identified from operations, they are later included into the FMEA, after resolution

22. Actual potential field failures and their impact on safety and environment
There are other warranty, and 3 complaints. They were analysed and found no impact to safety and environment.
See attachment XXX

23. Summary results of measurement at specified stages during the design and development of products and processes, as applicable <FAQ-16>
Available at project files. Last year only 1 project. All verification, validation and review carried out and all OK.
Project already approved for mass-production during May 2019

24. Output of Management Review

No	Improvement items	Due Date	PIC
1	HR to apply for budget to run an inhouse course for internal auditors, by external trainer	Mar 2020	HR
2	Consider some incentives for good improvement projects	Dec 2019	HR, Management
3	Work out standard costing to speed up submission of quotations.	Dec 2019	Financial Controller
4	Consider to recruit one more staff for process engineering	Mar 2020	HR, HOD, Management
5	Prevent repeat of customer disruption	Jan 2020	Marketing, QA, Production
6	Prevent the near-miss at Production (chemical drum rolled off from forklift)	Ongoing	Production, Maintenance
7	Look into using outsourced transporter to supplement to assist in delivery	Jan 2020	Planner, Purchasing
8	Monitor for 2-3 months and decide if needs to recruit more people at maintenance	Mar 2020	HR, HOD, Management

(Below only required if customer targets not achieved)

a. Customer Target not achieved

No	Corrective Actions	Status	Corrective action	PIC
1	OTD to XXX not achieve 100%	In progress	NCR-INT 23/18	Shipping
2	PPM at 6500 ppm, not OK to customer XXX	In progress	NCR-INT 24/18	Production/QA

Remarks given in this section explain on the Exhibit. Do not include them as part of your document

- This management review minutes is comprehensive and useful. But it is probably beyond most companies to go into this level of details
- Each organization can decide on the level of sophistication immediately. Gradual incremental may be a better way. However, the organization must ensure all the headings mentioned in the standard are discussed.

Exhibit 34-2. Cost of Poor Quality

A. Monthly

	J	F	M	A	M	J	J	A	S	O	N	D	Average
Target. % of sales	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%	
Actual	5	4	5	1	0.5	3	1	0.5	0.3	0.5	0.3	0.2	1.78%
Remark	New part	New part	New part										

Comments for non-achievement:

Dec: (Example)

- The new part XYZ is still not stable. Adjustment actions are still taking place since in Jan.
- Customer engineers have also been present to assist.
- The rejects were coming down steadily and by Jul, we are down to 1% which is the target
- The average for the year is still 1.78% due to earlier high rejects

Remarks given in this section explain on the Exhibit. Do not include them as part of your document

- This is a simple way to record COPQ. COPQ should be a KPI so as not to be overlooked.
- Whenever it is not on target, the cause shall be investigated for actions to be taken. But it does not mean every time is is not within the limits, actions must be taken. S
- Sometimes you need to observe the trend or problem a little longer. A slight delay up to 3 months is generally accepted.

Exhibit 34-3 Actual field analysis and Impact on Env & Safety

Actual field-failures and their impact on safety or the environment.

Date of Failure	Customer/Product Failure	Impact	Description	Significance Low, Mid, High	Action Needed Yes/No	Action Plan Ref No
Case 1. Missing component in part						
02 NOV 2016	Heat shrink casing missing in part	• Environment	No Impact	-	No	No Action needed
		• Safety	No Impact	-	No	No Action Needed
Case 2. Steering host bursts						
1 Dec 2017	Steering hose burst	• Environment	Hydraulic oil spillage onto road and drainage system	Mid	No	NA
		• Safety	Loss of car controls by driver.	High	Yes	AP 011/17. (To make it fail-proof)
Case 3. Chemical drums leak on delivery						
6 Sep 2018	Chemical drum leaks when delivered to customers	1. Envi	Chemical leaks into waterways and drainage system	High	Yes	AP013/17 (Train transporters on care and response)
		2. Safety	Chemical spills on the fore court of the customers- can cause industrial accidents	Low-Mod (clean up)	No	

Remarks given in this section explain on the Exhibit. Do not include them as part of your document

- This is the working document to analyse each failure. A wild claim that there is no failure, or no impact will not be acceptable without evidence.
- The above 3 cases are provided to illustrate how to comply with the IATF requirement. They are fictitious examples and not from the same organization.
- Some organizations say they have ISO14001 and ISO45001 so these are taken care off. This is incorrect, as the impact we are talking about is on customer and car owners. Your ISO14001 and ISO45001 are for your own plant and therefore irrelevant

>> End of Chapter 34 <<

Chapter 35. Improvement and Continual improvement

Contents:

0) Introduction

There is 3 related applicable clause in this chapter, but all centering around improvement. The reason why a whole chapter is devoted to this is because the clauses are commonly misunderstood and/or poorly catered for. Many NCs have been written on this clause alone.

