Quality Partner Newsletter

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Welcome to the seventh 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:

- Changes to VDA 6.3 2016
- 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

In the age of ever decreasing resources to do more work, it is becoming increasing difficult for organizations to release employees for training, especially for multiple days.

However, with changes to standards, requirements and technology there is an increasing need to educate employees to ensure their understanding and competency to perform their respective tasks.

In December 2016 Quality Partner released a series of 12 short videos to help companies understand the changes in IATF 16949 and to aid them in making a successful value added transition.

An introductory video is available on our You Tube channel at https://youtu.be/aWZa9PPLwvA

The **full series of 12 videos** are available for purchase at a cost of £240. However, as a valued reader of this newsletter, we can offer access to the **full set** for a just **£96!** to the first 100 readers. To take advantage of this offer please contact paul.hardiman@qualitypartner.co.uk to get your promotional code.

In March 2017 we will be issuing another full set of 12 videos looking at the effective application of the automotive core tools. Rather than trying to cover all the aspects of each tool in one big video, the tools will be broken down into bite size manageable chunks.

For more information on these videos, including a full list of topics and cost, please contact paul.hardiman@qualitypartner.co.uk

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VDA 6.3 Process Audit 2016. The changes

Introduction
In December 2016 VDA QMC released the 3rd edition of VDA 6.3, Process Audit. The publication has been "completely revised", while maintaining some of the key features of the previous 2010 edition. Compliance with VDA 6.3 is mandated by some vehicle makers and suppliers, in particular, those from Germany.

Overview of the changes

Auditor qualification
- The 2016 edition now contains much clearer requirements for the qualification of internal process auditors, supplier auditors and process auditors providing an external service.
- For internal and supplier (second party) auditors, the VDA sanctioned training is a four day course including a knowledge test.
- For people undertaking process audits as an external service supplier the four day course is required followed by an exam day to gain a VDA auditor card.

Audit of product development and product realization processes
- The overall process of undertaking a VDA 6.3 audit stays the same, but with more emphasis on understanding and auditing process risks.
- The chapters P2 to P7 remain but the high level questions and the detailed questions have all been reviewed and revised. The high level questions, and the minimum requirements for assessment, are now much more concise and translated into much better English. The total number of questions has been reduced from 60 to 58.

An example from P6, Production is shown below:

P6.1	What goes into the process ? (process input)
6.1.1	Has the project been transferred from development to serial production and is a reliable start guaranteed?
6.1.2	Are the necessary quantities / production batch sizes of incoming materials available at the correct storage location/work-station?
6.1.3	Are incoming materials stored appropriately and are the means of transport/packaging facilities suitable for the special characteristics of the incoming materials?
6.1.4	Are the necessary identifications / records / releases available and allocated appropriately to the incoming materials?
6.1.5	Are changes to the product or process made during the serial production tracked and documented?

- The 19 high risk * questions in the 2010 edition has been reviewed and reduced to 18 questions involving special product or process risk.
- Each of the detailed questions now contains two columns. The first column defines the minimum requirements related to the assessment and the second column defines examples for implementation. The notes column which contained references to the relevant VDA standards has been removed, but replaced with an overview matrix in chapter 13, which links the relevant high level question to the appropriate VDA or other relevant reference manual.

An example of a detailed question is shown below:

6.1.2	Are the necessary quantities / production batch sizes of incoming materials available at the correct storage location/work-station?
Minimum requirements relevant for assessment	Examples for implementation
The correct product (incoming material, part, component etc.)must be provided in the agreed quantity, the correct quality and the correct packaging, with the correct documentation, at the agreed time and at the agreed place. Parts/components must be available at the defined storage areas/work-stations. At the workplace, parts and materials are provided as needed, taking into account the order quantity/lot size (for example KANBAN), Just in time, FIFO), upstream processes are taken onto account. After order completion, the return of unneeded parts (surplus) including their quantities is regulated	• Sufficient and appropriate transport facilities • Defined storage points • KANBAN • Just in time/just in sequence • Inventory control • Change status • Exchange of information to the return of unnecessary components/surplus • Inventory • Production levels tailored to the customer's requirements • Special requirements for components and containers (ESD-protection for electronic components, residues etc.)

- The generic baseline in the 2010 edition has been removed from the 2016 edition, although the "transportation and handling of parts" is still included.
- The question scoring criteria of 10,8,6,4, and 0 remains but the guidance on scoring table has been revised with particular focus on risk related to the product, process or system.
- The A, B C classification system remains with the same level of compliance criteria, but all questions are now weighted equally.
- A detailed and very useful glossary is included in section 11 of VDA6.3 2016.

