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Firstly, wishing you all a very safe, happy, and successful 2021!

Welcome to the twenty first edition of the Quality Partner newsletter. The newsletter is designed to keep readers up to date with developments in Quality Management Systems.

For this edition I again sought ideas and inspiration from the IATF 16949 LinkedIn group. The group is a great forum to share and discuss issues with IATF 16949 and the associated scheme, with over 37,000 members.

Considering ideas from the group, this issue focuses on

- Roles responsibilities and authorities for manufacturing process improvement
- Undertaking effective remote audits
- QP remote training programme 2021
- Sanctioned interpretation 20, 10.2.3 Problem solving
- Questions from LinkedIn colleagues and answers

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

On reflection 2020 was a challenging year for many of us, with massive changes in working practices due to the Covid 19 pandemic.

Before the pandemic, like many others, I had not delivered remote training or undertaken a remote audit. I must be honest in saying that in the first couple of months it was incredibly challenging to stay motivated, but to survive we must adapt, learn, and always strive to do things better.

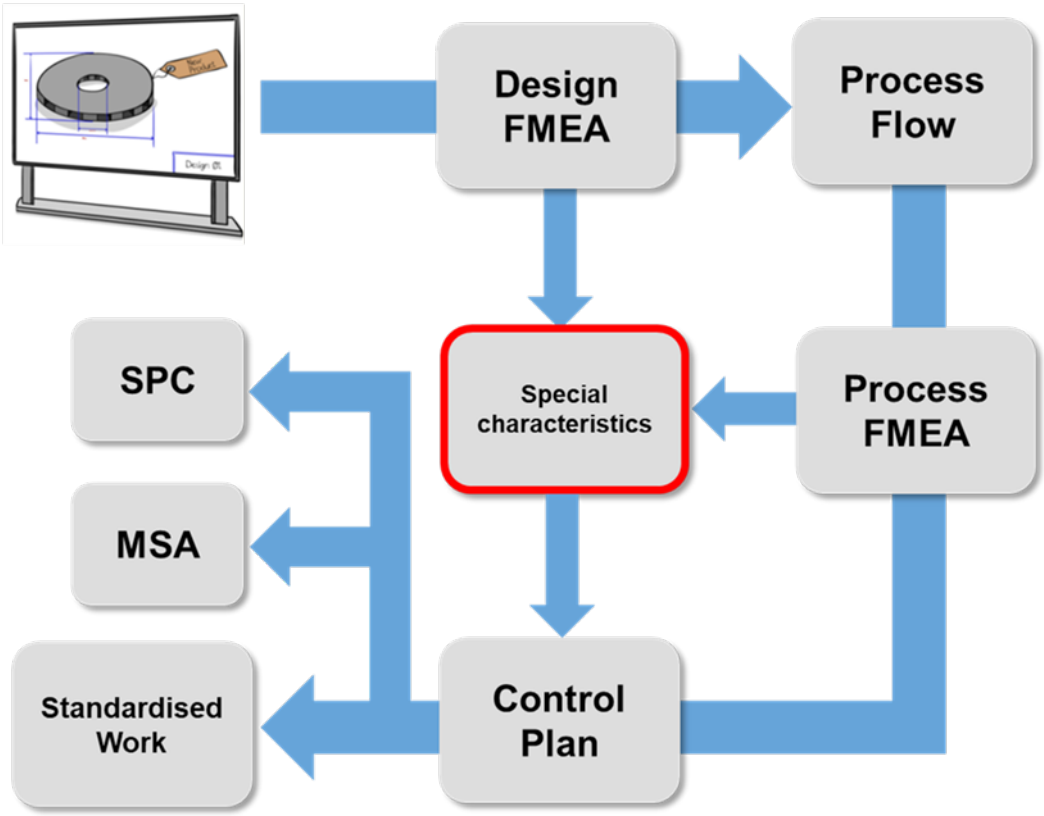
I believe every remote training course I have delivered I have learnt from and used to improve my teaching technique. I am sure the learning will continue in 2021!

Let us continue to network and learn together!