1) 10, 10.1 Improvement IS09001- General

(Clause Description-Paraphrase).

The organization shall determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction. These shall include:

a) improving products and services to meet requirements as well as to address future needs and expectations;

b) correcting, preventing or reducing undesired effects;

c) improving the performance and effectiveness of the quality management system.

NOTE Examples of improvement can include correction, corrective action, continual improvement, breakthrough change, innovation and re-organization

(Highlights of the clause)

- (Ref to old Standards). There had been a similar clauses, 8.5 with no content. So essentially this is a new clause with new requirements.
- The full requirements are given as a) to c). These are things that an organization would do as a matter of course, but now considered as improvement

(Compliance best practice)

10, 10.1 Improvement IS09001

1. *If you have taken efforts in terms of correction, prevention or reduction of undesired effects, you are in compliance of this clause. IATF Auditors won't be checking on this clause, because you are definitely in compliance.*
2. *But continual improvement is another matter. See next clause.*

2) 10.3 Continual Improvement (ISO9001)

(Clause Description-Paraphrase)

The organization shall continually improve the suitability, adequacy and effectiveness of the quality management system. The organization shall consider the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities that shall be addressed as part of continual improvement.

(Highlights of the clause)

- (Ref to old Standards). There had been similar clauses, 8.5.1, in the older version of ISO9001.
- The old clause was very simple; "The organization shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.
- The old sentence is totally replace.
- Continual improvement in the new clause, comes from results of analysis and evaluation, and the outputs from management review

(Compliance best practice)

10.3 Continual Improvement

1. *This clause refers to continual improvement which is a 'shall' item, meaning it is mandatory.*
2. *2 common sources for initiating continual improvement, as given in the clause are: a) results of analysis and evaluation, b) outputs from management review*
3. *However there are others areas to consider: customer requests, process study conclusions, operations meeting output, employee suggestions, specialists recommendations etc.*
4. *Project reports are required, but they need not be full 6-Sigma type. Simpler ones can be just as effective. See* ***Exhibit 35-1.***

3) 10.3.1 Continual Improvement-Supplemental (IATF16949)

(Clause Description-Paraphrase)

The organization shall have a documented process for continual improvement. The organization shall include in this process the following:

a) identification of the methodology used, objectives, measurement, effectiveness, and documented information;

b) a manufacturing process improvement action plan with emphasis on the reduction of process variation and waste;

c) risk analysis (such as FMEA).

NOTE Continual improvement is implemented once manufacturing processes are statistically capable and stable or when product characteristics

(Highlights of the clause)

- (Ref to old Standards). There had been a similar clauses, 8.5.1.1 Continual improvement of the organization, in the old version of ISO/TS16949.
- The old clause was very simple: "Organization shall define a process for continual improvement.
- The new clause to have a document process that include:
- the methodology, objectives, measurement, effectiveness, and record keeping etc.
- A manufacturing improvement plan with emphasis on reduction of variation and waste

- risk analysis

(Compliance Best Practice)

4) 10.2.4 Error-proofing (IATF16949)

(Clause Description-Paraphrase)

10.3.1 Continual Improvement-Supplemental

1. *A documented process is required, most companies don't have this. See* ***Exhibit 35-2.***
2. *Improvement is generally on QMS, how to improve the suitability, adequacy and effectiveness of the QMS.*
3. *A manufacturing improvement plan should also be included, with emphasis on reduction of variation and waste risk analysis*

The organization shall have a documented process to determine the use of appropriate error-proofing methodologies. Details of the method used shall be documented in the process risk analysis (such as PFMEA) and test frequencies shall be documented in the control plan. The process shall include the testing of error-proofing devices for failure or simulated failure. Records shall be maintained. Challenge parts, when used, shall be identified, controlled, verified, and calibrated where feasible. Error-proofing device failures shall have a reaction plan.

