Quality Partner Newsletter

October 2018

Welcome to the thirteenth edition of the Quality Partner newsletter.

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

This issue focuses on:

- Employee awareness of Management Systems
- Developing an effective management review process
- Implementing Autonomous Maintenance (AM) to improve the maintenance process
- Questions and answers related to IATF 16949

If you have any questions or topics for future editions, please feel free to mail to: paul.hardiman@qualitypartner.co.uk

IATF Transition summary

The 14th September 2018 saw the end of the IATF transition process.

Data indicates that approximately 10% of the organizations that were certified to ISO/TS16949 did not make the transition deadline (around 6000 organizations.)

This was due to the transition audit not being completed by the deadline, or the organization decided to drop the certification.

My fear now is organizations who successfully transitioned keeping the focus to maintain certification!

Although ISO9001: 2015 clearly states that the quality management system should be integrated into the organization business processes, in reality many organizations achieved certification to IATF 16949 by the dedication and skills of an individual (s), with process owners sometimes not fully understanding their responsibilities to manage their process activities on a day to day basis.

There could be the tendency for organizations to “take their eye of the ball” and this could lead to serious issues on the next audit.

This issue focuses on some of the potential problem areas and offers clarification and advice. Any feedback is welcomed! Email me at paul.hardiman@qualitypartner.co.uk

For More Information Visit www.qualitypartner.co.uk

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Introduction to Management System standards and requirements

To be in business these days organizations need to comply with various management system standards including ISO9001 (Quality), ISO14001 (Environment) and ISO45001 (Occupational health and safety).

To implement and maintain systems to comply with these standards it is essential all employees in the organization understand the intent of the standards and how they relate to their day to day activities.

Often employees are given the quality policy, asked to read the quality manual and then given the instructions to perform their job, without getting an insight as to why compliance with management systems is important for the organization and its customers.

Paul Hardiman, Director Quality Partner, has produced a series of 6 training videos as outlined below, which can be used by individuals or organizations to promote awareness of the relevant standards.

Each video is approximately 10-15 minutes long and are presented in an easy to understand format. They can be used as part of an employee induction process, for existing employees or by internal auditors. The videos can be purchased as single user access, either purchasing individual videos at £8 per video or £40 for the full set.

For information on purchasing multiuser access please contact paul.hardiman@qualitypartner.co.uk

Introduction to ISO9001: 2015

This video training will give delegates an overview of the scope, structure, content of the quality management standard ISO9001: 2015 and how successful implementation and maintenance of systems is very dependent on employee understanding and involvement.

Introduction to the ISO9001: 2015 requirements

This video training is designed for delegates looking to gain an understanding of the structure, content and examples of application of the requirements of ISO9001: 2015 in a process-based management system.

Introduction to ISO14001: 2015

This video training will give delegates an overview of the scope, structure, content of the environmental management standard ISO14001: 2015 and how successful implementation and maintenance of systems is very dependent on employee understanding and involvement.

Introduction to the ISO14001: 2015 requirements

This video training is designed for delegates looking to gain an understanding of the structure, content and examples of application of the requirements of ISO14001: 2015 in a process-based management system.

Introduction to ISO45001: 2018

This video training will give delegates an overview of the scope, structure, content of the occupational health and safety management standard ISO45001: 2018 and how successful implementation and maintenance of systems is very dependent on employee understanding and involvement.

Introduction to the ISO45001: 2018 requirements

This video training is designed for delegates looking to gain an understanding of the structure, content and examples of application of the requirements of ISO45001: 2018 in a process-based management system. There is also a video series available related to understanding and auditing IATF 16949: 2016, full details can be found at: https://qualitypartner.co.uk/iatf16949/

In addition, as mentioned in previous newsletter Quality Partner has produced a video series of training and online exams related to the automotive core tools.

The set of 11 videos are suitable to upskill engineers, supervisors, operators and auditors in the effective application of the tools, in simple, easy to understand language. Full details can be found at: https://qualitypartner.co.uk/core-tools/

Developing an effective Management Review process

As you will be aware, the list of inputs into the management review process keeps getting longer!
If we add together the input requirements in ISO9001: 2015 and IATF 16949: 2016 there are around 25 items to review.