For more information on onsite and remote courses related to IATF 16949, best practice auditing, and effective implementation of the automotive core tools contact: paul.hardiman@qualitypartner.co.uk

Are roles, responsibilities and authorities clear?

We have spoken several times before in this newsletter about the importance of the effective implementation of the automotive core tools in the new product introduction process, developed by a multidisciplinary team, within the framework of a project management approach.



In this article we will explore why, after new product introduction, so many nonconformities are found in 3rd party audits related to the effective review and update of the relevant core tool documentation.

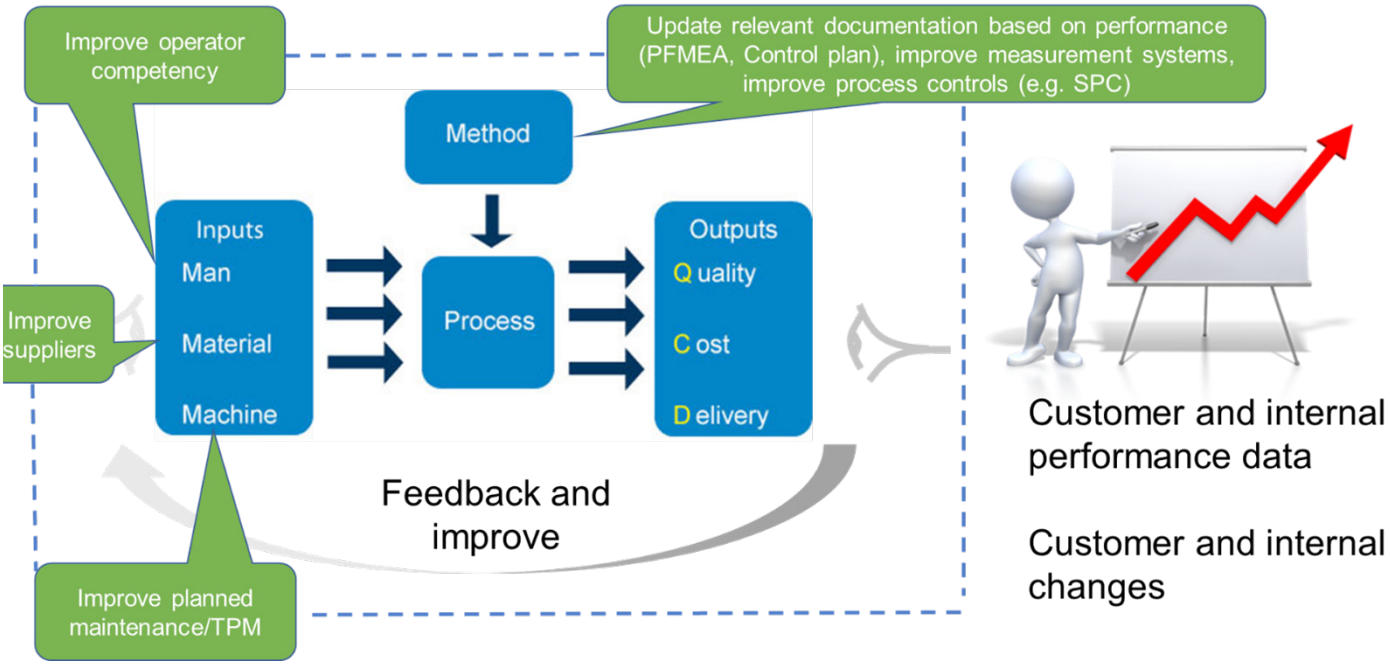
Let us go back to basics. For the manufacturing process, if we effectively control the 4M (Man, Machine, Method and Material (we could also add Measurement and Environment)) then the process should produce an output that meets the customer and relevant interested party expectations.

In accordance with IATF 16949, an organization must set measurable Quality Objectives (sometimes known as KPI's) to measure manufacturing process performance on an ongoing basis, considering customer and interested party expectations.

But after a successful new product introduction are roles, responsibilities and authorities defined to ensure ongoing manufacturing process compliance and drive process improvement?