(Highlights of the clause)

- (Ref to old Standards). There had been a similar clauses, 8.5.2.2 of same title, in the old version of ISO/TS16949.
- The old clause is very simple: "The organization shall use error-proofing methods in their corrective action process" The new clause is a total replacement, requiring:
- a documented process.
- Process shall include risk analysis. Method and test frequency to be documented in control plan.
- testing of error-proofing devices for failure or simulated failure is required. Records to be maintained
- Challenge parts, when used, shall be identified, controlled, verified, and calibrated where feasible. Error-proofing device failures shall have a reaction plan.

(Compliance best practice)`

10.2.4 Error-proofing

1. *Procedure is required by the clause. However, not many organizations have provided for this requirement. See* ***Exhibit 35-3.***
2. *Error proofing shall be identified on the FMEA and Control Plan.*
3. *Persons-in-charge should know how to use the error proofing devices, and use of challenged parts. Records shall be maintained on use of challenge parts*
4. *Challenge parts shall be identified, protected and maintained.*

5) SIs & FAQs

No SIs & FAQs for this Chapter

6) Supplementary Notes

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

Clause	Section	Clarification Subjects
10.1	CBP	**SN35.1. If corrective actions are considered improvement, then do I still need to do any continual improvement?**
10.3, 10.3.1	CBP	**SN35.2. Is there any other sources for improvement ideas, beside the results of analysis and evaluation, and the outputs from management review?**
10.3, 10.3.1	CBP	**SN35.3. How should the documentation be for continual improvement? Do we need professional documentations like a 6-Sigma project?**
10.3, 10.3.1	CBP	**SN35.4. Do the team members need to attend 6 Sigma training?**
10.3, 10.3.1	CBP	**SN35.5. If we have been doing small projects under a Kaizen program, is it consider continual improvement?**

SN35.1. If corrective actions are considered improvement, then do I still need to do any continual improvement?

Corrective actions are considered improvement in this new version. Continual improvement is still required. The word 'shall' is used for continual improvement. It is a non-compliances if no continual improvement is carried out.

SN35.2. Is there any other sources for improvement ideas, beside the results of analysis and evaluation, and the outputs from management review?

Customer requests, operations meeting output, employee suggestions, productivity consultant recommendations etc, are also possible sources.

SN35.3. How should the documentation be for continual improvement? Do we need professional documentations like a proper project paper?

Documentation can be simple, such as 'before and after' comparisons. It does not need a 6-sigma format. However, data is still needed for conclusions is the project taken is successful. An improvement project documentation should preferably show: a) name of project,
b) purpose, c) objective, d) team & members, e) investigation, f) action plans used, g) results, preferably with photo evidence, h) conclusion & recommendations.

SN35.4. Do the team members need to attend 6 Sigma training?

There is no such requirement from ISO/IATF. However, it will be great and more effective if team members are trained on improvement methodology e.g. 6 Sigma.

SN35.5. If we have been doing small projects under a Kaizen program, is it consider continual improvement?

Yes, but try to have the data to prove it is successful or otherwise.

7) Exhibits

Exhibit 35-1 Continual Improvement Reporting

Simple Report for Continual Improvement

Project No. PDN/01	Team: Xean Row (leader). Linda, Mahira
Project Selected: Assembly area to be re-arranged	Reasons Now very messy, work slow and sometimes accident
Current performance See picture below (before)	Target 1. Special Place for packing material on racks 2. Special location for WIP waiting for inspection 3. New door way to store to cut short journey
Budget requirement USD 20000	Approved XX
Before . Packing Material uncontrolled Photo before	After: Packing Materials on Racks Photo after
Travel route-before (long route) Photo before	Travel route-after (shorter via a doorway) Photo after
WIP no special location Photo before	WIP with dedicated location Photo after

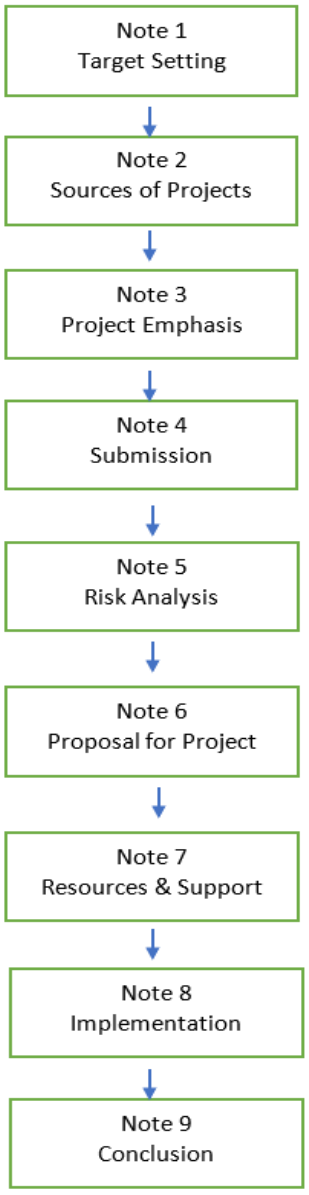
Conclusion:

