Quality Partner Newsletter

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Author: Paul Hardiman

Welcome to the eighth 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:

- Effective application of the automotive core tools
- Control of externally provided process, products and services
- Questions and answers related to ISO9001: 2015 and IATF 16949: 2016 requirements

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

Paul.hardiman@qualitypartner.co.uk

Effective learning by videos

Following the success of the first set of Quality Partner videos on the transition to IATF 16949, I have produced the next set of videos on the automotive core tools.

A free video on the introduction to the core tools is available at

http://qualitypartner.co.uk/core-tools/

The full series of videos covers:

- APQP
- Process FMEA
- Control Plan
- MSA variable Gauge R and R
- MSA variable Gauge R and R destructive
- MSA, Bias, Linearity and stability
- MSA Attribute
- An introduction to SPC
- Process capability
- PPAP

12 months unlimited access to the full series of 10 videos is available for purchase at a cost of £79.99 or for £14.99 for individual videos. To ensure effective understanding, each video is supported by a multi-choice exam to verify competence.

Any subscriber to the videos will get the full set of exams in Word format, along with the answer sheet for an internal training coordinator to mark. Following successful completion by delegates, Quality Partner will issue to subscribers a template certificate to record the completion of the training and exam.The videos are suitable for internal/second party auditors, or anybody involved in the use of any of the tools.

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Control of externally provided processes, products and services

With the publication of ISO9001: 2015, we saw a change in heading from the ISO9001: 2008 version "Purchasing" (7.4) to "Control of externally provided processes, products and services" (8.4)
Within IATF 16949: 2016 the automotive industry has added much more stringent requirements against this requirement, including supplier selection, supplier quality management system development, supplier monitoring, second party audits and supplier development, also taking into consideration risk based thinking.

This has led to questions on what is the scope of these requirements and what suppliers have to be included/ managed to meet the requirements.

The relevant definition in ISO9000: 2015 is an "external supplier provider that is not part of the organization (Examples are Producers, distributors, retailers or vendors of a product or a service)"

Under ISO9001: 2008 and ISO/TS16949: 2009 organizations tended to focus on the procurement of parts and materials, and not necessarily other key purchased products, processes and services that could affect the effective implementation of the Quality Management System, or the ability to meet customer requirements.

Now the scope of application is much broader.

So let's look in more detail at each type of external provider, namely processes, products and services.

Externally provided processes
In an ever-increasingly competitive automotive supply chain, many organizations look to improve efficiency by outsourcing certain processes, or aspects of processes.

IATF 16949: 2016, requirement 8.4.2.1 states: "The organization shall have a documented process to identify outsourced processes and to select the types and extent of controls used to verify conformity of

externally provided products, processes and services to internal and external customer requirements”

So let’s look at some examples of typical outsourced processes:

Manufacturing processes
Many organizations outsource aspects of their manufacturing processes, which may include painting, heat treatment, plating and other finishing services. Control of these outsourced providers is critical to ensure conforming product is shipped to meet customer requirements.

For these providers the expectation in IATF 16949: 2016 is that they would at minimum be certified to ISO9001: 2015 and that there be a plan in place to develop them towards certification to IATF 16949. It is important to note that IATF do not include any guidance or requirements on the timescale for suppliers to have to comply with IATF 16949. The amount of supplier development or second party audit activity will depend on factors such as their performance (Quality and delivery) and the risks they pose to the organization (for example some may be single source suppliers). Supplier development may be by second party audits, or working with suppliers on specific improvement projects (for example helping the outsourced supplier with problem solving techniques, understanding the core tools, etc.).

Performance of these outsourced suppliers has to be monitored and evaluated as defined in IATF 16949 8.4.2.4 Supplier monitoring, as a minimum monitoring:

a) delivered product conformity to requirements
b) customer disruptions at the receiving plant, including yard holds and stop ships
c) delivery schedule performance
d) number of occurrences of premium freight

Other outsourced processes
Organisations may also elect to outsource other processes that may directly affect achieving the customer requirements, or the effectiveness of the organization’s quality management system.

In IATF 16949: 2016 8.4.1.1 General — supplemental states:

“The organization shall include all products and services that affect customer requirements such as sub-assembly, sequencing, sorting, rework, and calibration services in the scope of their definition of externally provided products, processes, and services”

Bear in mind those identified above are only examples, other outsourced services could include:

- Transportation
- Tooling design and manufacture
- Testing services
- IT
- Resource provision
- Maintenance services
- Machine/equipment spare parts
- Design services

In these examples either the complete process may be outsourced, or certain aspects of the process. For example an organization may outsource all of its maintenance activity, or only for certain specialist equipment.

The type and extent of control of these suppliers will depend on the risks they pose to the customer and the organization, and their performance.