ISO9001: 2015, clause 5.3 requires: "Top management shall ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization."

Let us explore this using the 4M related to a manufacturing process:



Method: Considering customer and internal performance data, and any proposed customer or internal changes, who has the defined role, responsibility, and authority to:

- Instigate the multidisciplinary team to review the PFMEA, Control Plan and standardized work?
- Review the suitability and capability of the relevant measurement systems?
- Establish the need to change/improve process controls? (for example, implementation of SPC)

Man: Considering customer and internal performance data, and any proposed customer or internal changes, who has the defined role, responsibility, and authority to:

- Identify training needs because of external or internal performance issues?
- Identify training needs related to any product or process change?
- Ensure that training is provided in a timely manner to address any training needs?
- Measure the effectiveness of any training and ensure appropriate records of training are available?

Material: Considering customer and internal performance data, and any proposed customer or internal changes, who has the defined role, responsibility, and authority to:

- Investigate an issue cause by any incoming material to the process, including communication with any external suppliers as applicable?
- Ensure any changes to incoming materials to the process are effectively managed? (Permanent and temporary changes)

Machine: Considering customer and internal performance data, and any proposed customer or internal changes, who has the defined role, responsibility, and authority to:

- Investigate and resolve any issue with the machines used in the process?
- Update any maintenance instructions after any changes?
- Manage any changes proposed related to a machine, ensuring the appropriate risk analysis?

The key is to make sure people know their roles, responsibilities, and authorities, and know they are accountable to ensure customer and internal performance objectives are met.

Although the process owner is ultimately accountable for the manufacturing process performance, to be successful there needs to be a multidisciplinary approach, not just for initial product and process approval, but to drive ongoing process improvement.

Requirement 10.3.1 Continual improvement it states “The organization shall have a documented process for continual improvement. The organization shall include in this process the following:

a) identification of the methodology used, objectives, measurement, effectiveness, and documented information;
b) a manufacturing process improvement action plan with emphasis on the reduction of process variation and waste;
c) risk analysis (such as FMEA)”.

This may be the last requirement in IATF 16949 but is probably one of the most important!

Remote auditing best practice
Who would have thought at the beginning of 2020 that we would see such a radical change in the way audits are undertaken, driven by the global Covid 19 pandemic?

In October 2020 IATF sanctioned the use of remote 3rd party audits where an onsite audit cannot be undertaken as a direct result of the Covid 19 pandemic. In the same “IATF GLOBAL WAIVERS AND MEASURES IN RESPONSE TO THE CORONAVIRUS PANDEMIC (COVID-19)” document, frequently asked question 3 allows an organization to perform remote internal audits if an appropriate risk analysis is undertaken.

But is there enough guidance available on how to perform an effective remote audit?

In my view, no!

The Annex A, IATF remote audit requirements in the above document, focuses more on the technology aspect of a remote audit, not how to undertake one. In section 2.1 of Annex A it states “Conduct the audit using methods and approaches to replicate an onsite audit as much as possible.”

My reading of this is auditors should apply the “Automotive process approach incorporating risk-based thinking” in undertaking a remote audit.

Let us break this down into the steps in the audit process:

Audit planning
For 3rd party audits IATF state: “The certification body shall calculate 10% of the total audit days, but no more than a maximum of eight (8) hours, and apply this time to complete the additional audit planning steps required for a remote audit.”

From my experience, to undertake an effective IATF 16949 remote audit planning is even more important, hence the recognition by IATF that additional time is needed. This can also apply to internal or second party audits.

What should be reviewed in the planning of a remote audit?

Firstly, before starting planning, it should be ensured the scope of the audit is clear, which process(es) will be audited, who is the owner (s) of the process (es), and what technology will be used to undertake the audit.

Then relevant performance data should be sought and reviewed to identify the areas of highest risk.

For example, if the scope of the audit includes manufacturing:

Undertake a detailed review of customer performance/scorecard data to determine:
- Which customer products to focus on during the remote audit based on the performance/scorecard data. Planning needs to drill down to which specific part numbers there have been issues with, and which is/are the relevant manufacturing process to focus on during the remote audit. As defined in the IATF rules, “priority shall be given to products supplied to IATF OEM members.”