- The project took 2 months to implementation
- The place looks neater now, with packing material neatly stacked on racks
- Finished goods to store is much faster, via a doorway, instead of need to get out of building and go a big round to the warehouse, cut down 70% travelling
- With the packing material out of the way, space are allocated here for WIP waiting for inspection
- Project viewed by top management and concluded successful

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

- The above report is a very simple, no unnecessary story-telling, and direct to the point
- The main evidence will be in data and pictures (before and after)
- This kind of reporting should be good for continual improvement projects in most situations

Exhibit 35-2 Continual Improvement Procedure

Responsibility	Flow Diagram	Description
Kaizen Team		Note 1: • The kaizen team shall meet at end of the year to discuss about continual improvements. • The no of projects to be taken at the end of meeting shall be concluded Note 2: Primary sources for improvement projects are: • Primary areas are: results of analysis and evaluation, and the outputs from management review • Other areas are: customer requests, process study conclusions, operations meeting output, employee suggestions, productivity consultant recommendations etc, are also possible sources. Note 3: Nature of projects to objectives to emphasize are: • QMS-improve the suitability, adequacy and effectiveness • a manufacturing process -reduction of process variation and waste Note 4: • the meeting shall conclude the number and type of improvement projects • Each project shall include: objectives, method, measurement, effectiveness, and conclusion • Management will have final decisions on the project selection • The approval granted are conditional to risk analysis findings Note 5: • Risks analysis shall then be conducted on the selected projects, using FMEA

Description	Description
Note 6: Proposal of each project shall consist of the following Information: • Project no/title, purpose, background situation, targets, budget & resources, action plan concept, implementation period Note 7: • Resources and budget are to be approved by management • QMR will also mobilize further support where necessary	Note 8: • Once approved, the appointed team leader shall lead a core team to implement the plan • Further resources shall be applied through the QMR, who would bring to Management for decision Note 9: • Project report shall be submitted at end of the project • The report shall show minimum: project title, date, action plan, implementation period, comparison of before and after situations, conclusions

Remarks given here explain on the Exhibit. Do not include them as part of the document
A documented process is required for this clause. This is an example for the procedure

Exhibit 35-3 Error-Proofing Management

Responsible	Flow Diagram	Description
Process Engineering Production	Note 1 Use of Error Proofing ↓ Note 2 Risk Analysis ↓ Note 3 Testing of Error Proofing devices ↓ Note 4 Challenge Part Maintenance	Note 1 • Error Proofing is an Improvement tool in processes • It affords accurate and speedy capture of defects • Error proofing ideas are considered during APQP/PPAP stages and subsequent continual improvement activities Note 2 • Error proofing ideas shall be analysed before adoption • Tool for risk analysis is FMEA, or any other appropriate method • If risk analysed to be OK, the error proofing idea is adopted • If the analysis should high risk of failure or malfunction, improvement or modification shall be carried out to satisfactory before adoption • Once adopted, planning shall be made for maintenance, replacement frequencies • Reaction plans shall also be included in the FMEA which shall form part of the records Note 3 • The use of error proofing shall be on FMEA and control plan • The error proofing shall be periodically tested for failure or simulated failure • The frequency and timing of testing shall be specified in the control plan or WI • Testing records shall be retained Note 4 • Challenge parts shall be managed • They shall be Identified, controlled and stored in a secure places • Before use, they are verified • The challenged parts shall also be checked regularly for damaged or changes that can affect test results • For certain error proofing e.g. software calibration, testing using method provided by equipment OEM is needed

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

A documented process is required for the Clause. This is a simple procedure that can be used.

