

IATF 16949: 2016 has arrived!

Quality Partner Newsletter

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Hurry, time to make the transition is short

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Welcome to the sixth edition of the Quality Partner newsletter.

The newsletter is designed to keep you up to date with developments in Management Systems and Total Productive Maintenance (TPM).

This issue focuses on:

- IATF 16949: 2016 has been released. This edition focuses on the key changes and gives guidance, help and support in making an effective transition
- Questions and answers related to IATF 16949: 2016 requirements

To support organizations in making a successful transition to IATF 16949 Quality Partner has developed several documents to help:

Transition checklist

While I am not a supporter of checklists, in developing a transition plan an organization needs an effective tool to identify the gaps that need to be addressed. This document includes questions that could be asked in a self-evaluation to establish gaps between current systems and requirements of IATF 16949: 2016

Clause verses process matrix

At the transition audit to ISO9001: 2015 and IATF 16949: 2016 organizations will need to demonstrate

all requirements have been address in the business processes. This matrix will help demonstrate that.

To receive free copies of these documents e-mail paul.hardiman@qualitypartner.co.uk

Quality Partner Activities

On the 25th -26th January 2017 Paul Hardiman will be delivering a two day course focused on Risk Based Thinking, which is one of the fundamental changes in ISO9001: 2015 and IATF16949: 2016.

The course will be run in partnership with the Bridge Group and the Manufacturing Technology Centre in Coventry, UK. For more information visit www.qualitypartner.co.uk

Key changes in IATF: 16949: 2016

This article looks at the key changes between ISO/TS16949: 2009 and IATF 16949: 2016.

Firstly, and very important, when you see IATF 16949 you will see one fundamental difference. Whereas ISO/TS16949 contained the content of ISO9001: 2008 word for word, IATF 16949: 2016 does not. That does not mean you do not have to study and meet the requirements or ISO9001: 2015. You do. The only difference is the ISO9001: 2016 requirements are in a separate document that you have to purchase.

