Quality Partner Newsletter

April 2018

Welcome to the eleventh 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:

- The new version of ISO31000 “Risk Management”
- Questions and answers related to IATF 16949
- Update on the AIAG/VDA FMEA reference manual

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

IATF 16949 transition

According to IATF data, at the 1st February 2018 38% of the 68395 ISO/TS16949: 2009 certified companies had completed their transition audit and 17% had been certified to IATF 16949: 2016.

So still a long way to go, as the remaining organizations have to make the transition by the 14th September 2018.

As mentioned in previous newsletters, I produced a series of 11 short (15 minute) videos that focused on the changes in IATF16949 by process. With the completion of the transition period later this year, I offer newsletter readers the final chance to purchase access to the full set of the videos at the discounted price of £25, more that 90% discount on the full cost.

The videos are a great way to demonstrate you have made process owners aware of the changes, and an ongoing resource for training new employees.

If you are interested please contact paul.hardiman@qualitypartner.co.uk and I will send the discount code

AIAG/VDA FMEA reference manual

I have heard that the publication of the new FMEA reference manual had been delayed until at least the 3 quarter of 2018. Will keep you informed in future newsletters.

For More Information Visit www.qualitypartner.co.uk

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ISO 31000 Risk Management Guidelines

In February 2018 a revised edition of 1SO 31000 Risk Management Guidelines was issued.
Although compliance to this standard is not mandated by IATF, it provides some useful guidance in developing a structured approach to risk management.

Let's start with the definition of risk management:

"Coordinated activities to direct and control an organization with regard to risk."

At the beginning of the standard the importance of top management commitment is stressed and that management have to commit to a structured Plan, Do, Check and Act (PDCA) process to manage risk, including:

Integration: This section stresses the importance of integrating a risk management approach into the organization business processes, not as a stand-alone initiative.

Design: When designing a framework for management of risk this needs to be linked to the organization strategic direction and context. There is not an "off the shelf" solution that will suit all!

Articulating risk management commitment: Top Management should communication their commitment to risk management through a policy (could be integrated with the Quality Policy) and ensure the policy is communicated and understood throughout the organization.

Assigning organizational roles, authorities, responsibilities and accountabilities: Top Management should ensure that the authorities, responsibilities and accountabilities for managing risk and clearly assigned and communication. In the context of ISO9001 and IATF 16949, this should be linked to the owners of the QMS processes (IATF 16949: 2016, 5.1.1.3).

Allocating resources: As well as showing their commitment, Top Management need to allocate the appropriate resources to ensure the risk management process is implemented. From my experience this is an issue in many organizations in the automotive supply chain, especially in committing the resources for the effective implementation of FMEA!

Establishing communication and consultation: In implementing the risk management approach, there needs to be effective internal and external communication (customers, suppliers, regulatory bodies, insurers, etc.) and where relevant consultation, to ensure the risk management process meets the needs of all stakeholders.

Implementation: Once the process is designed and the resources are assigned and available, the next phase is the implementation, which could include developing timing plans and including key review milestones.

Evaluation: Once implementation has started Top Management then need to monitor the ongoing effectiveness of the risk management process though review (in ISO9001 and IATF 16949 integrated into the management review process).

Improvement: Based on the evaluation and the results, the risk management approach then needs to be continually improved and developed, in light of results, or internal or external changes in context.
Once the framework for a risk management approach has been developed, we now need to consider the detailed process to apply in practice.

In ISO 31000 this process is shown in the following diagram.