Undertake a detailed review of internal performance data to determine:
- Which products to focus on during the remote audit based on the internal performance data. Planning needs to drill down to which specific part numbers there have been issues with, and which is/are the relevant manufacturing process to focus on during the remote audit. Also, in the review, consideration should be given on which shift is causing the greatest number of issues, as this may influence the audit plan and timing of the remote audit.

Note: This is important to confirm in the planning as the process owner will need to prepare to be able to show you the specific work area on the relevant shift and allow you to interview the relevant production personal at the workstation/process area.

Based on the review of the above information, in advance of the audit, the relevant documentation can be requested from the process owner (for example the relevant PFMEA, control plan, QMS processes/ procedures etc).

The output of this review will be a detailed audit plan and detailed audit questions.

The audit plan may need to go into more detail than that for an onsite audit, to help the process owner (s) make sure the relevant personnel will be available for the remote audit at the right time, (bearing in mind that some personnel may not be at the site and could be working from home) and the relevant information

will be retrievable during the audit (for example project information, FMEA, control plans etc.)

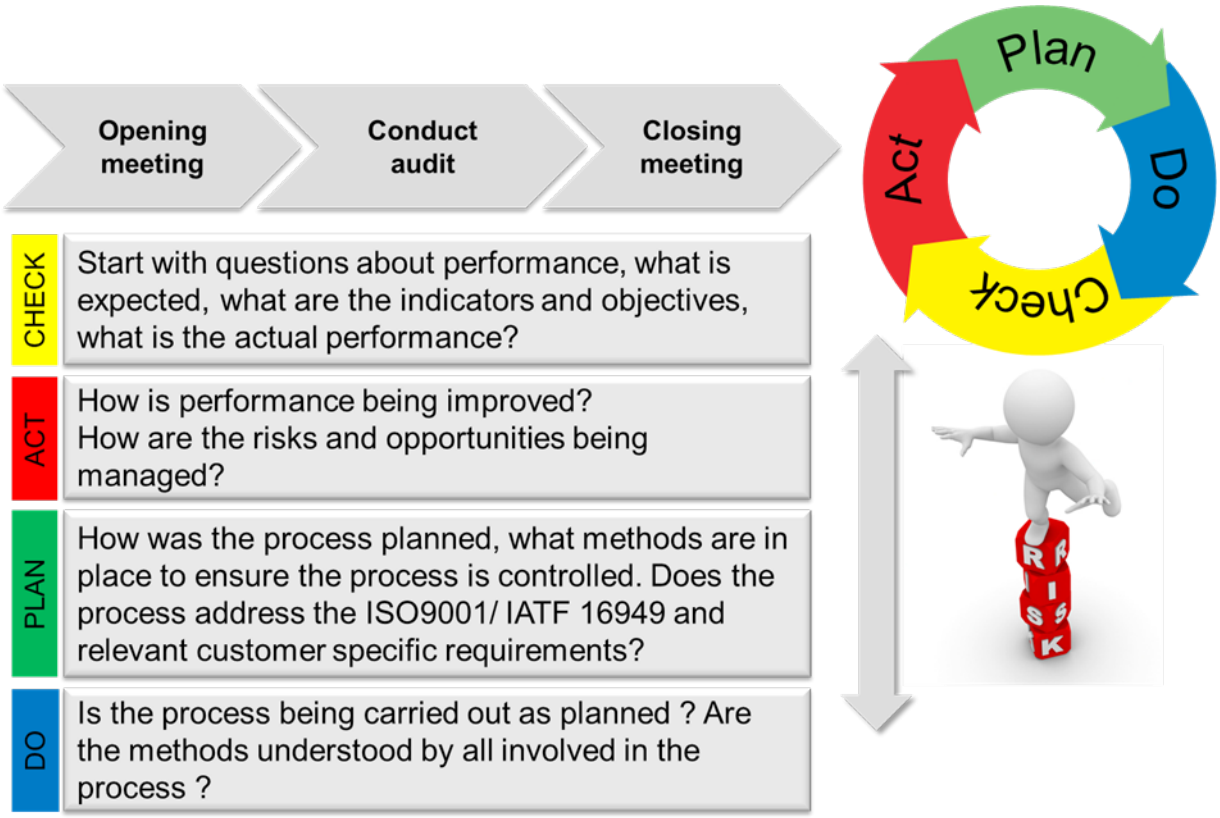
If multiple auditors are to be included in the audit team, it is essential that the logistics for this are fully understood, for example:

