Quality Partner Newsletter

September 2017

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Welcome to the ninth edition of the Quality Partner newsletter.

The newsletter is designed to keep you up to date with developments in Quality Management Systems.

This issue focuses on:

- IATF transition audits Top ten issues
- Video series on the IATF transition and the automotive core tools
- Team Leader training

If you have any questions for future editions please feel free to mail to

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IATF 16949 transition

Only 1 year to go for over 69,000 ISO/TS16949 certified organizations to transition to ISO9001: 2015 and IATF 16949: 2016.

At the end of July less than one thousand companies have had their transition audit, ensuring a busy year for the qualified IATF 16949 auditors!

Analysis shows the top ten issues being found in transition audits are:

- 8.5.1.5 Total productive maintenance
- 6.1.2.3 Contingency plans
- 7.5.1.1. Control plan
- 8.3.5.2 Manufacturing process design output
- 8.5.1 Control of production and service provision
- 8.5.1.3 Verification of job set up
- 8.5.1.4 Control of reworked product
- 9.1.1.1 Monitoring and measuring of manufacturing processes
- 9.3.2.1 Management review inputs – supplemental
- 8.4.2.4 Supplier monitoring

This issue of the newsletter looks at these requirements and suggests ways of making system improvements to prevent nonconformities in any transition audit

Top 10 issues being found on IATF 16949 transition audits

8.5.1.5 Total Productive Maintenance

I think most readers will not be surprised to see TPM in the top 10.

Whereas many companies have a “paperwork” maintenance system, observation on the shop floor often shows equipment not maintained in optimum condition.

Although the clause heading is “Total Productive Maintenance”, the requirement does not fully match the Japan Institute of Plant Maintenance (JIPM) definition (JIPM are the founders of TPM).

A true Total Productive Maintenance system (TPM) means:

Total: Involvement of all employees

Productive: Emphasis on effective and efficient utilisation of all the resources

Maintenance: Keeping man-machine-material system in optimal condition

In many companies the mentality is:

The operator operates the machine, when a problem happens with the machine call maintenance!

The fundamental principle of TPM is to move towards a system when the operators take more ownership regarding the condition of the machines they operate.

However by just developing checklists and asking the operators to do cleaning and inspection on the machine is doomed to failure. I have seen in several companies, when visiting on a Monday, the checklist already being filled out until Friday!

To succeed you need to get the engagement of operators, by educating them on why it is important to check machine condition and perform simple maintenance tasks, and getting their ideas on the development of any associated check sheets.

We also need to understand why IATF have put more importance on the requirements for TPM. Data shows that many delivery shortages/line stops in the vehicle manufactures are due to key equipment breakdown.

The first thing an organization needs to do is review the current status of the maintenance process by reviewing and analysing data. Whilst IATF 16949 mandates maintenance objectives, it leaves it to the organizations to establish what the measures are, giving examples of OEE, MTBF, MTTR and other preventive maintenance compliance measures.

If OEE is used, the availability part of the calculation gives the best indication of the effectiveness of the maintenance process.

From analysing this data, it gives the opportunity to focus the activities to improve the maintenance process and target breakdown reduction programmes on specific machines.

Then we need to question why machines breakdown. This could be due to one or more of the following:

- Inherent design weakness in the machine design: This information needs to be fed back to the people responsible for process design to address (8.3.3.2)
- Inadequate skills (either for operators or maintenance personnel). This information needs to be fed back to the process owner for people development and ensuring competencies (7.2)
- Operating instructions not followed (for machine or process). This information needs to be fed back to production management (7.2 and 7.3.2)
- Basic condition neglected and machine deterioration: For this it is recommended that an area is selected a pilot area to deploy TPM, then get a team of production operators and maintenance together to plan improvements. This may include a deep clean of the machine, tagging of the issues found, and development of a tentative cleaning and inspection checklist to keep the machine in optimum condition. (10.3.1)

Actions then need to be planned to address the issues identified by taking systemic corrective actions to reduce equipment breakdown.