>> End of Chapter 35 <<

Abbreviations

A, B, C

- CB: Certification Body
- CAR: Corrective Actions Request
- CSS: Customer satisfaction Survey
- CSR: Customer Specific Requirement
- CAP: Contingency (Action) Plan
- CP: Control Plan

D

- DFMEA: Design Failure Mode & Effect Analysis
- D&D: Design & Development
- DFM: Design for Manufacturing

E. F, G, H

- FIFO: First-in-first-out
- FMEA: Failure Mode & Effect Analysis
- HOD: Head of Department/Section
- FAQ: Frequently-asked Questions

I, J, K, L

- IATF: International Automotive Task Force
- IPNE: Interested Parties Needs and Expectations
- ISWE: Infrastructure and work environment,
- IAF: International Audit Forum
- JD: Job Description

M

- MPA: Manufacturing process audit
- MRM: Management Review Meetings
- MSA: Measurement System Analysis

N

NC: nonconformity
NCO: Nonconforming Outputs
NCP: Nonconforming Product (old term for NCO)

O

- Org: Organization
- Org: Organizational knowledge
- OJT: On-the-job training
- OEM: Original Equipment Manufacturer

P

- PIC: Person in charge

- PFMEA: Process Failure Mode & Effect Analysis
- PDA: Product audit
- PQCT: Control plan of Honda
- PFC: Process Flow Chart
- PM: Preventive Maintenance
- PEST: Political, economic, social and technological
- PESTEL: Political, economic, social and technological, environment and legal

Q

- QM: Quality Manual
- QMS: Quality Management System

R

- R&O= Risks & Opportunities

S

- SI: Sanction Interpretation
- SC: Special Characteristics
- SPC: Statistical Process Control
- S&R: Statutory & Regulatory
- SWOT: Strength, weakness, opportunity and threat

T

- 3P: Third Party
- TNA: Training Needs Analysis
- T-MGT: Top management

U, V, W, X Y, Z

- UAI: use as is
- WIP: Work-in-progress
- WI. Work Instructions

Exhibit List

Chapter 1. QMS Documentation Overview

Note: I = Illustration/PDF only. T= Template for editing

Exhibit No/Description	Type		Editable pages	Running Total
	I	T		
Exhibit 1-1. Annex A1 statement on Changing over to New Terminology	x		0	
Exhibit 1-2 A Simplified IATF QM		x	3	
Exhibit 1-3. Compliance Matrix		x	27	
Total			30	30

Chapter 2. Risk and Opportunity Analyses

Exhibit No/Description	Type		Editable pages	Running Total
	I	T		
Exhibit 2-1 External Analysis PESTEL		x	2	
Exhibit 2-2. External Analysis SWOT	x		0	
Exhibit 2-3 External Analysis. Modified SWOT		x	2	
Exhibit 2-4. Internal Analysis-Process based		x	23	
Exhibit 2-5A. Critical Internal Risks Areas	x		0	
Exhibit 2-5B. Risk based on obstacles to Purpose		x	5	
Exhibit 2-6. 4X3 Risk Table	x		0	
Exhibit 2-6A. 4X3 Risk Table (editable)		x	1	
Exhibit 2-7. Simple Action Plan		x	1	
Exhibit 2-8. Project Plan with Gantt Chart	x		0	
Exhibit 2-9. Review Evidence Type 1. Notes on the document	x		0	
Exhibit 2-10. Review Evidence Type 2. Doc change History	x		0	
Exhibit 2-11- Project Linkage Management	x		0	
Exhibit 2-12. Risk analysis following a failure		x	1	
Total			35	65

Chapter 3. Contingency Plans

Exhibit No/Description	Type		Editable pages	Running Total
	I	T		
Exhibit 3-1. Contingency Action Plan.		x	2	
Exhibit 3-2. Contingency Plan Testing-Simulation		x	1	
Exhibit 3-3. Contingency Plan Testing-Real Occurrence		x	1	
Exhibit 3-4 Contingency Plan Review.	x		0	
Total			4	69

Chapter 4. Needs and Expectations of Interested Parties

Exhibit No/Description	Type		

	I	T		
Exhibit 4-1. Interested parties' Needs and expectations.		x	3	
Total			3	72

Chapter 5. Scope Determination

Exhibit No/Description	Type		Editable pages	Running Total
	I	T		
Exhibit 5-1. Determining the Scope	x		0	
Exhibit 5-2. Scope Determination, Step-by Step Guide		x	1	
Exhibit 5-3. Scope Review		x	1	
Exhibit 5-4A Supported Sites on Certificates	x		0	
Exhibit 5-4B. Inclusion of supported sites in Remote Location's QM	x		0	
Total			2	74

