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:	Customer:
Blow Moulding Machine LX180	VFM Motors

Commitment with customer	Internal efficiency target:	Study Period
Customer: 1600 pc per day (2 shifts)	120 pc per hour (rate 135 pc/hour)	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 <<