Potential analysis of a new supplier

- P1 is still included for assessment of a potential supplier, but the number for questions to be asked has increased from 35 to 36. The traffic light (red, yellow and green) scoring system remains.

Auditing of a service supplier

- The criteria of assessing a service supplier has been completely revised.

Summary

The 2016 edition of VDA 6.3 is written with much more clarity, particularly the high level questions, and the detailed audit criteria in each question. An auditor should not assume anything, although the overall structure of P2-P7 remains, the detail of each question has been completely revised. In preparing to undertake an audit to the new version, the auditor should undertake a detailed review of the relevant questions.

Next steps

For existing VDA 6.3 qualified auditors there is the need to attend a one-day transition course by June 2018.

For new VDA 6.3 auditors, the training structure has been simplified, with a four day course to become a qualified internal or supplier auditor. For auditors wanting the highest level qualification, an auditor card, there is a fifth day, which includes a knowledge exam and interview case study.

Paul Hardiman is a qualified VDA 6.3 trainer to a VDA sanctioned training provider GAB.

For more information on courses and availability and costs contact paul.hardiman@qualitypartner.co.uk

Ask the expert

Quality Partner's expert, Paul Hardiman

Question: I have noticed the change in title of the purchasing requirement that was in ISO/TS16949: 2009 to "8.4 Control of externally provided processes, products and services" in IATF 16949. What is the meaning of services?

Answer: IATF 16949; 2016 8.4.1.1 gives some guidance on this. Whereas the purchasing requirements in ISO/TS16949 concentrated more on bought in products and materials, IATF 16949, led by the change in ISO9001: 2015, focuses on the selection and control of process, product and service suppliers. Remember we are talking about suppliers that directly affect an organizations ability to meet customer or quality management system requirements.

8.4.1.1 provides examples including sorting and calibration service suppliers, but it is up to an organization to clearly define what service suppliers are deemed to affect customer requirements or quality management system requirements (this could include maintenance service providers, transportation suppliers) and then define a process for how such suppliers are selected and monitored.

Question: 7.2 Competence and 7.3 Awareness in ISO9001: 2015 both include "persons doing work under the organization control". What does this mean and who does it include?

Answer: Organizations should already have systems in place to ensure that employees and temporary/ agency workers are competent and aware of the Quality Policy and relevant Quality Objectives. To meet the requirements 7.2 and 7.3 an organization needs to consider other people doing work under their control that could have any effect/impact on the Quality Management System.

For example, maintenance contractors coming on to site to repair or service machines. If the activity is not undertaken correctly it could have a direct impact on product quality. Whereas most organizations have a process to make contractors aware of safety and environmental consideration while on site, many do not have a process to check the person (s) coming on site are competent to perform the task, or make them aware of any relevant Quality Management System documentation they have to comply with.

This could be achieved by reviewing/ amending the site induction process, and maybe strengthening the purchasing process to ensure the supplier providing the service is aware of their responsibilities to provide competent persons (if they are ISO9001: 2015 approved this should be ensured) and working in accordance with the organization QMS requirements.

This requirement could also apply to calibration contractors coming on to site (which should be ISO/IEC accredited laboratories) and contractors providing building or infrastructure maintenance services (for example servicing of humidity control units that may be essential to product quality).

Question: IATF 16949: 2016 Requirement 9.2.2.2 Quality Management System audit states "The organization shall audit all quality management system processes over a three year calendar period, according to an annual programme". Could certification body auditors still want to see all processes audited annually?

Answer: The requirement is now written very clearly, so unless there is a customer specific requirement that adds to this, an auditor cannot impose their own requirements. However what you need to demonstrate that audits are planned taking into account:

- The importance of the process concerned.
- Changes affecting the organization.
- The results of previous audits.
- Risks.
- Internal and external performance trends.
- Criticality of the process (es).