Top management then need to review the maintenance objectives as part of management review (9.3.2.1 g)), and provide support and resources to ensure objectives are met.

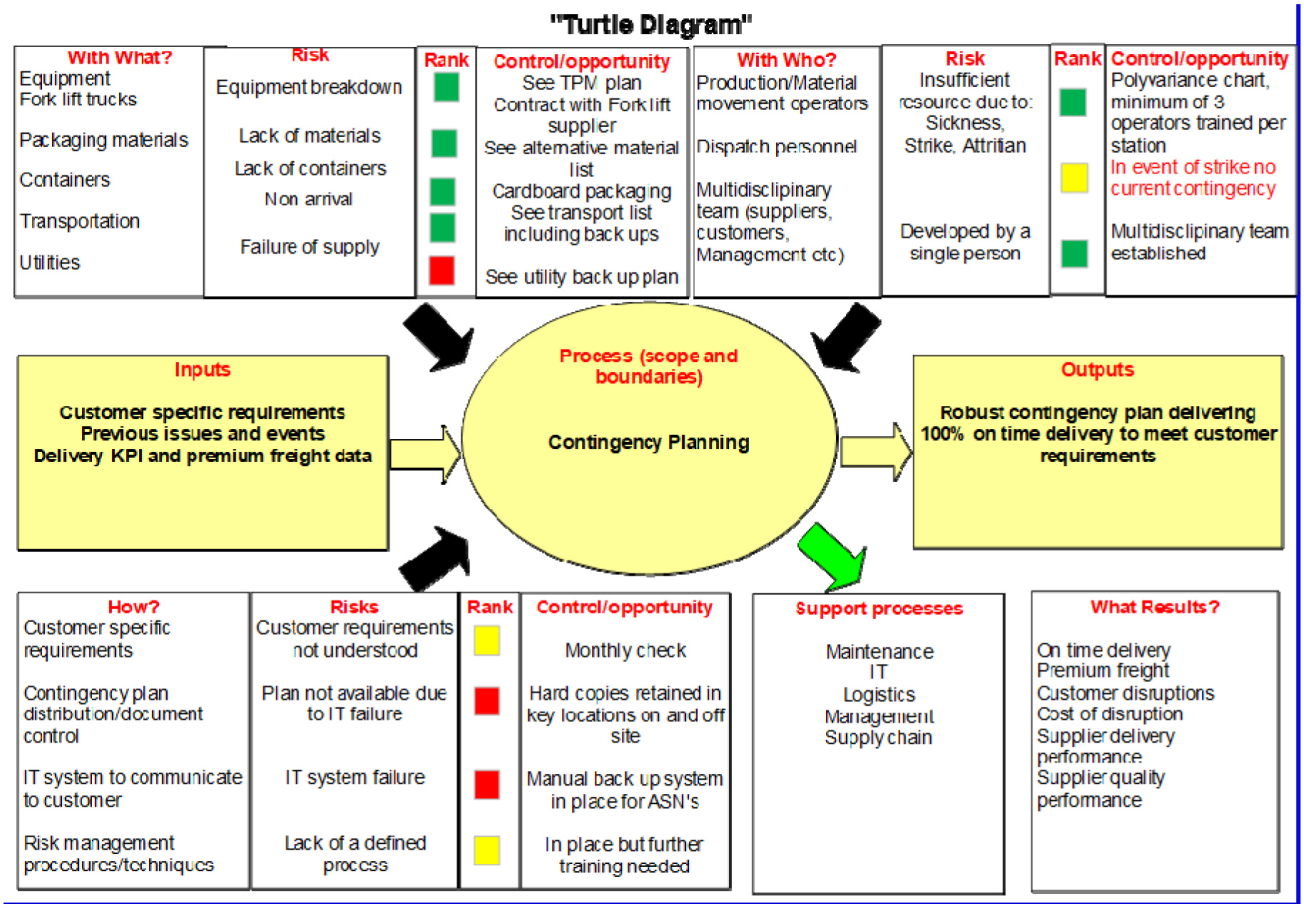
Finally I believe internal audit has a big role to plan to ensure that improvements are sustained. Too many internal audits are done by auditors sitting in the office reviewing documentation. When auditing maintenance, after reviewing the performance objectives and actual performance, auditors should select a sample of machines, focusing on those giving poor performance, and then go to the shop floor with representatives from production and maintenance to review machine condition, compliance with any machine checklists and competence of the relevant personnel to perform their assigned tasks.