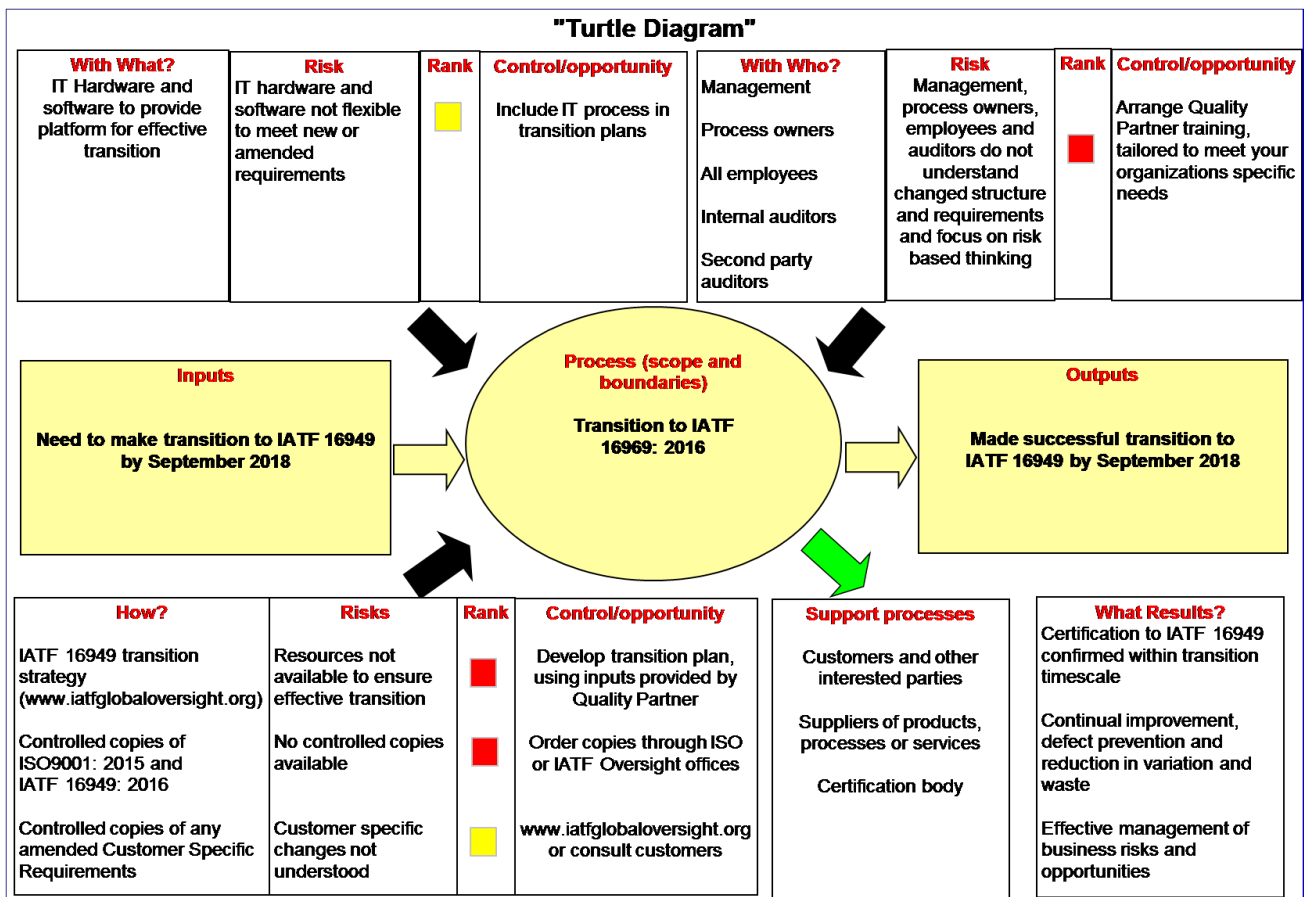
So, before we study the additional/ changed IATF 16949 requirements, let's look at the key changes in ISO9001: 2015. One of the fundamental differences is the structure as the revision incorporated the structure defined in Annex SL, a common framework developed by ISO for all future management system revisions.

So, those of us who can remember all the clauses in ISO9001: 2008 and ISO/TS16949: 2009 either need to change our jobs or start to learn the new structure!

The good thing is the process approach, a fundamental principle in ISO9001: 2008 and ISO/TS16949: 2009 remains and in fact has been enhanced with even greater alignment to IATF thinking. However, now there are requirements for an organization not only to understand their process but also the risks and opportunities in each process and that each process is managed by a competent process owner.

There is no set format to identify or rank risks, but as some of you have seen in previous editions of the newsletter (which can be downloaded by visiting www.qualitypartner.co.uk), one way to address this is using a modified version of the "Turtle Diagram".

