



Quality Partner Newsletter

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Welcome to the tenth 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:

- Common issues on IATF 16949 transition audits
- Developments with revised FMEA reference manual
- Developments with ISO45001
- Ask the expert questions related to IATF 16949

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

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Wishing you all a very happy and successful 2018!

IATF 16949 transition

2017 has been an interesting year with the transition to IATF 16949 underway. With the ongoing pressure of cost reduction giving ever present resource issues, in many organizations the transition has taken the back seat compared with the everyday pressures of supplying parts.

However, considering data from the first 7000 audits undertaken to IATF 16949, the high number of nonconformities being found indicate that companies are in for a stressful 9 months as they prepare to complete the transition.

A concern is that third party auditors have had no mandatory face to face training to prepare them for undertaking transition audits, and as such there have been many different interpretations of requirements applied.

In many cases the auditee does not feel competent to challenge the third party auditor, but I think that has to change.

Any finding raised by a third party auditor should be traceable to ISO9001: 2015, IATF 16949: 2016, the organization own management system, or customer (or interested party) specific requirements.

In many cases I have seen, the nonconformities are not against a documented requirement, but against the auditors, or the CB own point of view. This has to stop, and the only way to contest this is to challenge the auditor to show the specific requirement they are raising the nonconformity.

In October 2017 IATF published 9 sanctioned interpretations (these change a requirement) and 11 frequently asked questions (these clarify a requirement without changing it) against the requirements of IATF 16949: 2016. These are available free of charge from www.iatfglobaloversight.org

Let's take a look some of the sanctioned interpretations, in particular the requirement that is causing the biggest problem on transition audits:

IATF 16949: 2016: 7.2.3 Internal auditor competency.

Before we study this requirement, firstly we need to review the sanctioned interpretation 4. Taking into account the SI, the requirement 7.2.3 now reads:

Quality management system auditors shall all be able to demonstrate the following minimum competencies:

- a) understanding of the automotive process approach for auditing, including risk-based thinking;
- b) understanding of applicable customer-specific requirements;
- c) understanding of applicable ISO 9001 and IATF 16949 requirements related to the scope of the audit;
- d) understanding of applicable core tool requirements related to the scope of the audit;
- e) understanding how to plan, conduct, report, and close out audit findings.

Despite the interpretation of some third party auditors, competency does not need to be achieved by external training.

For many organizations going in to the IATF transition, they already had qualified auditors, who should have previously understood a) related to process approach, b) related to customer specific requirements, d) the core tools and e) how to plan, conduct, report and close out audit findings.

For the gaps (risk based thinking, understanding ISO9001: 2015 and IATF 16949: 2016), the organization needs to demonstrate how the auditors have gained the understanding.

The SI 4 states "If the organization personnel provide training to achieve competency, documented information shall be retained to demonstrate the trainer's competency with the above requirements."

Most organizations will meet this requirement by sending one auditor on external training (which may be focused on the IATF transition, no minimum/maximum days are stated), then they can become the internal trainer. In this case it is important to keep detailed training records. I normally suggested this is documented in a matrix, an example is shown below:

	Process approach and risk based thinking	Customer/Organization specific requirements	ISO9001/IATF requirements	Core tools	Planning, undertaking and reporting audits	Process audit Understanding of manufacturing processes	Process audit Understanding of PFMEA and control plan
Auditor name	Reference training and or experience	Reference training and experience in the customer specific requirements specific to the organization (e.g. VW, Ford etc.	Reference training and or experience	Reference auditors understanding of the core tools as appropriate to the scope of the audit	Reference any previous auditor training or experience	Reference auditors experience (work experience, training, education) List areas of process knowledge/expertise (e.g. Welding)	Reference training and or experience
Auditor 2							
Auditor 3							

Now let's take a look at manufacturing process auditor:

Taking into account the SI 4 the requirement now reads:

“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”

In simple terms IATF are saying the main focus of the manufacturing process audit is to verify the effective implementation of the PFMEA and control plan, and to do this auditors should have competency in understanding the purpose, content and application of the PFMEA and control plan.