I have been to many companies who continue to try do one big annual management review, which can often take days to prepare for and days of Top Management time to complete the review!

Let's firstly look at ISO9001: 2015 requirement 5.1.1 Management commitment which states:

Top management shall demonstrate leadership and commitment with respect to the quality management system by:

c) ensuring the integration of the quality management system requirements into the organization's business processes;

I do not know of any business which operates by top management meeting annually to review performance, changes etc.

IATF requirement 9.3.1.1 Management review- Supplemental states:

"Management review shall be conducted at least annually. The frequency of management review(s) shall be increased based on risk to compliance with customer requirements resulting from internal or external changes impacting the quality management system and performance-related issues."

There is nothing in ISO9001: 2015 or IATF 16949: 2016 that states that Management review must be a single event/ meeting, or how it should be recorded.

If we look at management review as a process, what we are trying to achieve is a review that ensures the quality management system is effectively implemented and maintained, to satisfy the customer requirements, the organization objectives and the IATF goal of:

- Continual improvement
- Defect prevention
- Reduction of variation and waste in the supply chain

I recommend, if you do not already do so, that you firstly look at the various management meetings that take place that include at least one member of the senior management team. Look at the purpose/ objective of each meeting, who attends, the frequency of the meeting, what is reviewed and how any output actions are recorded.

An extract of this type of review is shown below as an **example**:

Meeting	Attendees (owner in **Bold**)	Agenda Items	Output
Strategic planning and performance review Monthly	All management team **Managing Director**	Development and maintenance of business plan Review performance against objectives Audit results	Business plan Minutes with action plans to achieve objectives Updated audit programme
Sales review Weekly	**Sales Director** and Team	Sales performance Potential new customers including CSR	Sales action plans Feasibility review summary
Customer performance review Monthly	Managing Director, **Sales Director**, Quality Director, Logistics Director, customer representatives	Review customer scorecards, complaints, field failures and warranty performance	Actions to address any shortfall in performance
Engineering review Monthly	**Engineering Director**, Quality Director, Project teams	Review new project status	Actions to address and project slippages/ issues
Logistics review Weekly	**Logistics Director**, Warehouse Manager, Production Planner, Quality Director	Review supplier performance and issues Review production plan, material requirements and customer delivery performance	Action to address any supplier issues Supplier development plans Actions to address any customer delivery issues, including contingency plan update

Production review Weekly	**Production Director**, Maintenance Manager, Quality Director	Review production efficiency (OEE), maintenance performance, planned facility changes	Improvement plans, feasibility reviews for planned changes

The next task is to identify the links between the meetings and the input requirements in ISO9001: 2015 and IATF 16949: 2016, identify any gaps (things not covered in any of the regular meetings) and then address the gaps by adding to the agenda of the relevant meeting.

An overall review of the effectiveness of the quality management system may be combined with a review of the organization strategic direction (business plan) and setting the quality objectives for the next period. In most organizations this will be performed annually.

Process/meeting owners need to be aware of their responsibility to ensure meetings are recorded (the format/media for recording is the choice of the organization, could be electronic minutes, white boards etc.) and making sure the meetings happen at the required frequency (including a record of why certain meetings do not take place (e.g. Planned vacations etc.))

Taking this approach can result in saving wasted management time, and improve efficiency, while truly demonstrating the quality management system is integrated and reviewed within the normal business processes.

Implementing Autonomous Maintenance (AM) to improve the maintenance process

As mentioned in previous newsletters IATF 16949 requirement 8.5.1.5 Total Productive Maintenance has featured in the top 10 of major and minor nonconformities raised during transition audits to IATF 16949.

With businesses ever increasing focus on improving efficiency, improving profit and optimising non-productive employees, traditional maintenance structures are often being reviewed for opportunities to improve.

Often organizations are nervous on implementing a full TPM process based on the Japan Institute of Plant Maintenance (JIPM) eight pillar approach but want to do something.

One option an organization has is to utilize production operators to support the equipment inspection and maintenance activities. This is sometimes referred to as autonomous maintenance (AM).

One definition I have seen of AM is “A maintenance strategy wherein machine adjustments and minor maintenance is performed by operators who are deemed to have unique knowledge about the equipment.”