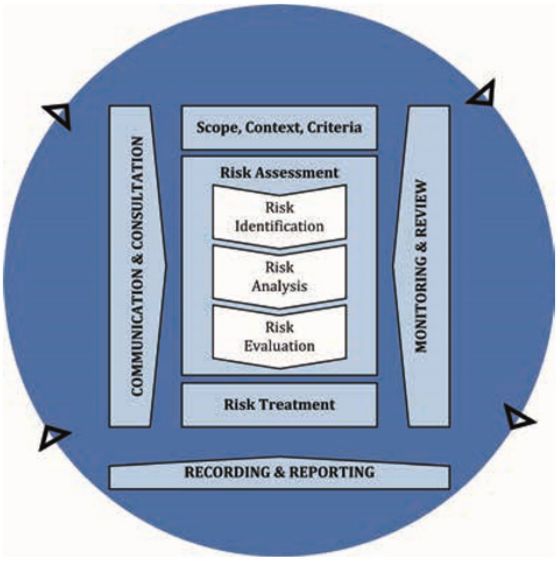


Figure 4 — Process

The core process activities include:

Scope, context and criteria: The organization should define the scope of its risk management activities. The risk management process may be applied at different levels (e.g. strategic, operational, programme, project and other activities).

When defining this, ISO31000 suggests consideration is given to:
- objectives and decisions that need to be made;
- outcomes expected from the steps to be taken in the process;
- time, location, specific inclusions and exclusions;
- appropriate risk assessment tools and techniques;
- resources required, responsibilities and records to be kept;
- relationships with other projects, processes and activities.

Risk assessment including risk identification, analysis and evaluation:

Risk identification: The purpose of risk identification is to find, recognize and describe risks that might help or prevent an organization achieving its objectives. The organization should identify risks, whether or not their sources are under its control.

Risk analysis: The purpose of risk analysis is to understand the nature of risk and its characteristics including, where appropriate, the level of risk. Risk analysis involves a detailed consideration of uncertainties, risk sources, consequences, likelihood, events, scenarios, controls and their effectiveness.

An event can have multiple causes and consequences, and can affect multiple objectives. Risk analysis can be undertaken with varying degrees of detail and complexity, depending on the purpose of the analysis, the availability and reliability.

The purpose of risk evaluation is to support decisions. Risk evaluation involves comparing the results of the risk analysis to determine what actions are required.

In conclusion ISO 31000 provides a useful guidance to organizations planning to implement or improve their risk management process.

Ask the expert

Quality Partner's expert, Paul Hardiman

The following are a series of great questions that have been posed to me related to requirements in IATF 16949. As well as sharing my responses in this newsletter, I also use them as inputs to IATF to generate new sanctioned interpretation and frequently asked questions. Feel free to send any other questions to me either via the LinkedIn IATF16949 group or to my mail at paul.hardiman@qualitypartner.co.uk

Question:
When planning manufacturing process audits, what do IATF mean by audit all "manufacturing process" on each shift over a three year cycle?

Answer:
A useful starting point is to review the manufacturing process flow diagrams.

The definition in IATF 16949 of manufacturing is:

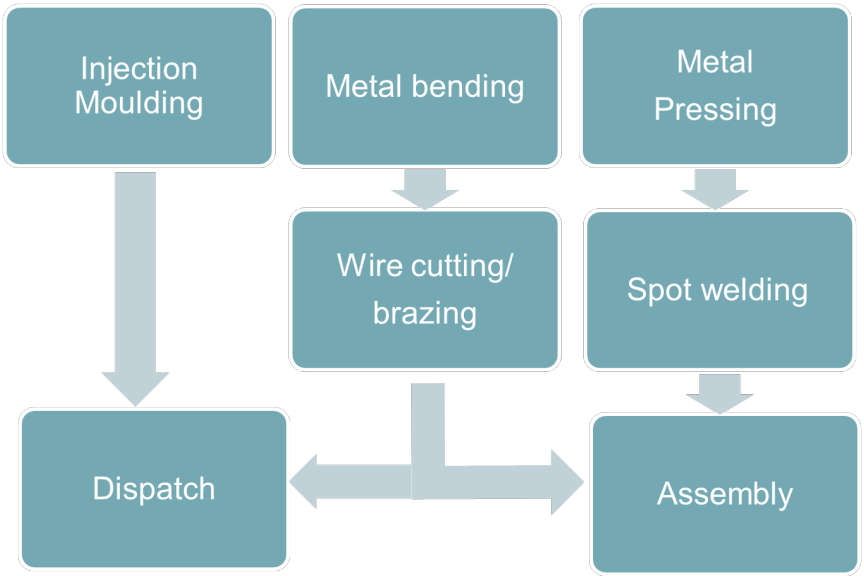
"process of making or fabricating

- production materials;
- production parts or service parts;
- assemblies; or
- heat treating, welding, painting, plating, or other finishing services"