Audit trails can then be followed to verify the spare part management for the machines concerned, the contingency planning, and how planned maintenance activities are factored into the production planning process (see 8.5.1.7).

To support organizations with understanding the principles of TPM, and how they link to the requirements of IATF 16949, Quality Partner has developed a one day training course that can be delivered onsite. The course covers the theories of TPM, but also includes many practical exercises and case studies. For more information on the course contact Paul Hardiman at paul.hardiman@qualitypartner.co.uk

6.1.2.3 Contingency plans

In a previous edition of a Quality Partner newsletter (all previous copies can be downloaded free of charge from www.qualitypartner.co.uk) we reviewed the concept of risk based thinking, a key concept in both ISO9001: 2015 and IATF 16949: 2016.



An example of a risk based turtle diagram of a contingency planning process is shown above. While contingency planning has been a requirement of ISO/TS16949 since 1999, IATF have taken this opportunity to significantly strengthen the requirement to ensure organizations develop robust contingency plans to ensure no production disruptions or line stops at customer plants.

The IATF 16949 requirement (6.1.2.3 Contingency plans) include:

6.1.2.3 Contingency plans

The organization shall:

a) *identify and evaluate internal and external risks to all manufacturing processes and infrastructure equipment essential to maintain production output and to ensure that customer requirements are met;* The key word here is risk. The requirement does not only cover manufacturing equipment, but also

infrastructure equipment necessary to ensure production output can be met. This could include compressors, air conditioning units, etc.

b) *define contingency plans according to risk and impact to the customer;*

The main focus of a contingency plan is to ensure customer requirements can be met, so when developing the contingency plans the main focus is on the risks that could affect this. To help ensure robust contingency plans, an input should be lessons learnt from any historic situations that caused a customer disruption, or shortfall in delivery performance.

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; labour shortages; or infrastructure disruptions;*

The key change here is “in the event of any of the following….” (Whereas in ISO/TS16949 they were only examples). Obviously the type and extent of the contingency will depend on the geographic location of an organization (e.g. Earthquake prone area) and other historic information.

d) *include, as a supplement to the contingency plans, a notification process to the customer and other interested parties for the extent and duration of any situation impacting customer operations;*

This requirement links to 5.3.1 Organization roles, responsibilities and authorities. The responsibilities to communicate any issue to the customer that may cause production interruption needs to be clearly defined and records of communication maintained.

e) periodically test the contingency plans for effectiveness (e.g., simulations, as appropriate);

This is a new requirement in the context of a Quality Management System (Emergency preparedness has always been a requirement of ISO14001). Obviously there are practical limitations in this, but things like fire evacuation, testing back up/response in the event of IT failure etc. can be tested.

f) *conduct contingency plan reviews (at a minimum annually) using a multidisciplinary team including top management, and update as required;*

Again this is a new requirement, to get management involved in the regular contingency planning reviews and ensure that the plan remains up to date in the event of changes.

g) *document the contingency plans and retain documented information describing any revision(s), including the person(s) who authorized the change(s).*