To implement AM effectively needs Top Management commitment, a structured plan and employee communication and involvement, otherwise it is doomed to failure.

An implementation plan may contain:

- An initial communication led by Top Management with employees from Maintenance and Production to outline ideas/proposals related to autonomous maintenance activities
- An initial plan to pilot AM in a defined area. The selection of this area is key to the success, typically this will be a small area of a few machines where maybe equipment reliability/performance has been an issue
- A training/awareness programme for those who will be involved in the pilot
- Initial cleaning and inspection activity of a machine/process by a cross functional group including Top Management, maintenance and production. The activity should identify and tag abnormalities found with the machine(s)
- Development of initial cleaning and inspection standards by the team to maintain machine/process condition
- Action plans to action the abnormalities found
- Review of progress and benefits achieved by top management
- Development of a roll out plan to other machines/process areas

It should be made clear in the beginning that this is not a process to cut the maintenance resource, but to give production operators more responsibility for maintaining their equipment in optimum condition.

If this is effective breakdowns should start to reduce, the process machine becomes more efficient and maintenance resource can be used on more proactive activities to improve efficiency (for example further deployment of predictive maintenance/machine improvements etc.)

Paul Hardiman is one of the few individuals outside Japan who has been formally trained in the JIPM approach to TPM. If you are considering trying to improve your maintenance processes and do not know how to start, there are options of short training courses, or an onsite review of current maintenance processes to develop practical implementation plans.

For more information contact Paul Hardiman at paul.hardiman@qualitypartner.co.uk

Questions & Answers

Question:
We have a customer who is asking us to repeat gauge R & R studies annually. I have reviewed IATF 16949, their customer specific requirements and the AIAG reference manual and can find no reference to this. To do this would take a significant amount of time and effort and we can see no real benefit in this. If this a requirement stated anywhere?

Quality Partner’s expert, Paul Hardiman

Answer:
This is a question I have been asked several times before and is another example of a customer trying to impose requirements that are not in IATF 16949 or their customer specific requirements.

To undertake a Gauge R & R study takes a significant amount of time and effort, in collecting the samples (which should represent the normal process variation), ensuring three of the normal users of the equipment are available to make measurements and having somebody to facilitate the study. Then there is time to take and record measurements, analyse results and implement any improvement actions.

In my view, Gauge R & R studies only need to be repeated when any changes in the measurement system are planned, for example:

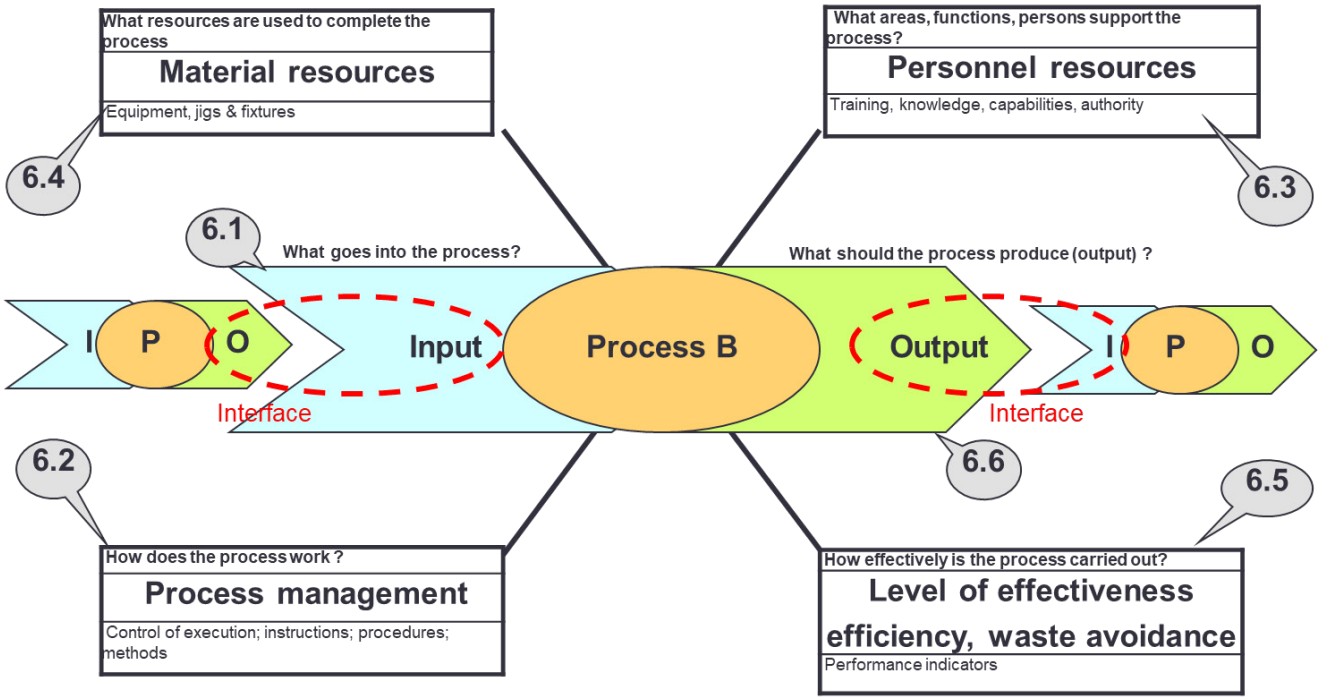
- Changes in the work environment (for examples moving the measurement process from a temperature-controlled environment)
- Changes in the skill level of employees making the measurement
- Changes in the tolerance of the part/material to be measured
- Changes in the method of measurement
- Changes in the measurement instrument (for example addition of a fixture)