- For what part of the audit do the audit team need to be together using the same connection link? (e.g., Opening meeting, etc.)
- Where auditors will need to connect with the relevant process owners/ auditees through separate links or use break out rooms?
- How will the auditors communicate and share audit information as the audit unfolds?

Undertaking the remote audit

Below are some key points to be considered in undertaking an effective remote audit:

- The audit should not just be undertaken with the client coordinator/management representative, but must be with the relevant process owner and those participating in the process
- The auditor must select the samples for the audit, not let the auditee dictate. The audit questions should be driven by the performance data and risks identified in the audit planning, driven by the CAPDo approach outline below:



- Do not get rushed into reviewing information/documentation. Ask the auditee to share screen to show the information you request, and only let them move/scroll the information when you have had a chance to review
- Allow auditee (s) sufficient time to be able to answer questions
- Make sufficient notes, to enable you to draw conclusions on compliance/noncompliance
- Where required, get the process owner to “take you” to the relevant work area by using the relevant remote technology (for example to a specific manufacturing area, where audit planning identified a specific risk to investigate). Where safe to do so, get the process owner/auditee to allow you to talk to the relevant people involved in the process (team leaders, operators etc.)
- Ensure regular communication with the process owner regarding any potential issues identified, and progress against the audit plan. Remember any nonconformity needs to be based on the objective

evidence collected during the audit
- Take regular breaks during the audit, remote audits are tiring for the auditor and auditee!

Reporting the remote audit
When the audit is completed, based on the objective evidence collected, a decision needs to be made on any potential nonconformities/opportunities for improvement identified.

A time needs to be arranged with the process owner to be able to verbally give the feedback on the result of the audit, and agree any nonconformities identified. My preference is to do this feedback before the final report is prepared.

Following agreement of the findings, the audit report must be issued and acknowledged by the process owner, including agreement on the corrective action timescales, and proposed follow up actions.

Conclusion
From my experience, undertaking an effective remote audit is more challenging than doing a “face to face, onsite audit”. The key to success is effective audit planning and ensuring the “Automotive process approach” is utilised, by driving audit questions based on performance and risk.

Would welcome feedback on your experiences.

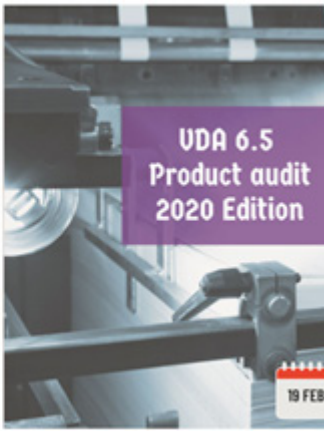
Remote training with recognised experts

I am delighted to announce that Quality Partner UK, in association with Quality Partner Thailand, will be delivering more online workshops in 2021.

The first series of workshops is arranged for the week commencing 15th February 2021. Each workshop is priced at an amazing $50 per delegate, fully inclusive of all course materials and course certificate.

All workshops have breakout sessions to work on case studies/group exercises to help ensure effective learning.

The programme is below:



Full details of each course, and how to book places can be found at:

https://www.qualitypartner.org/en/

IATF sanctioned interpretation SI 20

In December 2020 SI 20 was issued by IATF related to problem solving.

The SI changed the 10.2.3 Problem solving requirement to: “The organization shall have a documented process(es) for problem solving, which prevent(s) recurrence, including:

The SI is effective from the 1st January 2021. So, what will auditors look when auditing against the SI?

