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 <<