Or where measurement issues have been found internally or at the customer (for example where the customer has returned product for dimensional errors)

Question:
I want to improve manufacturing process audits within our organization. Although we have no customer specific requirements, I want to use VDA 6.3 Process audit as the basis for doing audits. Could we use the VDA 6.3 audits to meet the IATF 16949 requirement 9.2.2.3 Manufacturing process audit?

Answer
VDA 6.3 Process audit is recognised as a global best practice standard for undertaking effective process audits. The scope of VDA 6.3 covers the product realization process and is broken down in to sections P2 to P7, with section P6 being the questions related to production.

The P6 section is broken down into 6 sub-sections, structured around the six boxes in the turtle diagram as shown below:



With VDA 6.3 there are two options on how we can audit production:

The first option is to audit production as one process, starting from material receipt and following through to material dispatch to the customer.

The second option is to audit each manufacturing process step. This can be done in one big audit, or in a series of smaller audits.

Let's look at the requirement defined in IATF 16949 9.2.2.3, namely:

"The organization shall audit all manufacturing processes over each three-year calendar period to determine their effectiveness and efficiency using customer-specific required approaches for process audits. Where not defined by the customer, the organization shall determine the approach to be used.

Within each individual audit plan, each manufacturing process shall be audited on all shifts where it occurs, including the appropriate sampling of the shift handover.

The manufacturing process audit shall include an audit of the effective implementation of the process risk analysis (such as PFMEA), control plan, and associated documents."

To meet this requirement, it is recommended that option 2 above is adopted, with the audit programme covering all the manufacturing processes on all shifts over a three-year period.

Each VDA 6.3 audit must clearly show which shifts were included in the audit (for example if the shift pattern is 6.00am-2.00pm and 2.00pm-10.00pm, the audit could be undertaken from 12.00pm to 4.00pm, sampling the shift changeover)

The audit report should include the objective evidence collected and any nonconformities found.
As there are requirements in VDA 6.3 subsection 6.2 related to PFMEA and control plan compliance, and requirements in subsection 6.5 related to process effectiveness and efficiency, these audits will meet the intent of IATF 16949 9.2.2.3 Manufacturing process audit.

The advantage of using VDA 6.3 is that it will give a % compliance rating for each of the manufacturing processes, enabling benchmarking and sharing of best practices.

Also, many of the requirements in P6 go beyond that of IATF 16949 and can help to identify further opportunities for process improvement.

On final thing to consider. The auditors undertaking the VDA 6.3 audits need to be competent, considering the requirements in 7.2.3, namely:

"At a minimum manufacturing process auditors shall demonstrate technical understanding of the relevant manufacturing process(es) to be audited, including process risk analysis (such as PFMEA) and control plan."