Firstly, is the organization aware of the SI! It surprizes me that many certified organizations are unaware of SI’s and have not subscribed to updates at www.iatfglobaloversight.org

Secondly, has the organization reviewed their documented process (es) related to problem solving to ensure action to prevent recurrence is included. Remember 10.2.3 is not just related to customer complaints, but problem solving to address internal issues, internal and external audit nonconformities etc.

Then any audit must focus on the effectiveness of the problem-solving process. Remember the fact we are talking about problem solving the problem has already happened! This is different from preventive action (AITF 16949 6.1.2.2) which focuses on taking action to eliminate the causes of **potential** nonconformities in order to **prevent** their occurrence.

How can the effectiveness of the problem-solving process be measured?
In a typical problem-solving process, one step is “verification of effectiveness” of actions taken to address the root cause (s) of a problem. This could be by monitoring data (internal or external) to see if there are any repeat issues related to initial problem. The length of time to monitor could depend on the specific situation (for example for an infrequently manufactured part the monitoring time could be longer than for a frequently manufactured part).

The ultimate measure of effectiveness is how many repeat concerns have there been over a defined period. If there have been repeat concerns, the auditor should follow audit trails to see how the organization investigated this, considering what aspect of the problem-solving process failed and what actions were defined to improve the process.

Finally remember this is for all types of problems, not just customer concerns!

Quality Partner’s expert, Paul Hardiman

Ask the expert

Question
What is the situation regarding an update of ISO9001: 2015?

Answer
The committee responsible for reviewing ISO9001 is ISO/TC176/SC2

ISO 9001 is currently being formally reviewed to determine if it should be revised. Following the review process, a decision on whether or not to start a revision will be made by ISO/TC 176/SC2 towards the end of the first quarter of 2021.

As an input to making the decision, the subgroup SC2 sought to obtain the views of users of ISO 9001:2015 on whether the standard is adequate, or if it should be improved. The survey closed on the 31st December 2020.

In addition, ISO/TC 176 has been giving consideration to “future concepts” for quality. They would like to test the acceptability of such concepts with users, for potential inclusion in a future edition of ISO 9001.

It is unlikely that, if ISO decide to proceed with modifying ISO9001: 2015, that we will see any revised standard until 2023/2024 at the earliest.

In 2021 IATF will be working on an update of the Rules for Achieving IATF recognition, so it is unlikely there will be any new issue of IATF 16949 for some time! (apart from periodic sanctioned interpretations).

I think, given the very tough 2020 we have just experienced, the automotive supply chain will welcome this news, many organizations are still trying to catch up in fully understanding the 2016 edition!

Question
In IATF 16949 many times (62 times in total) the word risk is used. What is different between risk-based thinking and contingency planning?

Answer
Effective contingency planning is information that can be used as evidence that Top Management are “promoting the use of the process approach incorporating risk-based thing” (as required by ISO9001: 2015 5.1.1.d)

Whereas many of the requirements related to risk in IATF 16949 consider risks to the customer, the organization and relevant interested parties, contingency planning solely focuses on risks that could potentially affect the organizations ability to maintain production output and to ensure that customer requirements are met.

Obviously, there will be more focus on the effectiveness of the organizations contingency plan, considering the impact of the Covid 19 pandemic.

If 100% on time delivery has not been achieved, the organization should question “what in our contingency plan failed and what improvements do we need to make to prevent reoccurrence?

To address the other IATF requirements related to risk, there are many methods that can be promoted by Top Management.

Examples are:
- Brainstorming
- Questionnaires
- Industry benchmarking
- Scenario analysis
- Risk assessment workshops
- **Auditing***
- **FMEA***
- Turtle diagrams
- Fault tree analysis
- **Contingency planning***

- **Feasibility review***

*The ones identified in bold are mandatory in IATF 16949

Apart from FMEA, where there may be specific risk ranking criteria specified by the customer or applicable reference manual, there is no requirement to rank risks. But, if no ranking system is used, the auditor can challenge management on how they meet the management review requirement:

"The management review shall be planned and carried out taking into consideration: e) The effectiveness of the action taken to address risk and opportunity"

If there are no criteria to rank risk how do you decide which risks need to be addressed?