If for example, in reviewing the different process flow charts for the range of products you manufacture, you conclude the manufacturing processes and shift patterns are:

- Injection molding (5 machines), 2 shifts, 06.00-14.00 and 14.00 - 22.00
- Metal pressing (4 presses) 2 shifts, 06.00-14.00 and 14.00 - 22.00
- Metal bending (2 machines) 1 shift 8.00 -17.00
- Spot welding (8 spot welding bays) 3 shifts, 06.00 -14.00,14.00- 22.00 and 22.00 - 06.00
- Wire cutting and brazing (2 machines) 2 shifts, 06.00 -14.00 and 14.00 - 22.00
- Assembly (8 cells) 1 shift 8.00 -17.00

An example process flow diagram is shown below:



Each of the manufacturing processes would have to be audited at minimum once in a three year calendar period However in considering the frequency two things have to be taken into account:

Customer specific requirements. Customers, as well as mandating the methodology to undertake manufacturing process audits (VDA6.3, Layered process audits etc.) they may also mandate the minimum frequency they are undertaken.

Internal and external performance, changes and risk: While in theory manufacturing processes can be audited only once in a three year calendar period, it is very unlikely this frequency could be justified, as manufacturing processes pose the greatest risk to the customer. Also, typically some manufacturing processes perform better than others, taking into account customer feedback, and internal performance (scrap, rework, OEE etc.).

Now let's consider how to plan. There is nothing in IATF 16949 to say that every machine has to be covered by the manufacturing audit process or indeed every customer cell/product. Again we can use performance data to identify any specific problem processes or machines.

In considering shifts, the audit program has to ensure that all shifts are covered over a three year cycle, including an appropriate sampling of shift changeover (notice the requirement states shifts (time periods) and not all crews (teams of people)).

So, for example in the manufacturing processes working two shifts (in the case above injection molding, metal pressing, wire cutting and brazing), the audit could be started at 12.00 and finish at 16.00, including sampling the changeover at 14.00. In this case we would need to make clear in the audit report the timing of the audit and include the details of the objective evidence obtained at the shift changeover.