Chapter 6. Customer Specific Requirement

Exhibit No/Description	Type		Editable pages	Running Total
	I	T		
Exhibit 6-1.CSR Listing and Evaluation		x	1	
Exhibit 6-2.CSR-Processes Matrix.		x	2	
Total			3	77

Chapter 7. QMS & its Processes

Exhibit No/Description	Type		Editable pages	Running Total
	I	T		
Exhibit 7-1. Forming Processes from Procedures	x		0	
Exhibit 7-2. MP-COP-SP Process Map	x		1	
Exhibit 7-3 Business Flow Chart Process Map	x		0	
Exhibit 7-4. Process Input-Output, Resources Chart (PIOR)		x	6	
Exhibit 7-5. Turtle diagram Specimen		x	1	
Total			8	85

Chapter 8. Eligibility and Conformances

Exhibit No/Description	Type		Editable pages	Running Total
	I	T		
No Exhibit				
Total			0	85

Chapter 9. Product Safety Related

Exhibit No/Description	Type		Editable pages	Running Total
	I	T		

Exhibit 9-1. Product Safety Doc Process		x	1	
Total			1	86

Chapter 10. Leadership Related

Exhibit No/Description	Type		Editable pages	Running Total
	I	T		
Exhibit 10-1. Procedure to Guide Top Mgt		x	1	
Exhibit 10-2 Full Delegation Chart		x	1	
Exhibit 10-3. Customer Satisfaction Responsibilities		x	1	
Exhibit 10-4. QMS Monthly Report to Management		x	1	
Total			4	90

Chapter 11. Policies, Objectives and Action Plans

Exhibit No/Description	Type		Editable pages	Running Total
	I	T		
Exhibit 11-1. Updated Quality Policy	x		0	
Exhibit 11-2. Whistle Blowing Policy		x	1	
Exhibit 11-3 KPI List		x	1	
Exhibit 11-4. Quality Objectives (non-auto)		x	1	
Exhibit 11-5 Full KPI Performance Report			0	
Exhibit 11-5A KPI Performance Report. full length	2		2	
Total			5	95

Chapter 12. Changes Related

Exhibit No/Description	Type		Editable pages	Running Total
	I	T		
Exhibit 12-1. Planning for Changes		x	1	
Exhibit 12-2. ECN Form Specimen		x	1	
Exhibit 12-3. ECN Procedure Specimen		x	1	
Exhibit 12-4 Alternative method in PFMEA	x		0	
Exhibit 12-5. Procedure for Temporary and Alternative Methods		x	1	
Total			4	99

Chapter 13. HR, Training & Competency

Exhibit No/Description	Type		Editable pages	Running Total
	I	T		
Exhibit 13-1. Job Description	x		0	
Exhibit 13-2. On-the job Training	x		0	
Exhibit 13-3. Training related to JD	x		0	
Exhibit 13-4. Personal Training Records		x	1	
Exhibit 13-5. TNA		x	2	

Exhibit 13-6. Training Application Form		x	1	
Exhibit 13-7. Orientation Program		x	1	
Exhibit 13-8. Critical Knowledge by Process	x		0	
Exhibit 13-9. Organization Knowledge Evaluation		x	15	
Exhibit 13-10. Org Knowledge sharing specimen		x	1	
Total			21	120

Chapter 14. Infrastructure & Work Environment

Exhibit No/Description	Type			
	I	T		
Exhibit 14-1. ISWE Review		x	1	
Total			1	121

Chapter 15. Monitoring and Measurement Resources

Exhibit No/Description	Type		Editable pages	Running Total
	I	T		
Exhibit 15-1. M. Equipment Master List		x	1	
Exhibit 15-2. Individual Equipment Calibration Records		x	1	
Exhibit 15-3. Calibration Incident Records		x	1	
Exhibit 15-4 Internal Lab Capability		x	1	
Exhibit 15-5. Evidence by non-ISO17025 OEM	x		0	
Total			4	125

Chapter 16. Communication

Exhibit No/Description	Type		Editable pages	Running Total
	I	T		
Exhibit 16-1 Internal Communications		x	1	
Exhibit 16-2. External Communications Procedure		x	1	
Exhibit 16-3. External Communication Records		x	1	
Total			3	128

Chapter 17. Documentation

Exhibit No/Description	Type		Editable pages	Running Total
	I	T		
Exhibit 17-1. Record Retention		x	1	
Exhibit 17-2. Record Retention - Auto supplement		x	1	
Total			2	130