Question:
How can IATF 16949 help organizations manage the biggest risks in the supply chain due to the Covid 19 pandemic?

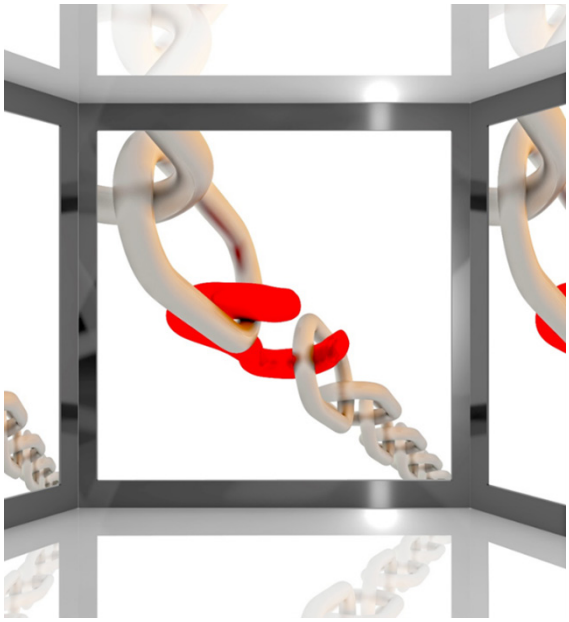
Answer:
In IATF 16949 there is a detailed requirement, 8.4.1.2 Supplier selection process, on things to consider when selecting a new supplier.

This includes "should be considered" requirements:
- The financial stability of the supplier
- business continuity planning (e.g. disaster preparedness, contingency planning);
- logistics process

Obviously, this information would have only been current at the time the data was collected.

The Covid 19 pandemic has significantly changed supply chain risk, notably by affecting supplier's financial stability, contingency planning, and logistics processes.

How does the organization monitor these changing risks, that if not managed effectively, could affect continuity of supply from the suppliers?



Obviously, performance data can be used, but acting on this alone would be more reactive, not proactive. In the IATF 16949 requirement 8.4.2.4.1 Second party audits it states:

The organization shall include a second-party audit process in their supplier management approach. Second-party audits may be used for the following:

*a) **supplier risk assessment;***
b) supplier monitoring;
c) supplier QMS development;
d) product audits;
e) process audits.

My audit question would be "What ongoing risk assessment is conducted related to suppliers, how is the information analysed and how is this information used to prioritise second party audits?"

Remember second party audits could be onsite or remote, and the scope of the second party audit could be based on the potential risks identified.

For example, if the supplier is in an area with a high Covid 19 infection rate, where government restrictions limit working or travel, what is the supplier doing to ensure continuity of supply?

Question
Could you please write about expectations of 3rd party auditors regarding production restart protocols related to COVID-19?

Answer
Firstly, let us look at the relevant IATF 16949 requirements:

8.5.1.4 Verification after shutdown

"The organization shall define and implement the necessary actions to ensure product compliance with requirements after a planned or unplanned production shutdown period."

This was a new requirement in IATF 16949: 2016, added way before Covid 19!

Obviously, this is an "umbrella" requirement to ensure that after any restart **all** the relevant actions are taken to ensure the product conforms to customer and any internal specifications.

I believe the most relevant requirements to help ensure this are:

- 8.5.1.3 Verification of job set-ups

After a shutdown, in addition to the normal verification of job set up, additional checks may have to be performed to verify the set up is correct to ensure conforming product.

- 8.5.1.5 Total productive maintenance

Depending on the type of process, before the process is restarted there may need to be additional checks performed on the machine (s) to ensure operator safety (checking safety guards etc) and to ensure effective machine operation (additional lubrication etc.)

- 7.2.2 Competence — on-the-job training

Depending on the length of any shutdown, operators may require refresher training to ensure they are competent to perform their given tasks

- 8.7.1.3 Control of suspect product

Finally, on the initial batches produced, there may need to be additional inspections/test to verify product compliance, including any relevant training in the containment process.