Also, the organization needs to take into account any customer specific requirements for process auditor competency. For example, many German based OEM's/tier 1 suppliers will require their suppliers to use VDA 6.3 for process audits, and as such auditors should have the relevant qualifications.

Again, to demonstrate process auditor competence, documented information needs to be maintained to demonstrate auditors understand PFMEA and control plan. This could be by training, education or experience.

To help meet this competency requirement, Quality Partner has developed a series of 11 short videos on the core tools, each with an online exam, with an automatically generated certificate for those meeting the minimum requirements. Readers of this newsletter can buy the complete set with 50% discount, including access to the online exams, for a total of \$50, a very competitive price.

If you would like the discount code please mail paul.hardiman@qualitypartner.co.uk or to find out more details visit <http://qualitypartner.co.uk/core-tools/>

Finally let's take a look at Product auditor.

At a minimum product auditors shall demonstrate competence in understanding product requirements and use of relevant measuring and test equipment to verify product conformity.

This would mean the auditor needs to be competent to read and understand product specifications/drawings etc. and use the equipment to measure the product.

IATF 16949: 2016 Lead Auditor training

Quality Partner has developed a five day lead auditor programme for ISO9001: 2015 and IATF 16949: 2016, suitable for internal or second party auditors. The course fully meets the qualification requirements in IATF 16949: 2016 7.2.3 for internal auditor and 7.2.4 for second party auditor. The course includes many practical case studies and delegate exercises, as well as a knowledge and application exam on day 5.

The course was recently delivered to a group of internal and external auditors from ST Microelectronics in the Philippines, with great feedback. Feedback included the following comments:

“Trainer is Excellent in all aspect”

“Informative, examples given are appropriate”

“Very informative, excellent facilitator, expert in the subject, effective trainer”

"Very helpful to have a clear understanding of IATF16949; excellent trainer"

A group of approximately 20 people, mostly women, are posing for a group photo in a room with yellow walls and green carpet. They are arranged in two rows, with some standing and some sitting. Many are wearing lanyards and smiling at the camera. The room has a blue light strip along the top of the wall.

VDA/AIAG FMEA reference manual development

A working group, consisting of both German and American OEM's and suppliers, has been working on developing a new FMEA reference manual, with a focus on standardizing the scoring criteria for severity, occurrence and detection.



The “yellow” version (draft) was released at the end of November 2017 and the final publication by May 2018.

Before looking at the detail, it is important to point out that, compliance to either the existing VDA or AIAG FMEA manuals, or the new joint publication, is not mandated by IATF 16949. The reference manuals that have to be referred to by an organization will be specified in customer specific requirements. If there are no customer specific requirements, the organization needs to define the reference manual/methodology/criteria used.

It is likely the new reference manual will be based on a six step approach, namely:

Step 1: Scope definition: This is important to set the boundaries, and decide on what is to be included/excluded.

Step 2: Structure analysis: This is to establish the design interfaces (e.g. block diagram) or the steps in the process flow (e.g. process flow chart).

Step 3: Function analysis: This includes visualization of the product or process functions, taking into account customer and internal requirements.

Step 4: Failure analysis: Brainstorming, (e.g. using 4M analysis or fishbone diagram) to establish potential failure modes, effects and causes.

Step 5: Risk analysis: Rating of severity, occurrence and detection.

Step 6: Optimization: Taking actions based on risks identified, continual improvement.

Rather than using RPN ($S \times O \times D$) there is a proposal to use an Action Priority (AP) ranking, high, medium and low (based on how S, O and D have been scored).

Some validation activities have already been completed by the workgroup and I am sure this will continue following the copy of the yellow version, with the group taking into account user feedback prior to final publication.

To date no transition timescale has been communicated, but it is likely that, after the release of the final version in 2018, that organizations will be given timescales from customers to implement the manual for new FMEA's developed and update existing FMEA's. If there are no customer specific requirements, an organization can decide when to use the new reference manual.

I will provide an update in future editions of the newsletter.