How any outsourced suppliers are selected needs to be covered in a documented process (see IATF 16949: 2016 8.4.2.1). Whereas there is no requirement as a prerequisite that these supplier are ISO9001: 2015 certified, this may be an organization-defined minimum criterion. If not, the organization has to define how they ensure the supplier has the capability to meet the defined contract requirements, taking into account the IATF 16949: 2016 requirement 8.4.1.2 Supplier selection process.

Once an outsourced supplier is selected, their performance has to be monitored to ensure they are meeting the defined contract, and any customer specific requirements. The performance measures used may vary dependent on the type of service provided.

For example, for a transportation supplier the performance may be measured by on-time collection, and/or on-time delivery to customer, and any instances of product damage.

For a calibration provider, performance may be measured by on-time delivery of the service provided and accuracy of the calibration certificates.

For an IT provider, effectiveness may be measured by response time to user issues, and % fix rate. Irrespective of the measures defined, a summary of the outsourced providers' performance has to be summarised and reported as an input into management review. (ISO9001: 2015, 9.3.2 Management review input).

IATF 16949 also requires: "The monitoring process shall include the criteria and actions to escalate or reduce the types and extent of controls and development activities based on supplier performance and assessment of product, material, or service risks."

Externally provided products
In IATF 16949: 2016 the definition of product is:

"Applies to any intended output resulting from the product realization process."

This seems to indicate that, under this requirement, we are talking about externally provided products that are going to be used by the organization in their product realization process, not other products purchased such as spare parts. (This would be covered by the outsourced processes above.)

This could include purchased:

- Components
- Raw materials
- Gases and other materials used directly in the manufacturing process

Again for these suppliers the expectation in IATF 16949: 2016 is they would at minimum be certified to ISO9001: 2015 and there be a plan in place to develop them towards certification to IATF 16949 (Again no timescale defined). The amount of supplier development or second party audit activity will depend on factors such as their performance (Quality and delivery) and the risks they pose to the organization (for example some may be single source suppliers). Supplier development may be by second party audits, or working with suppliers on specific improvement projects (for example helping the outsourced supplier with problem solving techniques, understanding the core tools etc.).

If second party audits are used, you should ensure that any second party auditor meets the competency requirement defined in IATF 16949: 2016 requirement 7.2.4.

Performance of these suppliers has to be monitored and evaluated as defined in IATF 16949 8.4.2.4 Supplier monitoring, as a minimum:

a) delivered product conformity to requirements
b) customer disruptions at the receiving plant, including yard holds and stop ships
c) delivery schedule performance
d) number of occurrences of premium freight

If a supplier has IATF 16949 certification and is giving good performance, there would be no need mandatory need for supplier development, but an organization may elect to do, for example as part of an efficiency improvement programme (cost down).

The area that has never been clear is where an organization buys products not from a manufacturer but through a distributor. Whereas the distributor should be ISO9001: 2015 certified, they are not eligible for IATF 16949 certification as they do not add value to the product, only sell and distribute.

However this restriction does not exempt the organization from considering the risk posed by these suppliers, or developing then based on their performance and risk. Also IATF 16949 requires monitoring of their performance using the indicators above.

Externally provided services
This is where an organization needs to be very clear on the application of the scope of this requirement. Remember we are talking about the service suppliers that can directly affect the performance of the Quality Management System. So, for example, every organization in the automotive supply chain needs to purchase utilities, such as electricity, gas, water etc., and if uninterrupted supply is not provided this can have a direct effect on meeting customer requirements.

Also this requirement could include suppliers providing specialist training services (e.g. Management system training, machine training, etc.).

Whereas there is not the expectation that these service suppliers have to be ISO9001: 2015 certified, again the organization needs to define their selection process and how the risks are managed (linking to contingency plan where relevant).

The organization needs to make clear in an external audit that this requirement does not cover certain types of suppliers that are not within the scope of the quality management system. For example, some suppliers may be more relevant to other management system standards (for example, suppliers of PPE, environmental services, etc.).

Again, an organization needs to consider the need for development of these suppliers based on performance and risk, but it is likely this will not be a high priority compared with the other groups of suppliers outlined above.

Conclusion
Whereas, while I agree that organizations have maybe focused in the past too much on “product” suppliers, and maybe purchased only key processes and services more based on cost rather than consideration of risk, I think there is a lack of clarity in the IATF requirements on the scope of application of the related requirements in IATF 16949: 2016 8.4.

That is why it is essential that certified organizations take the lead in removing any ambiguity and clearly state in the quality management system how product, outsourced process and service suppliers are selected and managed taking into account performance and risk based thinking.

Ask the expert

Quality Partner’s expert, Paul Hardiman

Question
What is the difference between the requirement 7.1.5.2.1 Calibration/ verification records g) and i)?

Answer
Firstly let’s look at the definition of software in the context of this requirement. These requirements relate to software used in the measurement process, either related to measuring the product or the manufacturing process.