Chapter 18. RFQ, Handling, Orders processing, Production Planning & Scheduling

Exhibit No/Description	Type		Editable pages	Running Total
	I	T		
Exhibit 18-1. Simple Contract Review		x	1	

Total			1	131

Chapter 19. Product, Service, Statutory & Regulatory Requirements

Exhibit No/Description	Type		Editable pages	Running Total
	I	T		
Exhibit 19-1. Statutory and Regulatory Requirements		x	1	
Exhibit 19-2 Determination for after-delivery activities		x	1	
Total			2	133

Chapter 20. Special Characteristics

Exhibit No/Description	Type		Editable pages	Running Total
	I	T		
Exhibit 20.-1.Use of Classification Column in FMEA & CP	x		1	
Exhibit 20-2.Harmonized SC Symbol Approach		x	1	
Total			2	135

Chapter 21. Automotive Core Tools

Exhibit No/Description	Type		Editable pages	Running Total
	I	T		
Exhibit 21-1. APQP Chart	x		0	
Exhibit 21-2. PSW Form	x		0	
Exhibit 21-3. PPAP Requirement	x		0	
Exhibit 21-4. GR&R	x		0	
Exhibit 21-5. Attribute GR&R		x	1	
Exhibit 21-6 DMEA Form	x		0	
Exhibit 21-7 PMEA Form	x		0	
Exhibit 21-8 Control Plan	x		0	
Exhibit 21-9. Showing Setup in Control Plan_	x		0	
Exhibit 21-10 SPC	x		0	
Total			1	136

Chapter 22. Design & Development

Exhibit No/Description	Type		Editable pages	Running Total
	I	T		
Exhibit 22-1.Team Feasibility Form from AIAG	x		0	136
Exhibit 22-2 Capacity Study-Specimen		x	1	
Exhibit 22-3 Product Design Process		x	1	
Exhibit 22-4. Process Design Process		x	1	
Exhibit 22-5 DD Input & Objectives		x	1	
Exhibit 22-6 Project Schedule		x	1	
Total			5	141

Chapter 23. Production & Process Controls

Exhibit No/Description	Type		Editable pages	Running Total
	I	T		
Exhibit 23-1 WI with safety caution, and in local language		x	1	
Exhibit 23-2. Manufacturing Process Efficiency Study - Copy		x	1	
Total			2	143

Chapter 24. Purchasing and Control of External Providers

Exhibit No/Description	Type		Editable pages	Running Total
	I	T		
Exhibit 24-1. Approved Supplier List		x	1	
Exhibit 24-2 Approval after Proper Evaluation		x	1	
Exhibit 24-3 Supplier Evaluation includ 3 critical		x	1	
Exhibit 24-4. Describing control on outsourcing (in Compliance Matrix)	x		0	
Exhibit 24-5. IAF & AB on authenticity of certificates	x		0	
Exhibit 24-6. Supplier Tracking on 3 critical criteria		x	1	
Exhibit 24-7. Second Party Audit Management Model		x	1	
Exhibit 24-8. Second Party Audit Schedule		x	1	
Exhibit 24-9. Second Party Audit Report		x	1	
Exhibit 24-10 Specific Objective 2P Audit Checklist		x	1	
Exhibit 24-11. Full QMS 2P Audit Checklist		x	5	
Total			13	156

Chapter 25. Performance Monitoring and Analysis

Exhibit No/Description	Type		Editable pages	Running Total
	I	T		
No Exhbit			0	
Total			0	156

Chapter 26. Customer Satisfaction & Feedback, Post-Delivery Activities

Exhibit No/Description	Type		Editable pages	Running Total
	I	T		
Exhibit 26-1. Critical Customer Satisfaction Criteria		x	1	
Exhibit 26-2. Warranty Procedure		x	1	
Exhibit 26-3. Warranty Records		x	1	
Exhibit 26-4. Customer Complaint Procedure		x	1	

Total			4	160

Chapter 27. Maintenance Related

Exhibit No/Description	Type		Editable pages	Running Total
	I	T		
Exhibit 27-1. Equipment Master List		x	1	
Exhibit 27-2. Spare Part List		x	2	
Exhibit 27-3. Preventive Maintenance		x	1	
Exhibit 27-4. Daily Maintenance Checklist		x	1	
Exhibit 27-5. Tooling Shot Count Tracking		x	1	
Total			6	166

Chapter 28. Identification and Traceability, Properties Belonging to External Parties

