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?

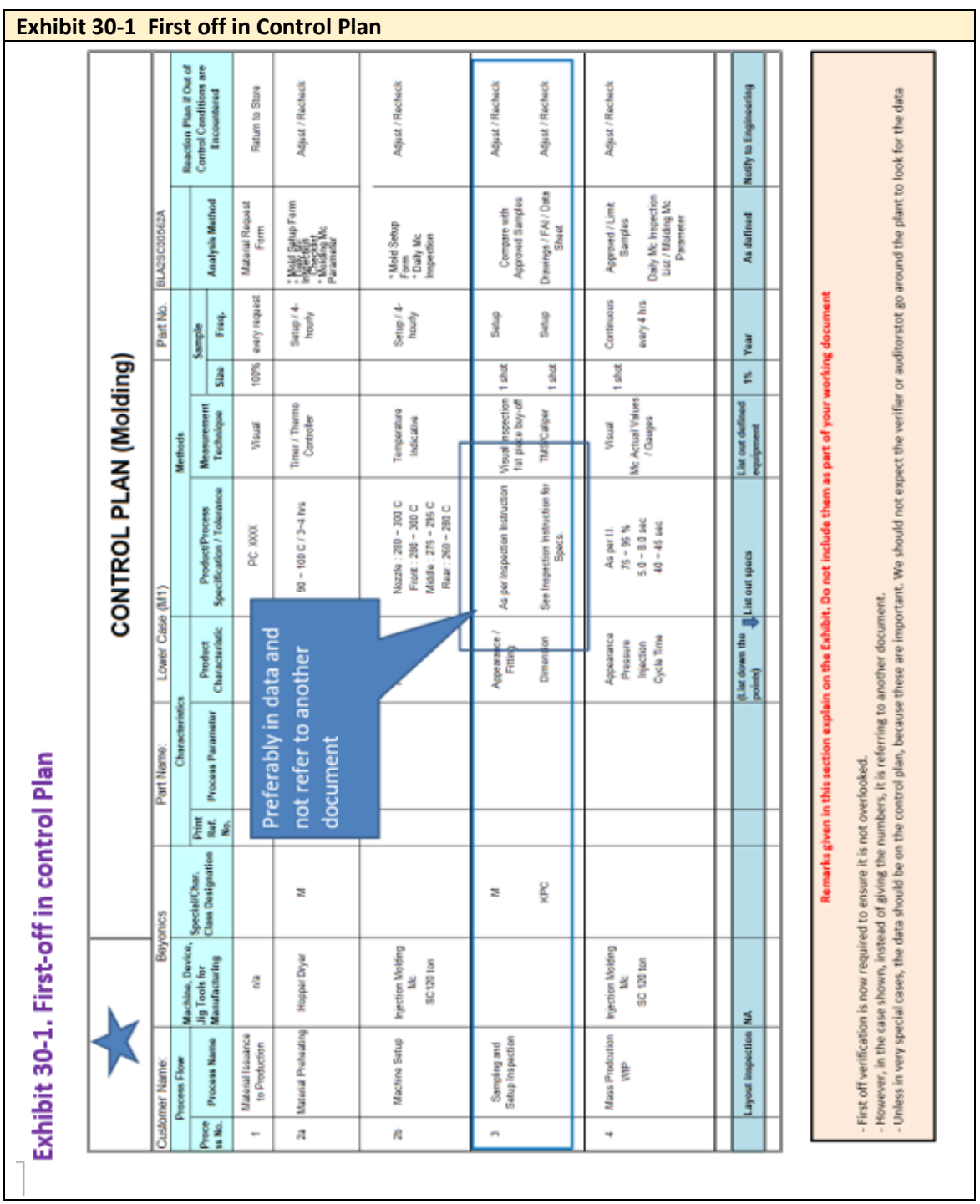
A supplier has many customers with different requirements and specs. The criteria listed on the COC may be a generic set, and not suitable for you. You should use your own defined list of specs.

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



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