Development of ISO45001

Over 6300 people die each day from work-related accidents or diseases, that's nearly 2.3million every year. The impact of occupational injuries and diseases is significant, both for employers and the wider economy, resulting in losses from early retirements, staff absence and rising insurance premiums.

To help address the problem, ISO is developing a new standard, ISO 45001, Occupational health and safety management systems - Requirements, that will help organizations develop an effective process based management system to improve employee safety, reduce workplace risks and create better, safer working conditions, all over the world.



The standard is currently being developed by a committee of occupational health and safety experts, and will follow other generic management system approaches such as ISO 14001 and ISO 9001, using the structure of Annex SL. It will take into account other International Standards in this area such as OHSAS 18001.

The final draft of ISO45001 was released in November 2017 and the expected final publication will be in March 2018.

There is some link to ISO9001: 2015 and IATF 16949: 2016 requirements:

ISO9001: 2015 7.1.4 Environment for the operation of processes

“The organization shall determine, provide and maintain the environment necessary for the operation of its processes and to achieve conformity of its products and services”

IATF adds the following note (as guidance)

NOTE Where third-party certification to ISO 45001 (or equivalent) is recognized, it may be used to demonstrate the organization’s conformity to the personnel safety aspects of this requirement.

Also in the development of standardised work requirement IATF 16949: 2016 8.5.1.2:

“The standardised work documents shall also include rules for operator safety”

As for ISO9001: 2015 and IATF 16949: 2016, the draft of ISO45001 places a significant emphasis on risk management, integration the health and safety management system into the organization business processes, and employee participation (in IATF referred to as employee motivation).

My advice to companies looking to integrate quality, environment and health and safety management systems into one business management system, is to analyse business processes and process risk using the risk based turtle diagram.

A simple example to demonstrate the concept is shown below.

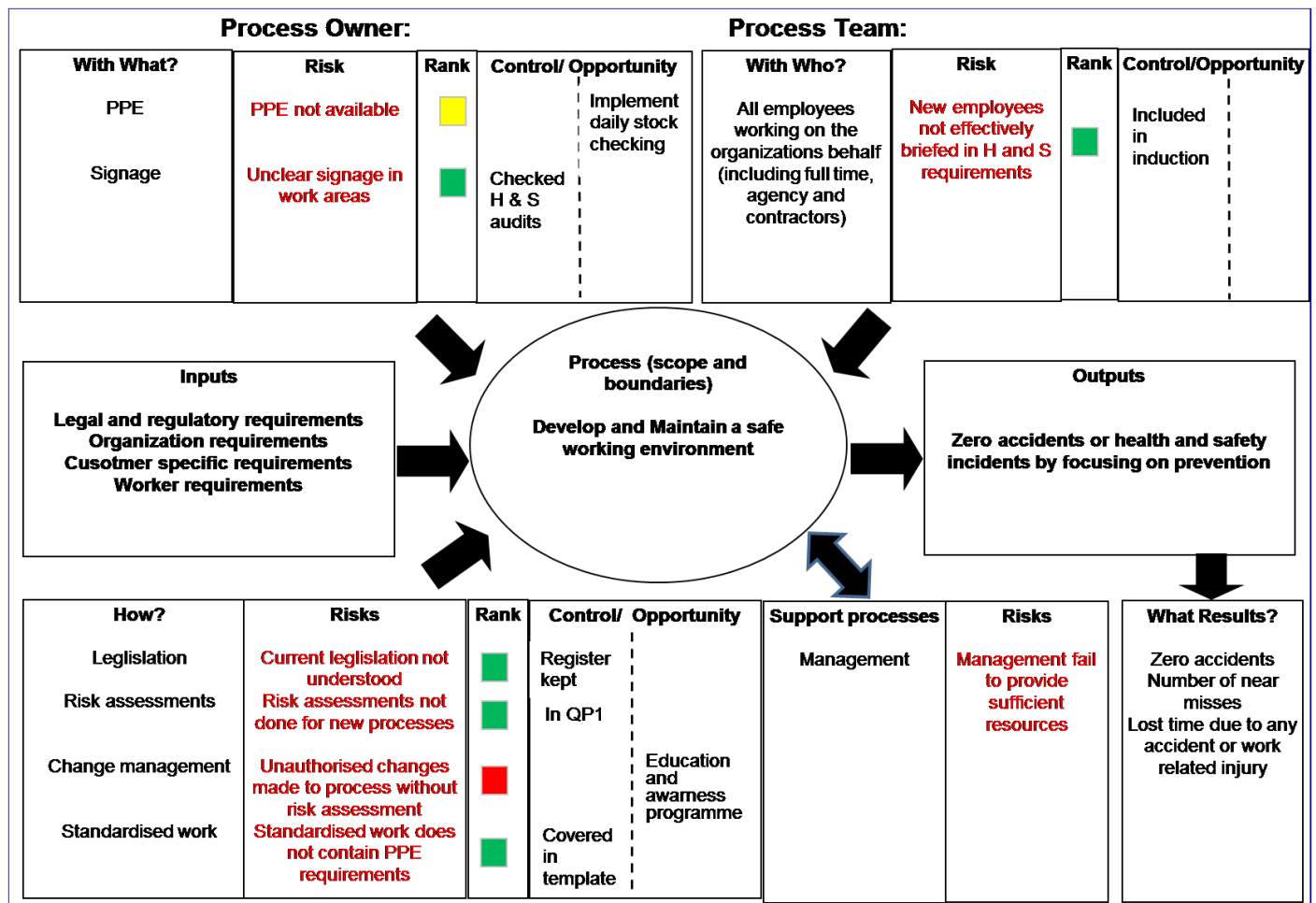
A team, led by the relevant process owner, brainstorms the scope of the process to be evaluated and then the primary inputs and outputs.