Exhibit No/Description	Type		Editable pages	Running Total
	I	T		
Exhibit 28-1. Traceability chart		x	2	
Exhibit 28-2. External Property Management		x	1	
Total			3	169

Chapter 29. Storage & Delivery

Exhibit No/Description	Type		Editable pages	Running Total
	I	T		
Exhibit 29-1. Preservation Control		x	1	
Total			1	170

Chapter 30. QAQC Activities

Exhibit No/Description	Type		Editable pages	Running Total
	I	T		
Exhibit 30-1 First off in Control Plan_	x		0	
Total			0	170

Chapter 31. Nonconformity, Correction Action & Preventive Action

Exhibit No/Description	Type		Editable pages	Running Total
	I	T		
Exhibit 31-1. NC, CA & Problem Solving		x	1	
Exhibit 31-2. NC Horizontal Replication		x	1	
Exhibit 31-3. Preventive Action Request (PAR)		x	1	
Total			3	173

Chapter 32. Nonconforming Outputs

Exhibit No/Description	Type		Editable pages	Running Total
	I	T		
Exhibit 32-1. Customer Concession Management		x	1	
Exhibit 32-2. Rework and Repair Procedure		x	1	
Exhibit 32-3 Onhold Label		x	1	
Exhibit 32-4 Concession Records		x	1	
Exhibit 32-5 Disposition of scrap Form		x	1	
Total			5	178

Chapter 33. Internal Audits

Exhibit No/Description	Type		Editable pages	Running Total
	I	T		
Exhibit 33-1. 1 Year Internal Audit Program		x	3	
Exhibit 33-3. Single Year Audit Plan		x	1	
Exhibit 33-4. Automotive Process Approach Checklist		x	1	
Exhibit 33-5. Manufacturing Process Audit Checklist		x	1	
Exhibit 33-6 Product Audit Checklist		x	1	
Exhibit 33-7. Internal and Supplier Auditors List		x	2	
Total			9	187

Chapter 34. Business Planning & Management Review

Exhibit No/Description	Type		Editable pages	Running Total
	I	T		
Exhibit 34-1. Management Review Minutes		x	9	
Exhibit 34-2. Cost of Poor Quality (COPQ)		x	1	
Exhibit 34-3 Actual field analysis and Impact on Env & Safety		x	1	
Total			11	197

Chapter 35. Improvement & Continual Improvement

Exhibit No/Description	Type		Editable pages	Running Total
	I	T		
Exhibit 35-1 Continual Improvement Reporting		x	1	
Exhibit 35-2 Continual Improvement Procedure		x	1	
Exhibit 35-3 Error-Proofing Management		x	1	
Total			3	200

The Author

Jack started working after his GCE A-Level (Issued by Cambridge University, UK) in 1973, which gives him 47 years of working experience as of this year. He picked up his education again some 20 years later for an executive MBA, followed by a PhD in Management.

He first job was with a large food plant in Kuala Lumpur as an admin officer, and stayed on the job for some 3 years. His next job was with Nalco Chemical Inc, a US company dealing with water treatment and environmental care. The job was to provide technical support to various industries, on water and waste systems. To equip for the job, Jack had been trained locally and abroad, on lab work, related application equipment, water and waste treatment technologies, as well as the various types of industries and their water and waste processes. He stayed for 13 years with the last appointment as a District Manager responsible for a few countries. He had later joined a similar company as a partner, and its general manager, for another 12 years, before the company was sold.

Being restless man, instead of going into retirement, he went to work as a QA Manager for a SME on metal stamping, and tooling fabrication for 3 years. With some 27 years of technical background and management experience, he ventured into ISO consulting. Business was good, but the job was getting strenuous after some 10 years, with age catching up. He felt he needed another change in order to continue working. Jack had decided to transition to ISO auditing where he already had a good foundation. He subsequently attended the third-party auditor courses and had passed the necessary exams, to get started.

Today, Jack is a full-time, third-party auditor, mainly for IATF16949 (since 2012), and occasionally on ISO9001. ISO14001, ISO45001, and ISO22000. Since 2 years ago, ISO/TS22163:2017 Railway QMS, was added to his audit scope. Besides his home country, he audits extensively throughout Asia, including the middle east.

Before calling it a day, Jack wishes to pen down the knowledge and skill he has learned, to share with whoever wishes to know the subjects.

Jack Chiew MBA, PhD
Kuala Lumpur, Malaysia
May 2020