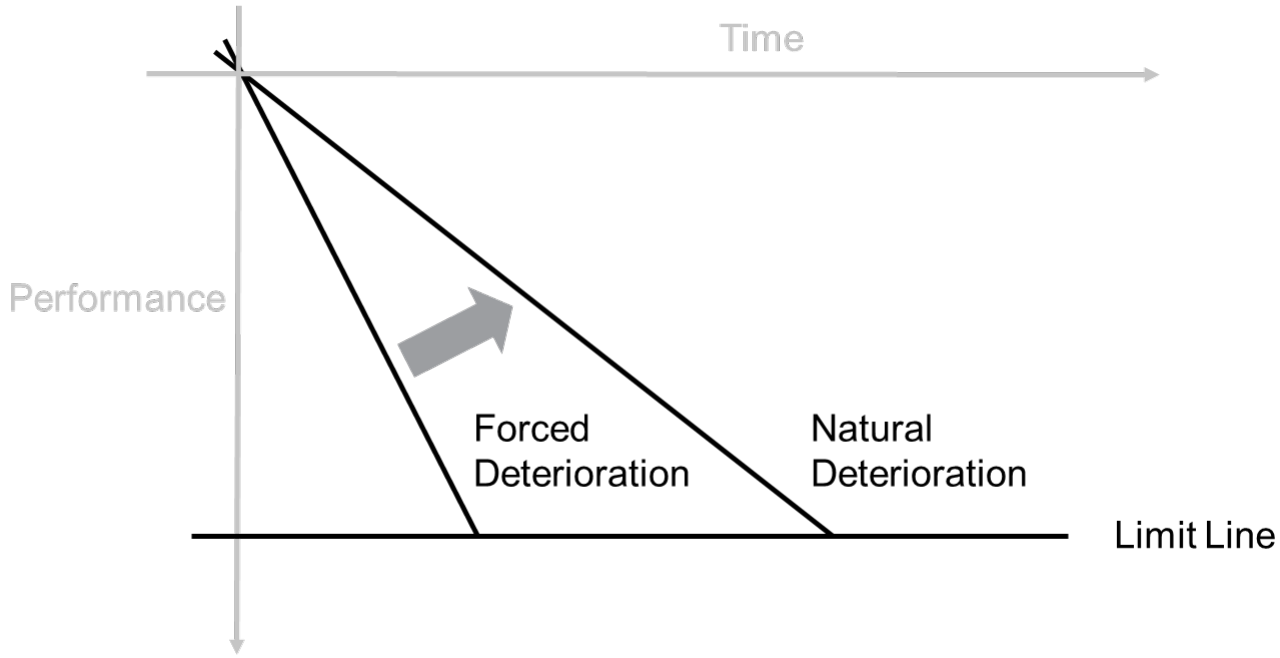
For spot welding, working three shifts, it would be impractical to try to cover all three shifts in one audit, the most logical way would be to breakdown in two audits, one say starting at 12.00 and finishing at 16.00 and another starting at 20.00 and finishing at 24.00.

The process explained above also applies to third party audits, where the IATF rules mandates that on initial, recertification and transition audits all manufacturing processes are audited on all shifts, with a minimum of 1/3 of the total audit time spent in manufacturing. In the surveillance audit cycle, all manufacturing processes again have to be covered on all shifts (not the word cycle rather than each audit however on each audit all shifts have to be covered (but not for each process)).

Question:
What do IATF mean by equipment overhaul and how do we apply this requirement?

Answer:
The IATF definition of periodic overhaul is:

"maintenance methodology to prevent a major unplanned breakdown where, based on fault or interruption history, a piece of equipment, or subsystem of the equipment, is proactively taken out of service and disassembled, repaired, parts replaced, reassembled, and then returned to service"



If we consider a new piece of equipment introduced into production. The equipment will have a theoretical design life and if we undertake effective planned maintenance activities the machine, although it may show signs of deterioration, will still perform effectively until the “limit line” is reached. (Point of anticipated failure or repeat breakdowns occur). If we do not maintain the machine effectively the machine will experience forced deterioration (as shown in the diagram above), and the failure will/could occur at an earlier point in time.

The principle of equipment overhaul is, based on the review of breakdown and interruptions, to take the equipment out of service before the limit line is reached, dissemble the machine, clean, replace parts where necessary and then rebuild. In other words a “big planned maintenance”.

This equipment overhaul has to be covered in the documented TPM system, which would at minimum cover the planning, undertaking the planned overhaul, provision of the spare parts, rebuild and then the verification when re-introduced into production.

If the equipment overhaul activity is outsourced, this still has to be managed in the maintenance system, including the selection and management of the contractors.

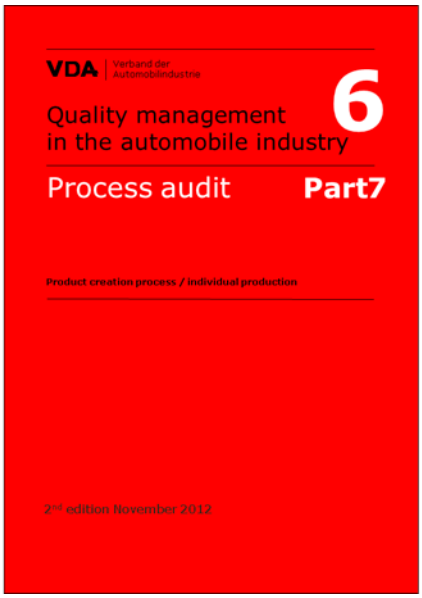
Question:
Do we have to have a separate KPI for every process in our quality management system, including where IATF 16949 has a requirement for a documented process?

