Quality Partner Newsletter

July 2018

Welcome to the twelth edition of the Quality Partner newsletter.

The newsletter is designed to keep readers up to date with developments in Quality Management Systems. This issue focuses on:

- Top 10 major nonconformities found in IATF audits (2018)
- ISO19011: 2018 Guidelines for auditing management systems: What are the changes?
- The IATF 16949 appeals process
- Questions and answers related to IATF 16949

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

Auditor competency

As many of you are aware there are enhanced requirements in IATF 16949: 2016 related to internal and second party auditor competence.

This month has also seen the publication of a revision to ISO19011: 2018: Guidelines of auditing management systems, which also has an enhanced guideline on auditor competency, focused on the process approach incorporating risk-based thinking.

Following last year's launch of successful video series on the IATF transition and the automotive core tools, Quality Partner has produced a series of videos on the audit process, from developing an audit programme, through to full completion of an audit.

These are suitable for new management system auditors or existing auditors look to further enhance their skills.

The series includes 10 videos suitable for any management system audit (ISO9001, ISO14001 and ISO45001) and there are 4 specific to IATF 16949: 2016 (introduction, system, manufacturing process and product audit).

There are several cost-effective purchase options, from renting individual videos online to unlimited use of the full series in downloadable format. For those purchasing the full series there is also a comprehensive online exam. If you would like more details on this new video series, please contact paul.hardiman@qualitypartner.co.uk

For More Information Visit www.qualitypartner.co.uk

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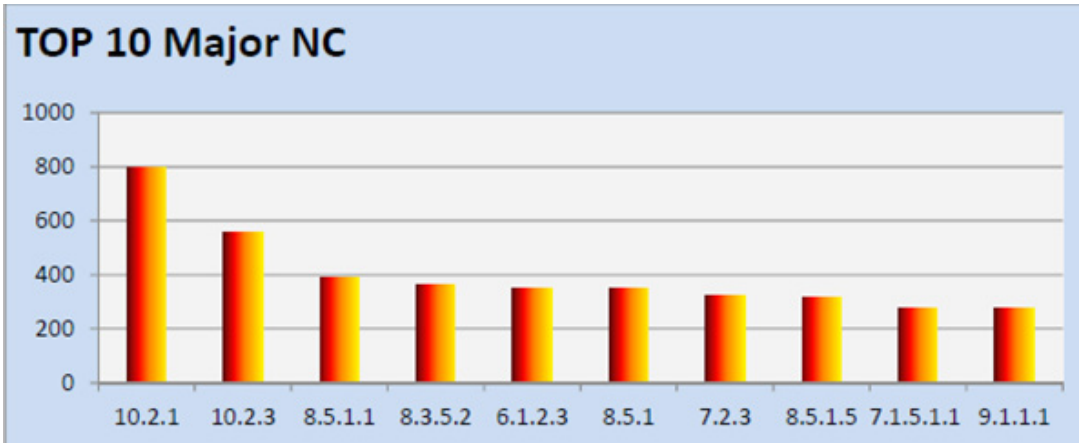
Top 10 Major nonconformities found in IATF 16949 third party audits in 2018 YTD



10.2.1 Nonconformity and corrective action and 10.2.3 Problem solving

I find it disappointing that, nearly 20 years after the first issue of ISO/TS16949 that organizations still are having a major problem in ensuring employees are competent in effective problem solving and applying the relevant tools and techniques. Whereas many organizations have, due to customer pressure, improved dealing with customer concerns, these requirements also cover dealing with internal concerns, internal and external audit findings. Since the IATF rules were changed (4th to 5th edition), where, if a minor nonconformity was not addressed effectively from a previous third-party audit it is changed to a major nonconformity, and an additional major nonconformity raised against corrective action (10.2.1), this has helped contribute to the high number of nonconformities against these requirements.

Quality Partner offers a one-day course on practical problem solving including case studies and practical exercises. For more information contact Paul Hardiman at paul.hardiman@qualitypartner.co.uk

8.5.1 Control of production and service provision, 8.5.1.1 Control plan, and 9.1.1.1 Monitoring and measuring of manufacturing processes

Again, this is surprising, as these are not new IATF requirements, they have been almost the same for the last 20 years or more! With the IATF rules now mandating that third-party auditors spend a minimum of 1/3 of the available audit time in the production process, with a focus on the effective implementation of the PFMEA and control plan, it is even more essential for an organization to have a robust internal manufacturing process audit programme to identify any issues and ensure systemic corrective action is taken to address them effectively.

8.3.5.2 Manufacturing process design output

This requirement contains some interesting additional requirements compared to ISO/TS16949, including capacity analysis and maintenance plans/work instructions for any newly introduced processes/equipment. An organization needs not only to ensure that all the part approval documentation is prepared and accepted by the customer, but all the required internal documentation required by production, needed to make the product at the required quality level at the required rate, is prepared, communicated, and the relevant people trained/ verified as competent in the new product/process introduced.