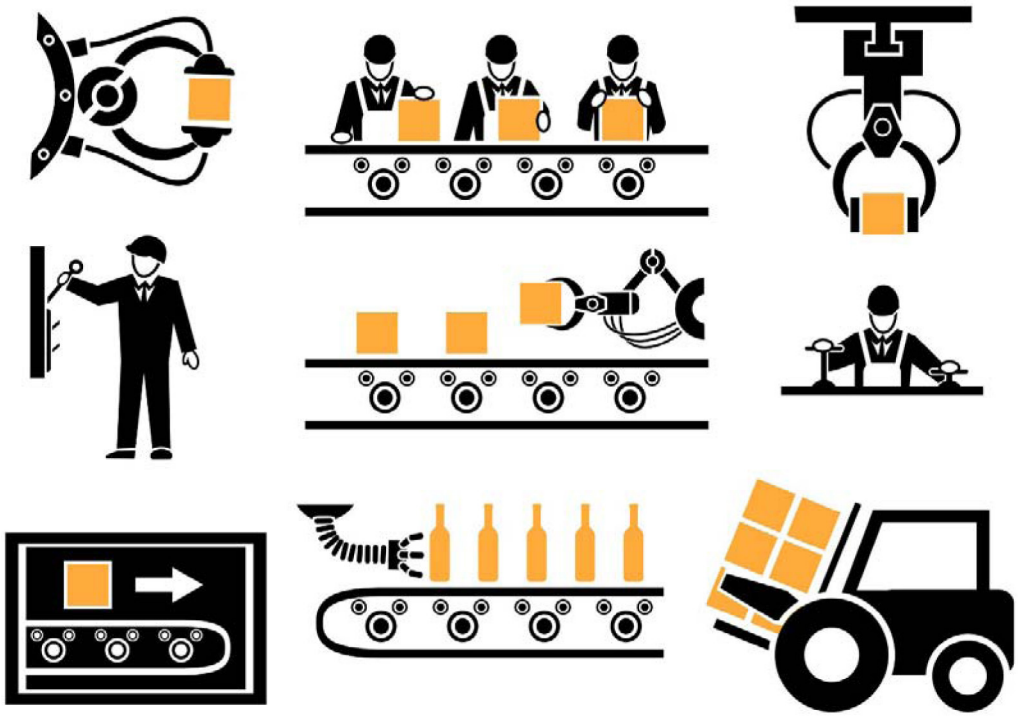
Like any QMS document the contingency plan should be included in the document control system, including controlled distribution, and contain evidence of the approval from the person (s) management have defined as responsible for the update. The accessibility of the plan needs to be ensured in the event of system downtime, fire etc.

The contingency plans shall include provisions to validate that the manufactured product continues to meet customer specifications after the re-start of production following an emergency in which production was stopped and if the regular shutdown processes were not followed.

This links to the requirement 8.5.1.4 *Verification after shutdown* that requires *“The organization shall define and implement the necessary actions to ensure product compliance with requirements after a planned or unplanned production shutdown period.”*

The organization needs to demonstrate how the restart of production is managed and how revalidation of the product and or process is performed.

In conclusion, it does not matter what the document is called (could be disaster recovery plan, business continuity plan etc.), the key thing is to develop and manage plans to ensure the customer requirements can be met. Ultimately this should help an organization move towards achieving 100% on time delivery.



8.3.5.2 Manufacturing process design output

Whereas organizations can exclude product design, where they do not have product design responsibility, no IATF organization can exclude process design.

Using project management or APQP an organization has to design/modify manufacturing processes to ensure customer requirements can be met.

There are a few subtle changes in this requirement compared with ISO/TS16949, namely:

c) *Identification of process input variables that impact characteristics;*

As part of PFMEA consideration needs to be considered on what changes in input requirements could affect product or process characteristics and then implement the necessary controls in the control plan to minimize the risk. A characteristic matrix can also be used (see APQP manual).