Answer:
At minimum you have to measure the effectiveness and efficiency of all of your high level quality management system processes, not for every sub-process or where there is a documented process/ procedure.

So for example, an organization may have a high level process called procurement and supplier management, and for this they would need to define measures of process effectiveness and efficiency (e.g. KPI’s) but not specific measures for every sub-process activity/process (for example supplier selection, second party audit, supplier development etc.). If any of the sub-processes were not performing well, this would show in the higher level indicator, and then action would need to be taken to analyse and improve.

Question:
We are planning to undertake a second party audit at a number of our tooling suppliers. They are already ISO9001: 2015 certified but have been giving us a number of problems. We feel doing the audit against the requirements of IATF 16949 is not suitable as they are a non-production supplier. Is there any best practice reference standard we can use to undertake the audit?

Answer:
You are right, while you could use some of the relevant requirements of IATF 16949 in the scope of an audit of a tooling supplier, as you say IATF 16949 is more written for direct material suppliers.
There is a VDA publication, VDA6.7 that has been specifically developed for a process audit of a production equipment supplier.



VDA 6.7 requirements are broken down into the following sections:

1. Project Management
   The scope of this section covers from initial enquiry, receipt of contract, through to final acceptance by the customer
2. Product development
   This section covers both design of new or modified product.
3. Sourcing
   This section covers the sourcing and receipt/storage of products, materials and services
4. Production, including process preparations and manufacturing
   This section covers what VDA call “process preparations” (what IATF call process design, for example how a tool will be manufactured) and the manufacturing of the relevant product (e.g. a tool)
5. Processes after shipment including work site and service
   This section covers shipping and any services provided by a supplier to an organization (for example commissioning, installation etc.) and provision of ongoing support to customers.

Each section has a defined set of requirements to be evaluated and scored. The scoring criteria is similar to VDA 6.3 process audit, namely:

Points	Evaluation of achievement of individual requirements
10	Requirements achieved in full: No risks
8	Requirements generally achieved*
6	Requirements partially achieved and/or no special risks
4	Requirements inadequately achieved and/or significant risks
0	Requirements not achieved

* The term generally indicates more than ¾ of all stipulations are shown to be effectively implemented and, at most, a slight risk exists

At the end of the audit, the classification of the supplier is calculated by as on the degree of compliance in the overall score from the audit.

Classification	Overall level of achievement	Description of the classification
A	≥ 90%	Quality Capable
B	80- 89%	Conditionally quality capable
C	< 80%	Not quality capable

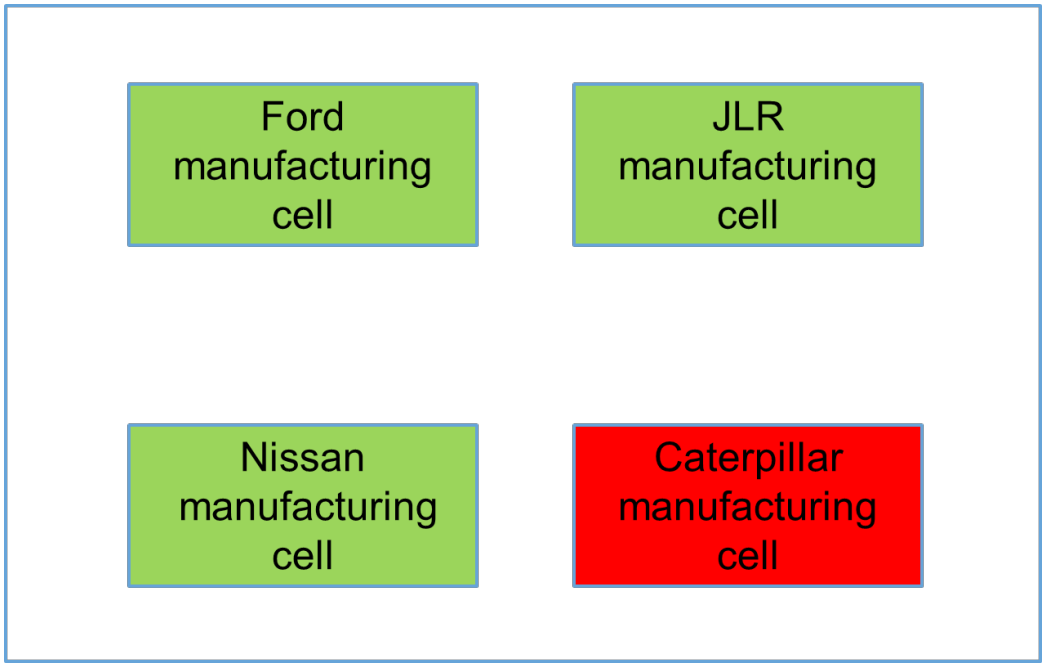
In considering the final classification, the VDA "downgrading" rules have to be considered. For example if the overall score is greater than 90%, but one sections (e.g. Project management) is scored at less than 80%, the supplier would be downgraded from an A to a B.