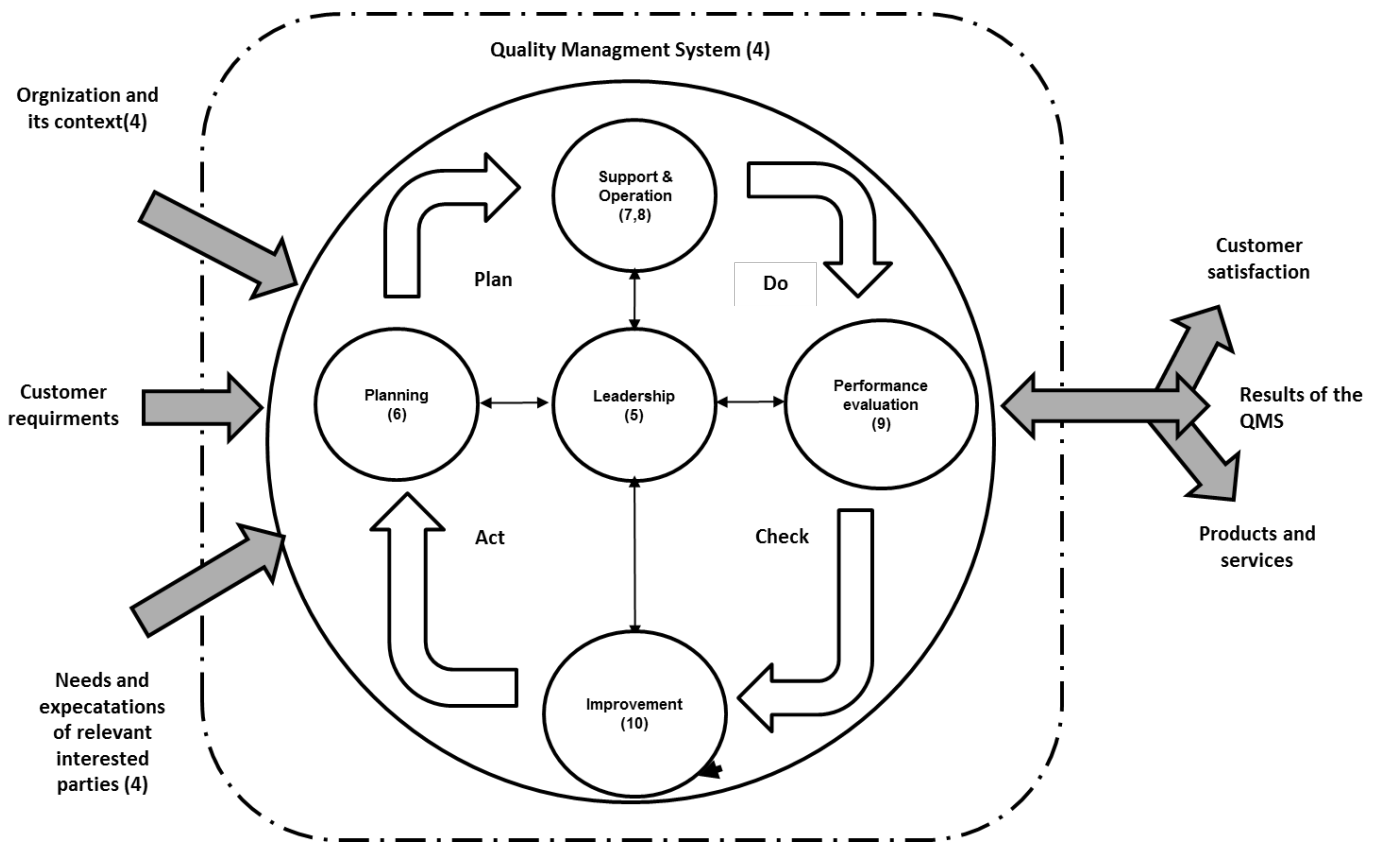
To understand this approach, let's look at an example Turtle Diagram for the transition process from ISO9001: 2008 and ISO/TS16949: 2009 to ISO9001: 2015 and IATF 16949: 2016.



The example does not attempt to cover every potential risk in making the transition, but demonstrates that unless the risks are understood and managed effectively existing certification may become invalid, potentially resulting the potential loss of automotive business.

So, now let's take a look at the structure of ISO9001: 2015 and IATF 16949: 2016. You can see from the model below is based on Plan: Do: Check: Act (PDCA), with Top Management at the centre, providing leadership and commitment to the effective implementation of the Quality Management System.

You will also see that rather than just focusing on the requirements of the customer, an organization needs to understand the needs of all interested parties. This could include regulators, local government, suppliers, outsource partners, the local community and trade association/unions.