Although there is no definition in IATF 16949, a typical dictionary definition is:

“Software is a general term that describes computer programs. Related terms such as software programs, applications, scripts, and instruction sets all fall under the category of computer software. Software can be difficult to describe because it is “virtual,” or not physical like computer hardware.”

So 7.1.5.2.1 g) requires “verification that the software version used for product and process control is

as specified". It is essential that an organization has good control of the version (or release level) of any software used in the measurement process, because, if not, this could directly affect the measurement results.

7.1.5.2.1 i) requires i) "production-related software verification used for product and process control (including software installed on employee-owned equipment, customer-owned equipment, or on-site supplier-owned equipment)."

This requirement focuses on ensuring that the output from any software used in the measurement process gives a correct output and this is verified as part of the control or monitoring and measuring equipment. This could involve measuring the output of the software against a known standard/master at defined periods, the period dependent on risk.

Question
I see in IATF 16949: 2016 several requirements related to embedded software. Can you explain what is meant by embedded software and are these requirements that we can explain are not applicable during a third party audit?

Answer
I am surprised that IATF have not included a definition on the meaning of embedded software. A dictionary definition is:

"Embedded software is specialized programming in a chip or on firmware in an embedded device to controls its functions."

So the first thing to understand when reading these requirements is that we are talking about software that is embedded in a product that is supplied for an automotive application (for car, bus, truck or motorcycle). Increasingly many functions of a vehicle are controlled by software, whereby, if the software does not function effectively, it will affect the vehicle performance and maybe legal compliance.

If you can demonstrate that no products your organization provides to automotive customers contain any software, then you can state these requirements are not applicable, but you cannot state them as exclusions in the scope of the Quality Management System.

If you do supply products with embedded software let's look at the intent of the requirements:

8.3.2.3 Development of products with embedded software:

"The organization shall use a process for quality assurance for their products with internally developed embedded software. A software development assessment methodology shall be utilized to assess the organization's software development process. Using prioritization based on risk and potential impact to the customer, the organization shall retain documented information of a software development capability self-assessment."

This requirement is only applicable where organizations have design responsibility for embedded software development. The development and assessment methodology to be used is not specified, but could be influenced by customer specific requirements (e.g. Automotive SPICE). If this is applicable, the internal audit programme must include an audit of the software development process using a competent internal auditor who has specific knowledge and/or qualification of software development methodologies.

8.4.2.3.1 Automotive product-related software or automotive products with embedded software:

This requirement is similar to 8.3.2.3 but where the software is not developed by the organization, but is outsourced to a qualified external provider. In this case, there needs to be a process defining supplier selection, supplier monitoring, and any second party audit needs to verify the assessment methodology used by the supplier and how the relevant risks are managed.

10.2.6 Customer complaints and field failure test analysis:

"Where required by the customer the organization shall have the capability to perform analysis of the interaction of software within the system of the final customer product."
Again this is only applicable where there is a requirement in the customer contract to provide this testing capability.

Question
I see in ISO9001: 2015 we have to identify not only the needs of our customers but also the needs of interested parties. Can you give us guidance on who may be interested parties and what auditors may be looking for to meet this requirement?

Answer
You are right, the requirement is "4.2 Understanding the needs and expectations of interested parties".

"Due to their effect or potential effect on the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, the organization shall determine:

a) the interested parties that are relevant to the quality management system;
b) the requirements of these interested parties that are relevant to the quality management system.

The organization shall monitor and review requirements about these interested parties and their relevant requirements"

The first thing to remember is that these are interested parties related to the Quality Management System. In reality, to be in business an organization will already be meeting these requirements, but the challenge is

how to demonstrate this in an audit!

I would recommend the best way would be to produce a simple matrix, explaining who the interested parties are and what their requirements are.

An example is shown below:

Interested party	Requirements	Related documents if applicable
Shareholders	Achieve strategy, including customer satisfaction and profit targets	Customer scorecards Profit and loss accounts
Local community	Provide secure jobs, promote good communication on proposed changes	Annual “open house” day
Legal bodies/regulators	To meet relevant product safety requirements and a legally compliant factory	Legal register and compliance audits
Trade associations	Promote effective communication, participate in trade forums, provide benchmark data	Membership handbooks
Employees	Provide a safe work environment, promote good communication, promote employee learning and development	Staff handbook including appraisals
External providers	Effectively communicated forecast and order requirements in the agreed timing, settle accounts within agreed credit terms	Supplier handbook
Insurers	Mitigate risks	Risk register and actions
Trade unions	Effective communication on any proposed changes, union participation in decision making	Monthly consultative review

Once defined, the organization has to review “customer satisfaction and feedback from relevant interested parties” as part of the management review process, including ensuring that any relevant objectives and targets have been met (9.3.2 Management review input).