In conclusion VDA 6.7 provides a great framework for evaluation performance of production equipment suppliers, in particular if an organization is looking to develop the supplier beyond the requirements of ISO9001: 2015.

For more information, or for details of training courses on VDA 6.7 contact Paul Hardiman at paul.hardiman@qualitypartner.co.uk

Question:
We manufacture products of several automotive and also non-automotive customers. Do we have to include all automotive products in the score of IATF certification, or only those that mandate certification in their customer specific requirements?

Answer:
The IATF rules make it very clear that all automotive product has to be included in the scope of IATF certification, whether or not required by the customer. The organization may elect to apply the IATF requirements to non-automotive products, but these would not be included in the scope of certification. So in the example below the products to Ford, Nissan and JLR would need to be included, but Caterpillar products would be excluded from the IATF scope (but all employees used in calculating audit days).



Question:
I still do not fully understand the difference between customer requirements and customer specific requirements, can you help with further clarification?

Answer:
Firstly let's start with the IATF definitions:

Customer requirements
- all requirements specified by the customer (e.g., technical, commercial, product and manufacturing process-related requirements, general terms and conditions, customer-specific requirements, etc.)

Customer-specific requirements (CSRs)
- interpretations of or supplemental requirements linked to a specific clause(s) of this Automotive QMS Standard

So customer specific requirements are all requirements specified by the customer (some of these may be specific to a product), whereas customer specific requirements are linked to a specific clause of IATF 16949 (these will apply to all contracts with the relevant customer).

Some people have read this that customer specific requirements only apply if the customer has specifically written the requirements specifically aligned to the IATF 16949 structure/clauses, I do not agree with this. In the IATF rules it makes clear customer specific requirements could be published as IATF OEM specifics, contract terms, service level agreements, SQA procedures etc.
So if any of the requirements are linked to an IATF requirement, even if they do not mention the specific clause, by inference they are a customer specific requirement.

The important thing is to be able to demonstrate compliance with:

4.3.2 Customer-specific requirements

“Customer-specific requirements shall be evaluated and included in the scope of the organization’s quality management system.”

Whereas some customer specific requirements are made available at www.iatfglobaloversight.org others are often more difficult to find.

A useful site for reference is www.customerspecifics.com

This site offers a free registration and a search facility for customer specific requirements, not just in the automotive sector, but in a range of other industries. Although there is no 100% guarantee that the version posted will be the latest, it is a good starting point to establish if customer specific requirements exist.

I hope you have enjoyed the content of the newsletter. If you have any questions, or have any training needs related to IATF 16949, the core tools, VDA 6.3 or VDA 6.7, or other management system standards do not hesitate to contact Paul Hardiman at paul.hardiman@qualitypartner.co.uk or call on +44 (0) 7341845930.