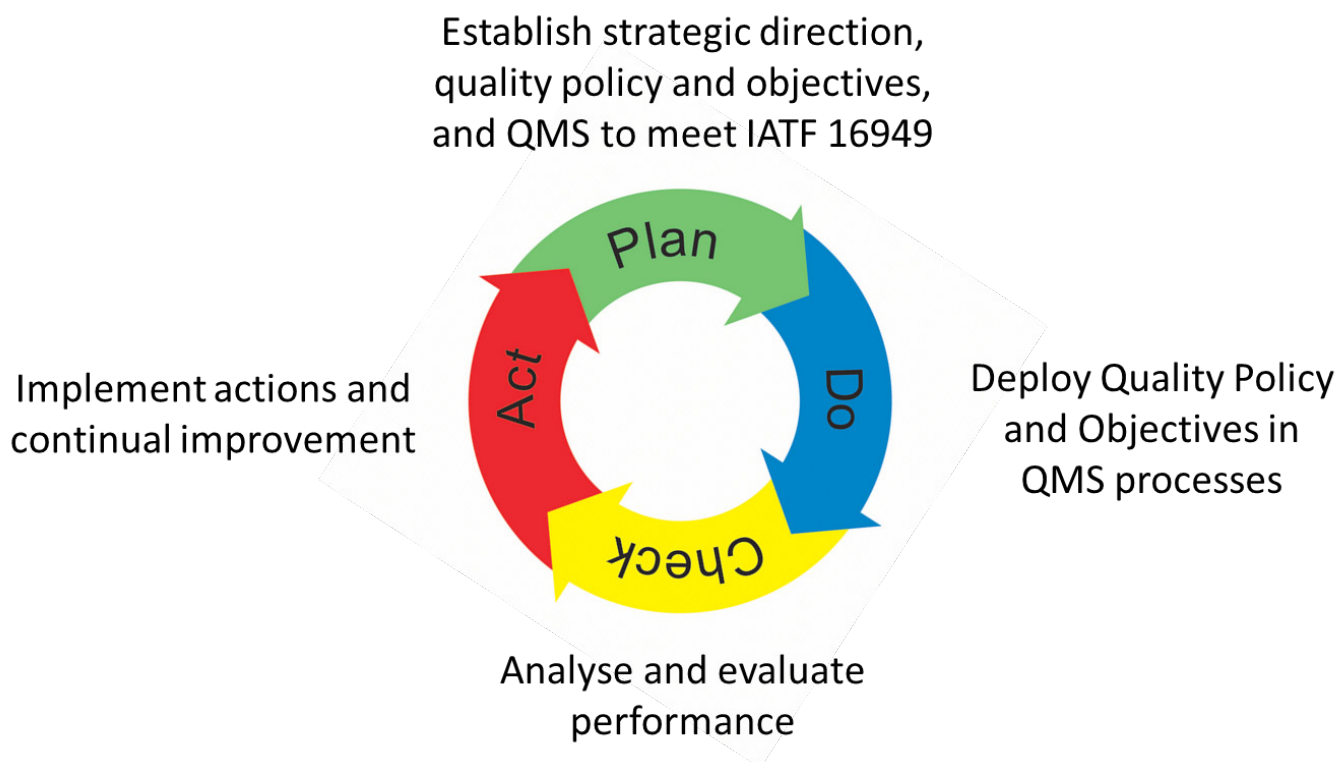
So now let's look at some of the key changes, section by section.

4. Context of the organization

While ISO/TS16949 had always had a requirement for a Business plan, showing the linkage to the organization's quality objectives, ISO9001 did not, which I always felt was a fundamental weakness. Now that has changed. ISO9001: 2015 now requires an organization to determine its strategic direction based on internal and external issues. This may include, but not limited to, external issue related to legal, technological, competitive, market, cultural, social and economic and internal issues including values, culture, performance and knowledge of the organization. Interestingly, IATF 16949 does not add to this requirements, removing the requirement that was in ISO/TS16949: 2009 related to business plan.