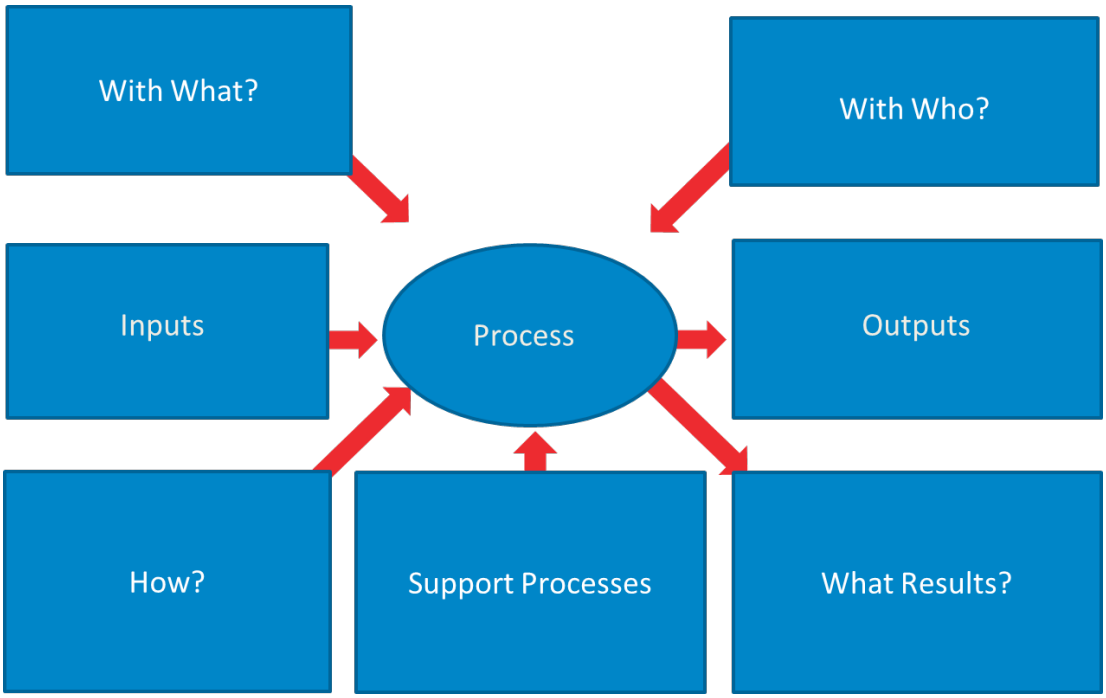
This input can be used to prioritize the audits included in the annual programme. It may be beneficial to also develop a tentative programme for year 2 and 3 to demonstrate that all processes will be covered. The programme should be regularly reviewed as part of management review (time not specified in the standard but suggest every 3-6 months), taking into account the list above, and updated as necessary.

A similar approach can be taken in the development of a programme for manufacturing process audits.

Question: It states in IATF 16949 9.2.2.2 Quality Management System audit that system audits shall be undertaken using the process approach. For system audits under ISO/TS16949 we have fixed checklists referencing the clauses of the standard. Will this be acceptable under IATF 16949: 2016?

Answer: The short answer is NO! System audits must be planned and undertaken using the process approach. This means the role of the auditor is not only to check compliance with the relevant process documentation (e.g. Procedures) but to verify that the process is implemented effectively to ensure the planned results are achieved. There is no defined way this approach has to be recorded, but many companies use the turtle diagram to help auditors to plan and undertake audits.

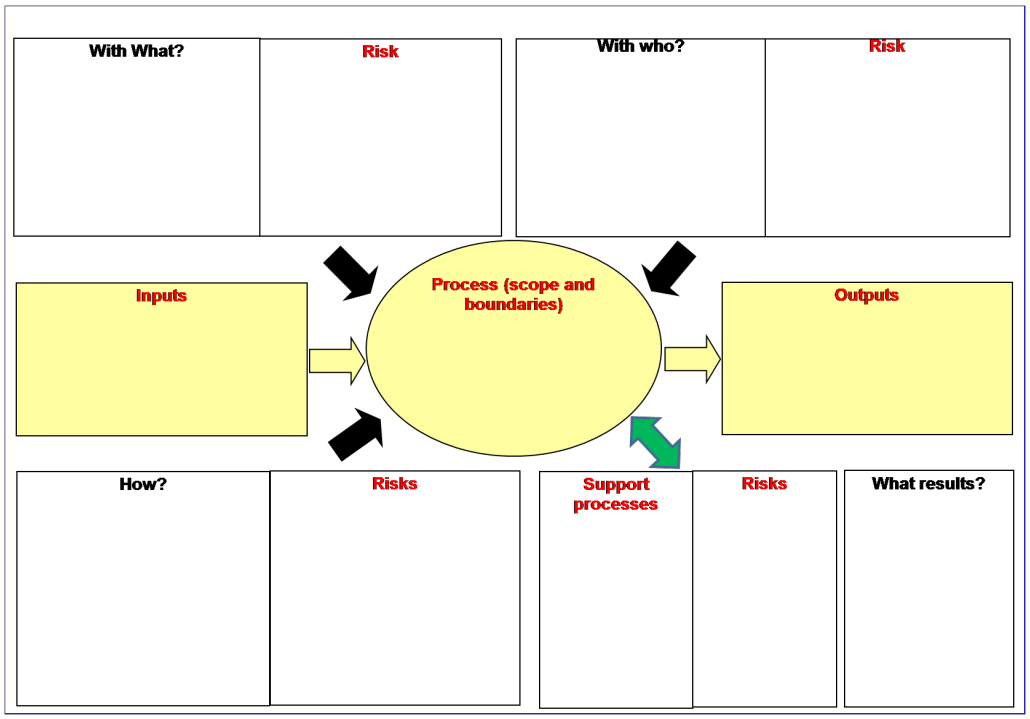
The "traditional "turtle" approach is shown on the next page:



The input and output helps clearly define the scope of the audit to be undertaken. The auditor then should focus on the results that the process is striving to achieve, and what controls are in place related to “With Who” (people), “With What” (physical things) and “How” (QMS documented information and controls) to ensure “results” (KPI’s and other indicators) are achieved. The support processes box is to prompt an auditor to verify effective process interaction with other processes.

One of the competencies defined for internal and second party auditors IATF 16949: 2016 clauses 7.2.3 and 7.2.4) is that, as well as applying the process approach, risk based thinking is integrated into the audit process.

An auditor can demonstrate this by focusing on areas of process risk, which could be documented using an “extended turtle diagram shown below:



In planning the audit, the auditor could review performance (what results) and based on this identify potential areas of risks to focus on in the audit.

To support the audit the auditor could develop a checklist of questions, but these should not be purely to verify compliance with the standard, but used to get evidence to verify process effectiveness.

Question: Under IATF 16949 requirement 9.3.2.1 Management review, Management are required to review "identification of potential field failures identified through risk analysis (such as FMEA). Does this mean that management has to review the detailed FMEA's at management review?

Answer: Management do not have to review the detail of FMEA's but need to be aware of the risks identified that could result in field failures of the product. This could be done by the process owner (es) responsible for FMEA providing management a summary of the areas of highest risks identified. This could be by a combination of RPN, Severity, or Severity x Occurrence, taking into account any customer specific requirements for ranking and action.

Question: IATF 16949: 2016 requires as part of management review a review of internal and external nonconformance. We are part of a group of companies certified under a corporate scheme. Each plant calculates the cost of internal nonconformance using a standard formula, but external cost is handled by corporate. The data is supplied to plants, but only as a total figure for the group, not broken down to data for each plant. Is this acceptable?

Answer: I do not believe this meets the requirements. The plant needs the breakdown on the costs, and the details of failures caused by their plant in order to analyze and take appropriate corrective and preventative actions. ISO9001: 2015 clause 9.1.3 requires "Analysis and evaluation" of data, and IATF 16949: 2016 clause 9.1.3.1 requires "Prioritization" in taking actions to improve customer satisfaction. This cannot be done by the plant if they do not have the detailed data.

Question: We have reviewed IATF 16949 and determined that several of the requirements are not applicable to us. For example we have no products with embedded software; we do no equipment Overhaul etc. Can we write these as exclusions?

Answer: No! The only requirements that can be excluded are related to product design where an organization does not have product design responsibility. There may be certain requirements not applicable to you at the time of audit. You need to demonstrate to the auditor that you have reviewed all the ISO9001: 2015 and IATF 16949: 2016 requirements determine which are applicable to your scope of activity and then show where the applicable requirements are addressed within the relevant processes. This can be done in a matrix format, an example is shown on the next page.

Process		4.1 Understanding the organization and its context	4.2 Understanding the needs and expectations of interested parties	4.3 Determining the scope of the quality management system	4.3.1 Determining the scope of the QMS supplemental	4.3.2 Customer specific requirements	4.4 Quality management system and its processes	4.4.1.1 Conformance of products and processes	4.4.1.2 Product safety	5.1.1 Leadership and commitment general	5.1.1.1 Corporate responsibility	5.1.1.2 Process effectiveness and efficiency	5.1.1.3 Process owners	5.1.2 Customer focus	5.2.1 Establishing the quality policy	5.2.2 Communicating the quality policy	5.3 Organizational roles, responsibilities and authorities
Define your organization here						Identify here which requirements are applicable or not applicable											

This could be used at the transition audit document review to shown all the relevant requirements have been addressed within the applicable process (es).

If you would like a copy of the complete matrix e-mail paul.hardiman@qualitypartner.co.uk

Exclusive Offer!

Don't miss out on the promotional price of £96 for the full set of 12 IATF 16949 training videos!

Contact paul.hardiman@qualitypartner.co.uk