If there are no customer specific requirements related to auditor qualification, there is no mandatory need for auditors to attend any VDA sanctioned training. If you require more information on VDA 6.3, or would like to discuss training options contact paul.hardiman@qualitypartner.co.uk

Question
I would like some clarification on the requirement 9.3.2.1 Management review inputs — supplemental e) assessments of manufacturing feasibility made for changes to existing operations and for new facilities or new product (see Section 7.1.3.1);

Why have IATF added this as a management review input?

Currently we manage these types of changes under our change management process.

Answer
Good question. I think it is because there have been several instances quoted by vehicle manufacturers where suppliers have made changes without top management involvement and it has major consequences on the organization ability to meet their customer requirements.

This requirement is putting the emphasis on top management being aware of planned changes, ensuring that an effective feasibility review has been undertaken, and the risks fully assessed before the planned change is made.

In many organizations a structured, documented feasibility review is only undertaken for customer led changes, not internal changes.

An example maybe where an organization is planning to make some layout changes, for example in the receiving or dispatch areas. Whereas the people close to the change may think the change would improve efficiency, the change may have knock on effect to other processes that may not have been considered. An effective feasibility review process, undertaken by a multidisciplinary team would ensure that all the risks are covered before any changes are made, and then the change is approved by top management before implementation.

A record of this review needs to be retained as part of the evidence of the management review process.

Question
Several requirements in IATF 16949 are not applicable to our current business activities. For example, we have no warranty agreements with any customers, no embedded software, and receive no customer supplied products. Can we write these requirements in our quality manual as permissible exclusions?

Answer
The short answer is no! The only permissible exclusion that can be written in the quality manual, or included in the IATF certificate, is product design, where an organization is not product design responsible.

For requirements that are not applicable to an organizations current scope of activities, the organization can identify these exclusions in a matrix showing the link between the organization processes and the ISO9001: 2015/IATF 16949: 2016 requirements. An extract of such a matrix is shown below:

Process	9.2.2.4 Product audit	9.3.1 Management review general	9.3.1.1 Management review -supplemental	9.3.2 Management review inputs	9.3.2.1 Management review inputs-Supplemental	9.3.3 Management review outputs	9.3.3.1 Management review outputs-Supplemental	10.1 Improvement general	10.2 Nonconformity and corrective action	10.2.3 Problem solving	10.2.4 Error proofing	10.2.5 Warranty management systems	10.2.6 Customer complaints and field failure test analysis	10.3 Continual improvement	10.3.1 Continual improvement-Supplemental
Laboratory															
Not Applicable Requirements												x			

When any changes occur (for example if a new customer has warranty requirements), the matrix can be reviewed and updated, and any relevant changes made to the quality management system.

Question
We currently have a warranty agreement with one of our customers. We are finding the customer is sending back product that is out of its warranty period. Are we required by IATF 16949 to analyse these returns?

Answer
If the product is outside its warranty period there is no mandatory need to analyse these products.

However, you should communicate with your customer to inform them of the returns that are outside the warranty agreement.

Also, there could be benefit in analysing the returns to learn more about the product failures and use this as input to improve the design and/or the manufacturing process.

Question:
We manufacture a range of components for automotive customers. To complement this range and meet customer requirements, we source some components from our sister company, which we receive, stock and supply to the customer without doing any product checks or validation. Our sister company is also IATF 16949 certified and the products are included within their scope. How do we manage this within the scope of our IATF 16949 certification?

Answer:
In the initial issue of IATF 16949 this was not considered. However, a sanctioned interpretation gave some clarification:

SI 7. Where characteristics or components “pass through” the organization’s quality management system without validation or controls, the organization shall ensure that the appropriate controls are in place at the point of manufacture.

So, in this case, you would be responsible for understanding the customer requirements (e.g. shipment schedules etc.), procuring the parts from your sister company, doing receiving verification when the parts are received at your site, storing to ensure preservation, identification and traceability, and then shipping to the customer.

You would also need to treat your sister company as a supplier, monitor their performance and act when performance targets are not met (e.g. Customer complaints, returns etc.).

This process could be audited as part of you IATF 16949 external audits and would need to be covered in your internal audit process.