However, auditors will challenge Top Management on how they have established the strategic direction, how this links to the quality policy and quality objectives and how it is deployed to processes and down to all appropriate levels within the organization. Also, when developing the strategic direction, Top Management not only need to consider requirements of the customer, but take into account the needs of all "interested parties" (e.g. stakeholders, regulators, suppliers, local community, employees etc.) and take into

account risks associated with meeting their requirements.”



The other significant addition in section 4 is more focus on product safety, maybe influenced by some of the major global product recalls in recent years. There is a need for document process on how product safety is assured, including how and safety requirements are cascaded through the supply chain.

Section 5 Leadership

Before reading IATF 16949 requirements in this section we need to understand some of the fundamental changes in ISO9001: 2015. There is far more emphasis on Top Management providing leadership and support to ensure the effective implementation and maintenance of a Quality Management System. As part of this requirement, Top Management need to promote the process approach and risk based thinking and engage, direct and support employees to contribute to the effectiveness of the quality.

In previous versions of Quality Management System requirements there has always been the need to appoint a management representative. This requirement has now disappeared. This means that the responsibility to implement the Quality Management System and report performance can be delegated to all appropriate personnel, including the designated process owners.

Some of the specific changes in section 5 in IATF 16949: 2016 include:

- The need for a corporate responsibility policy, including at a minimum an anti-bribery policy, an employee code of conduct, and an ethics escalation policy.
- As well as having to ensure each process in the quality management system has a defined owner, you need to ensure you can demonstrate they are competent to manage the process!

Section 6 Planning

As well as building on the ISO9001: 2015 requirement to understand risk and opportunities in all processes, IATF 16949 adds more requirements related to effective contingency planning to ensure supply to customers (see issue 5 of newsletter, available at www.qualitypartner.co.uk)

Section 7 Support

The requirement related to plant, facility and equipment planning now includes ensuring an understanding of all of the risks in achieving manufacturing process effectiveness, including consideration of capability planning when either taking on new business or changes to existing business.

Although IATF 16949 does not add any requirements related to Organization Knowledge, this is a significant change in ISO9001: 2015. (See issue 4 of newsletter, available at www.qualitypartner.co.uk) Whereas it has always been a requirement to demonstrate competence of auditors, the requirements are now far more explicit, and include competence requirements for second party, as well as internal auditors. This does not mean you have to start from scratch, but you will need to be able to demonstrate how the defined competence requirements have been met and then how is competence maintained (for example by carrying out a defined minimum number of audits).

Quality Partner can assist in either providing training in the changes in ISO9001: 2015 and IATF 16949 to existing auditors, or training for new auditors to meet the defined requirements for internal of second party auditors. For more information contact enquiries@qualitypartner.co.uk

For more information on system, process and product audits see issue 4 of the newsletter available at www.qualitypartner.co.uk

And, do not throw away your quality manual, even though ISO9001: 2015 removed the requirement, IATF 16949 reintroduces it!

Section 8 Operation

One significant change in ISO9001: 2015 is that rather than focus on purchasing “products” requirement 8.4 covers control of externally provided **processes, products and services**.