However, when developing the PFMEA, an assumption is made that incoming goods will be conforming to requirements. Therefore, under supplier management, the organization should decide the necessary supplier/incoming controls needed to assure product conformity (see *IATF 16949: 2016 7.4 8.4 Control of externally provided processes, products and services and 8.6.4 Verification and acceptance of conformity of externally provided products and services*)

f) *Capacity analysis;*

In ISO/TS16949: 2009 there was no specific references to capacity, only production planning. In IATF 16949 several references are made to capacity (5.3.1, 7.1.3.1, 8.2.3.1.3, 8.5.1.7). In this requirement the organization has to ensure that capacity of any new machines/equipment has been factored into the capacity planning model, and that the projected volumes for the new product are also inputted.

h) *Maintenance plans and instructions;*

Above we spoke about the enhanced requirements for TPM. This requirement focused on how any new equipment/tooling/infrastructure are incorporated into the maintenance plans, and any necessary work instructions (which could include equipment manuals) are provided to maintenance at the handover of the new product/process to production.

8.5.1 Control of production and service provision

One of my fears with the issue of IATF 16949: 2016 was that auditors would not also verify compliance with ISO9001: 2015, focusing only on the additional IATF requirements. This requirement being in the top 10 has proved me wrong!

This is the general ISO9001: 2015 requirement for management of production activities, including having the correct monitoring and measuring equipment, physical work environment, competent persons and validation activities to ensure product requirements can be met. It also includes an interesting requirement “g) The implementation of actions to prevent human error”.

In an IATF I6949 organization, this should be addressed by effective use of DFMEA and PFMEA, to identify opportunities for error proofing to reduce the risk of human error (however how many times do you see “human error” included a root cause in 8D reports!).

8.5.1.3 Verification of job set up

This requirement is not new, but maybe, when read in conjunction with 8.5.1.4 Verification after shutdown, I can see why this requirement is in the top 10. The requirements now makes it clear that the organization has to ensure that verification is completed after any planned or unplanned shutdown, or after any changes that have occurred in the process that could affect product quality. This could include starting up on a Monday after a scheduled weekend break, start up after a 30 minutes breakdown, or after any utility interruption.

Although first off/last off can be used, this is not mandated (as “where appropriate), other validation methods can be used.

8.7.1.4 Control of reworked product
When IATF 16949 was issued I predicted this requirement would cause some organizations issues. In summary this requirement focuses on:

- Undertaking a risk analysis before the decision to rework is made
- The need for a documented process to control rework
- The need for rework instructions including any traceability requirements
- The need to retain documented information related to the rework undertaken

Regarding risk analysis, an organization can consider this in 2 ways. One way is to consider the possible need for rework in the new product introduction process, considering the risks in the PFMEA and the associated controls in the control plan. The other way, where the need for rework was not identified in the new product introduction, the organization would need to implement a process of review the risks in undertaking the rework before rework commences. In this case it does not necessarily need to be PFMEA, other risk analysis techniques could be used. Consideration has to be given on whether the customer needs to be informed of rework prior to commencing, consulting the relevant customer specific requirements.

The key difference between this requirement and 8.7.1.5 Control of repaired product is that for rework the product has to be returned to the original specification by the rework operation, whereas repair does not necessarily return the product back to the original specification, but to an agreed specification with the customer (maybe concession).

9.1.1.1 Monitoring and measuring of manufacturing processes

Again this is not a new requirement, but with certification body auditors being instructed to spend 1/3 of audit time on the shop floor auditing the manufacturing process, including use of the PFMEA and control plan, the likelihood is more nonconformities will be found against this requirement.

The first thing to consider is process capability. Process capability has to be verified for any new manufacturing processes.

Next is monitoring existing process to ensure capability levels are maintained in accordance with customer part approval requirements. The capability index (Ppk, Cpk etc.) and acceptance value will depend on customer specific requirements.

To achieve this, the organization needs to ensure the control plan is effectively implemented, including adherence to the specified measurement techniques etc. This should be audited for effectiveness as part of manufacturing process internal audits.

