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.

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
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.

7) Exhibits

There is no Exhibit for this Chapter

>> End of Chapter 25 <<