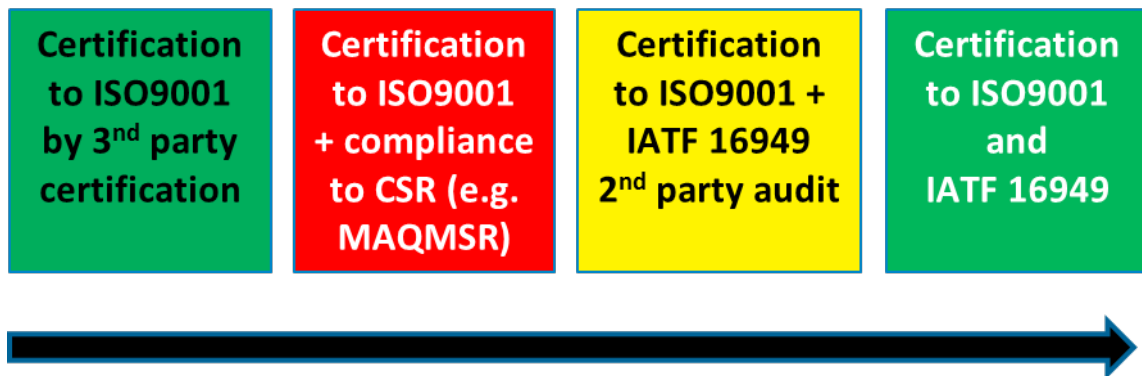
This is important to remember when looking at your current process for supplier selection and monitoring. Does the process cover selection of suppliers for not just raw materials/ products, but also selection of outsource process or service suppliers that could have an impact on quality (e.g. Outsourced heat treatment supplier, transportation supplier, maintenance service supplier etc?).

IATF 16949 introduces more stringent requirements related to supplier selection. Before a supplier is selected, the risks need to be understood that could affect supply, their quality and delivery performance (to their other customers) and what quality management systems approvals they have. 8.4.1.2 also lists other factors that should be included, including the potential supplier financial stability, their capability, the available resources (do they have spare capacity) and whether they have design and development/project management capability (if this is a requirement)

For an organization’s existing suppliers IATF 16949: 2016 now includes a much more structured requirement related to supplier development (8.4.2.3).

In simple terms, the requirement’s ultimate objective is that all eligible suppliers will be developed to become certified to IATF 16949, using a structured supplied development process outlined below.

To meet this requirement it is essential to have qualified second party auditors (see section 7 above)



Also in section 8 we see specific requirements related to selection and monitoring of suppliers involved in the development of automotive product related software. Whereas this will not affect all organizations, for those that it does there will be more audit focus on not just control of suppliers of software, but how software is managed and controlled within the organization to ensure customer requirements are met.

In 8.5, production and service provision, IATF 16949 requires standardized work (in ISO/TS16949 this requirement was work instructions) to be available in a language understood by the personnel responsible to follow them and now they must include rules for operator safety.

One of the significant changes relates to temporary changes of process controls (8.5.6.1.1). This means that if an existing control defined in the control plan is for some reason not available (lack of availability of measuring device, error proofing device etc.) approved alternative controls have to be defined and referenced in the control plan and have to be controlled using standardized work instructions. The effectiveness of the controls then needs to be monitored through daily reviews until returning to standard process.

I feel, maybe because I am biased by being a JIPM approved TPM assessor, that most organizations certified to ISO/TS16949 do not have a truly effective Total Productive Maintenance (TPM) System. Whereas many organizations can show a paperwork system to meet the requirements, a visit to the shop floor often shows machines are not being kept in optimum condition to prevent breakdowns and there is no operator involvement in the process. For a TPM system to work, I believe operators have to be involved, they are the ones using the equipment every day and can often hear/feel symptoms that means there is a potential problem with the machine.

We also see that there is more emphasis on monitoring effectiveness of the maintenance process through documented maintenance objectives, such as Overall Equipment Efficiency (OEE), Mean Time Between Failure (MTBF) and Mean Time To Repair (MTTR) and then having a regular review process, including actions taken when objectives are not met.

Finally, there is now a requirement related to how periodic overhaul of equipment is planned and managed.

Section 9 Performance evaluation

In this section we see some significant clarifications related to planning and undertaking internal audits.

- An annual audit programme covering all QMS process and manufacturing processes over 3 year cycle (9.2.2.2)
- More emphasis on reference to the Failure Mode and Effects Analysis (FMEA) and control plan in undertaking manufacturing process audits, and the sampling of shift handovers where appropriate
- More emphasis on review and update of the audit programme based on risks, changes and performance (9.2.2.1)

- More emphasis on understanding customer specific requirements related to internal audits (9.2.2.3, 9.2.2.4)

For management review, (9.3) it is now clearly stated that reviews shall be undertaken at least annually, but the frequency shall be increased based on risk. Management review inputs now include warranty performance (if applicable) and review of customer scorecards.