Then the team decide what the intended results (e.g. KPI's) are (What results)

Then working anticlockwise, with who, with what and how are established, with the associated risks.

Using a ranking criteria (in this example red, yellow and green), the team evaluate the rankings, control (what is currently in place), and where improvement can be made, these are identified as "opportunities". These "improvements" would then be tracked for effective implementation.

Quality Partner has developed practical training related to ISO45001, both implementing and auditing the requirements using the process approach incorporating risk based thinking.



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

Total Productive Maintenance (TPM)

I am proud to announce that Quality Partner have been awarded the "Best TPM Training Specialist 2017" by the CV Magazine. This is in recognition for supporting organizations on their TPM journey. Paul Hardiman, Director Quality Partner, was the first JIPM assessor outside of Japan to be qualified as a TPM award assessor.



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

Ask the expert

Question

I have a question related to IATF requirement 8.7.1.7, nonconforming product disposition. We use a licenced waste carrier to take away the waste, and in the contract they are responsible for rendering the products unusable, by stripping down the products in to recyclable waste streams. Is this acceptable?

Answer

IATF have issued guidance on this in the recently issued FAQ 11:

“Yes, it is acceptable to contract the process of rendering the product unusable to a service provider. If a service provider is used, the organization needs to approve, and periodically verify, how the supplier is rendering the product unusable.”



*Quality Partner's expert,
Paul Hardiman*

As an auditor I would check:

- What was the process to approve the service supplier? (What quality of environmental system approvals do they have, what legal permits etc.)
- I would review the contract to see if the rendering of the product unusable is defined.
- Have any supplier audits been planned to verify product is being rendered unusable? (Maybe including photographs of waste streams)
- What ongoing verification of the service provider is planned based on risk?

Question

I have a question related to IATF 16949 requirement 8.2.3.1.3 Organization manufacturing feasibility. Since we first implemented ISO/TS16949: 1999 we have used the manufacturing feasibility form in the APQP reference manual. Is this acceptable as evidence to meet the feasibility requirement in IATF 16949?