Finally the requirement specifies the actions to be taken where a process is found not to be statistically capable or unstable. The norm would be 100% inspection as short term containment, with a documented action plan to ensure the process becomes stable/capable.

I believe the key preventive action an organization can take to prevent nonconformities against this requirement is to promote internal awareness of the need to comply with the control plan, ensuring that the relevant personnel have awareness of the appropriate statistical tools, and then a robust internal audit system developed to verify control plan implementation.

9.3.2.1 Management review inputs –supplemental

IATF have added requirements that have to be covered in the Management review process (management review does not have to be one single meeting, but the input requirements can be covered during a series of meetings.)

These include:

a) *cost of poor quality (cost of internal and external nonconformance);*

Although this was a requirement in ISO/TS16949: 2009, the need to include internal and external non-conformance costs is now included.

e) *assessments of manufacturing feasibility made for changes to existing operations and for new facilities or new product (see Section 7.1.3.1);*

This is a more difficult requirement to understand. However I think the intent of the requirement is, before any significant change is made to the layout of an organizations facility, or taking on new business, Top Management are involved in the decision making process, to verify changes are in line with the strategic direction, and that any changes will not impact on the ability to meet customer requirements.

g) *review of performance against maintenance objectives;*

This requirement matches the strengthened requirement for TPM reviewed above, and requires Top Management to review performance against the maintenance objectives.

h) *warranty performance (where applicable);*

This requirement would only be applicable for organizations who have warranty agreements with their customers, and links to the new requirement 10.2.5 Warranty management systems.

j) *identification of potential field failures identified through risk analysis (such as FMEA);*

Although this was a requirement in ISO/TS16949: 2009, it was coupled with the requirement for analysis of actual field failures. Many organizations management reviews focused on the actual rather than potential, hence the IATF decision to split the requirement.

Whilst the requirement does not ask Top Management to do a detailed review of FMEA's, one way of addressing the requirement is for the relevant process owners to provide management a summary from the FMEA process, for example high severity, severity x occurrence, or high RPN's. This can help management to demonstrate they understand the biggest potential failures, and provide the resources to take proactive actions to reduce risk.

8.4.2.4 Supplier monitoring

Again this is not a new requirement, but contains some amended requirements.

The scope now covers "externally provided products, processes, and services to internal and external customer requirements." (To align with the ISO9001: 2015 requirement 8.4)

As well as monitoring suppliers of production materials, this now includes process suppliers (For example where an organization outsources plating, heat treatment etc.) and service suppliers that can directly impact meeting customer or internal QMS requirements. (For example suppliers providing a sorting service, calibration service, maintenance service etc.)

This does not necessarily mean a complex vendor rating system for all suppliers, but a system to ensure structured feedback from the user of the service as to whether their needs have been met. A summary of external provider performance needs to be an input into management review.

Where data is provided by the customer, the requirements below also apply:

e) special status customer notifications related to quality or delivery issues;

f) dealer returns, warranty, field actions, and recalls.

This means in the supplier monitoring system, when a supplier is responsible for the organization being placed on a special status or causes dealer returns, warranty issues, or other field actions/recalls, this is included in the relevant supplier performance rating.

Quality Partner Video series on the transition to IATF 16949

There is still time to use the comprehensive series of short videos to help your organization through the transition process. Full details, including a free sample video can be found at: http://qualitypartner.co.uk/iatf16949/

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To help raise awareness of the automotive core tools within an organization, Quality Partner has produced a series of 11 short videos covering APQP, FMEA, MSA, SPC, Control plan and PPAP.

This are a cost effective way of educating operators, engineers, technicians and internal auditors in the tools.

Anybody purchasing access to the videos also has access to online examinations, and for those scoring more than 8 out of 10 in each exam an automatically generated certification is received, which can be used as evidence of understanding in any internal or external audit.

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