Section 10 Improvement

One of the key changes in this section relates to the verification of error proofing devices. Whereas it's great to have error proofing built into a process, we need to ensure that the devices actually work! To achieve this the requirement includes verification/calibration of the challenge parts and the documented information to show the challenge parts are used to verify the effective operation of the relevant error proofing device.

Finally, where applicable, we see a requirement (10.2.5) related to warranty management systems.

In summary there are some significant changes in ISO9001: 2015 and IATF 16949: 2016.

In reviewing the changes keep in mind the goal of IATF 16949: 2016:

The goal of this Automotive QMS standard is the development of a quality management system that provides for:

- continual improvement
- emphasizing defect prevention
- the reduction of variation and waste in the supply chain

In making any change to the Quality Management System you should ask the question how the change will help your organization improve customer satisfaction and internal efficiency.

Quality Partner has a global network of qualified trainers and consultants to help you make a successful transition. For more information contact enquiries@qualitypartner.co.uk.

Ask the expert

Question

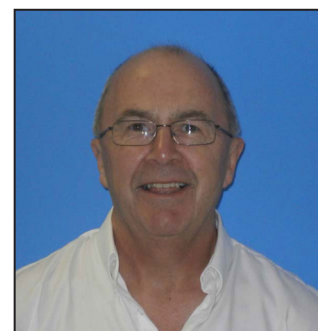
I see in IATF 16949 reference to both rework and repair, however there is no definition. What is the difference?

Answer

Good questions, I asked the same question when I reviewed the draft and have yet to get an answer. However, in the historic QS-9000 the definition was:

- Repair: Action taken on nonconforming product so that the product will fulfill the intended usage although the product may not conform to the original requirements.
- Rework: Action taken on nonconforming product so that it will meet the specified requirements.

I have proposed to IATF Oversight that a definition is communicated as a FAQ, watch this space.



Question

I see in the requirement 6.1.2.3 Contingency planning it mentions about validating the restart of production when the regular planned shutdown was not followed. Is this referring to the action after breakdown or other issues?

Answer

This could relate to a breakdown, but could also apply in the case of a utility interruption, for example, where the normal shutdown process is not followed (for example it may be practice to cool down a furnace at the end of shift, but if there is a utility interruption this normal shutdown is not followed. In this case the question is, when the process is restarted, how the process is revalidated to ensure the forced shutdown did not have a detrimental effect on either the machine or the process.

Question

I see in IATF 16949 that in many places it uses the term 'documented process'. However, I can see no definition for this term in either ISO9001: 2015 or IATF 16949: 2016. What does this term mean?

Answer

You are right, there is no definition. So given no guidance, it is up to an organization how to document how the activity is performed. This most commonly will be by a process flow chart, but could be in a written procedure/instruction. However, the important thing to remember is that, as it refers to "a process", it should be clear from the document who owns the process, what are the inputs and outputs, and how it is ensured the intended results are met.

Question

I see in IATF 16949 8.4.2.3 it references Minimum Automotive Quality Management System Requirements for Sub-Tier Suppliers (MAQMSR). What is the purpose of this document and where can I find it?

Answer

The document is a useful reference documented in the supplier development process, and in fact is mandated in certain customer specific requirements. It is in simple terms a half-way house between ISO9000: 2015 and IATF 16949: 2016. So for example if you identify a supplier who has ISO9001: 2015 certification and you want to develop towards IATF 16949: 2016, but the supplier is put off by the size of the task, encouraging them to use MAQMSR to help them on the journey may be beneficial. The document can be downloaded free of charge by visiting: <http://iatfglobaloversight.org/content.aspx?page=FordMotorCompany> At the moment the document is still written to ISO/TS16949 but an update is expected shortly.