Answer

I believe the APQP feasibility form alone does not fully meet the requirement. Taking into account risk based thinking, an organization need to consider all risks when quoting for new business with an existing or new customer. While the APQP form prompts questions on whether it is possible to make the proposed product (s) with the current facilities, it does not consider risks such as:

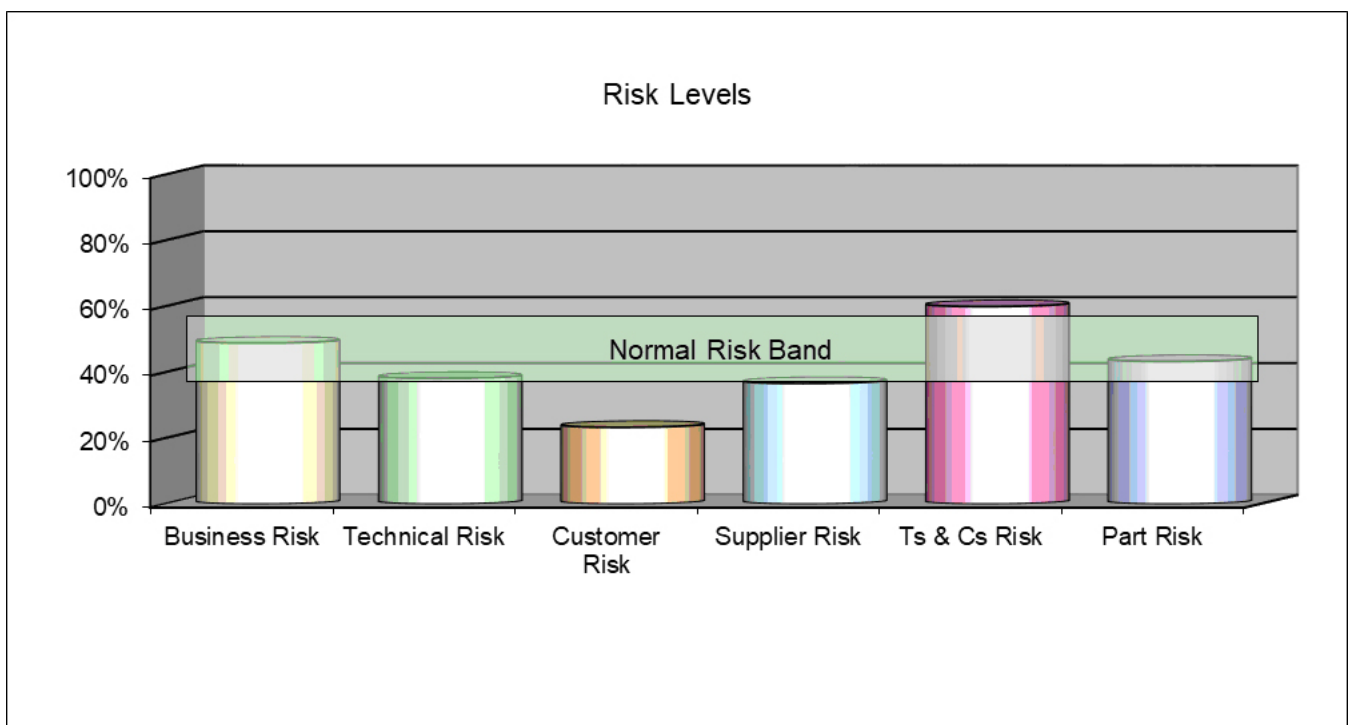
- Are there any financial risks (customer financial stability, payment terms, currency requirements etc.?)

- Are there any customer specific requirements (In particular that may have financial impact)?
- Have we sufficient organization knowledge?
- Have we got sufficient capacity if we win the business?

To help clients understand all the implications of considering risk when quoting new business I have developed a risk ranking spreadsheet that considers:

- Business risk
- Technical risk
- Customer risk
- Supplier risk
- Terms and conditions risk
- Part (Product) risk

Against each criteria, there a number of prompt questions to rank the level of risk.



The risk band can be adjusted by the organization, depending on what management see as an acceptable level of risk.

If any readers would like a copy of this Excel spreadsheet contact paul.hardiman@qualitypartner.co.uk