6.1.2.3 Contingency plans

I am not surprised by this being in the top ten! In many organizations I believe the contingency planning process is not robust (if they are why are there so many organizations not meeting 100% on time delivery!) and often contingency plans are developed by an individual rather than a team.

The enhanced requirement in IATF 16949 puts more emphasis on the process to develop/review the plan(s) with a multidisciplinary team including top management and mandating the contingency plan includes key equipment failures, interruption from externally provided products, processes and services, recurring natural disasters, fire, utility disruptions, labour shortages or infrastructure disruptions.

Some companies have also failed to provide evidence of testing the contingency plan for effectiveness. Obviously, this is where practical! I advise clients that one way to do this is by simulation, maybe in an audit situation, where the people responsible for the relevant aspects of the contingency plan are interviewed on how they would respond in certain situations, and then compare responses back to the defined contingency plan. Evidence of these “audits” can be maintained as evidence of the simulation.

7.2.3 Internal auditor competency

As soon as this requirement was defined by IATF, it was always going to be “low hanging fruit” for third party auditors to raise nonconformities.

Firstly, note that the requirement does not say internal auditors have to be “trained” (whether in an external course or internally). However, an organization needs to ensure auditors are competent and understand the process approach including risk-based thinking, the relevant customer specific requirements, the automotive core tools, ISO9001:2015 and IATF 16949: 2016 requirements, and know how to plan, undertake and report audits.

Many organizations have used the set of videos and exams produced by Quality Partner to address auditor understanding of the automotive core tools. If you need further information on this series and the costs, please contact Paul.hardiman@qualitypartner.co.uk. As well as being suitable for internal auditors, the videos can also help in developing operator, supervisor and engineer understanding of the tools.

Quality Partner has also just released a full set of videos on the audit process, from creating an audit programme, planning, undertaking, reporting and closing out audit findings. These videos, and the exam completed at the end of the series, are a cost-effective way either to train new auditors or to act as a refresher for existing auditors and are relevant to any management system standard audit (suitable for ISO9001, ISO14001, ISO45001 etc.) An addition 4 videos, included in the series, cover more detail on IATF 16949, and system, manufacturing process and product audits.

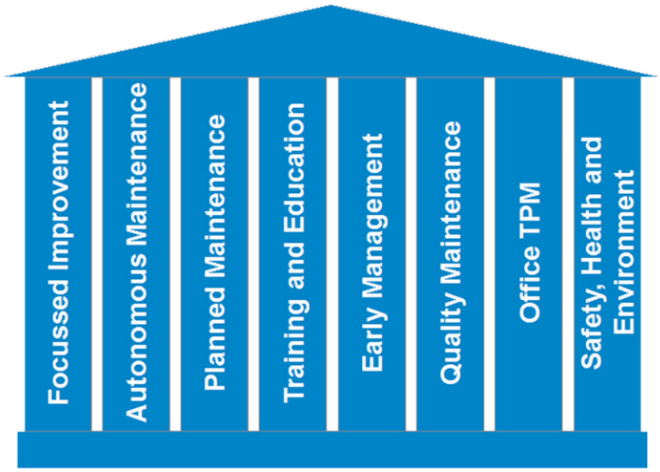
For more details and costs contact paul.hardiman@qualitypartner.co.uk

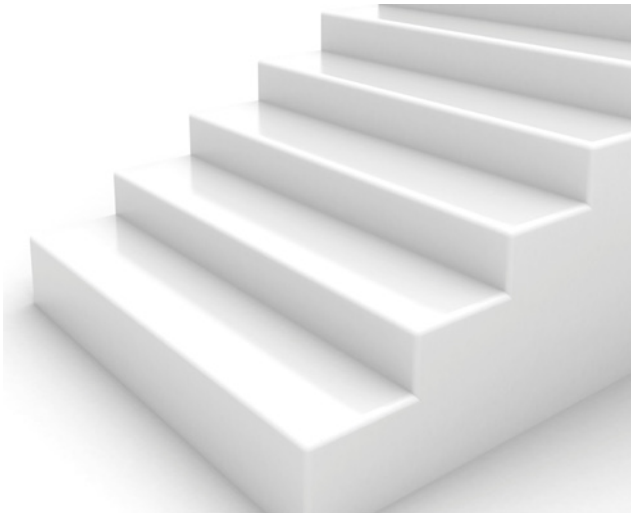
8.5.1.5 Total Productive Maintenance

I have mentioned in previous newsletters that I do not believe the requirements stated in IATF 16949 are a reflection of “true TPM”.

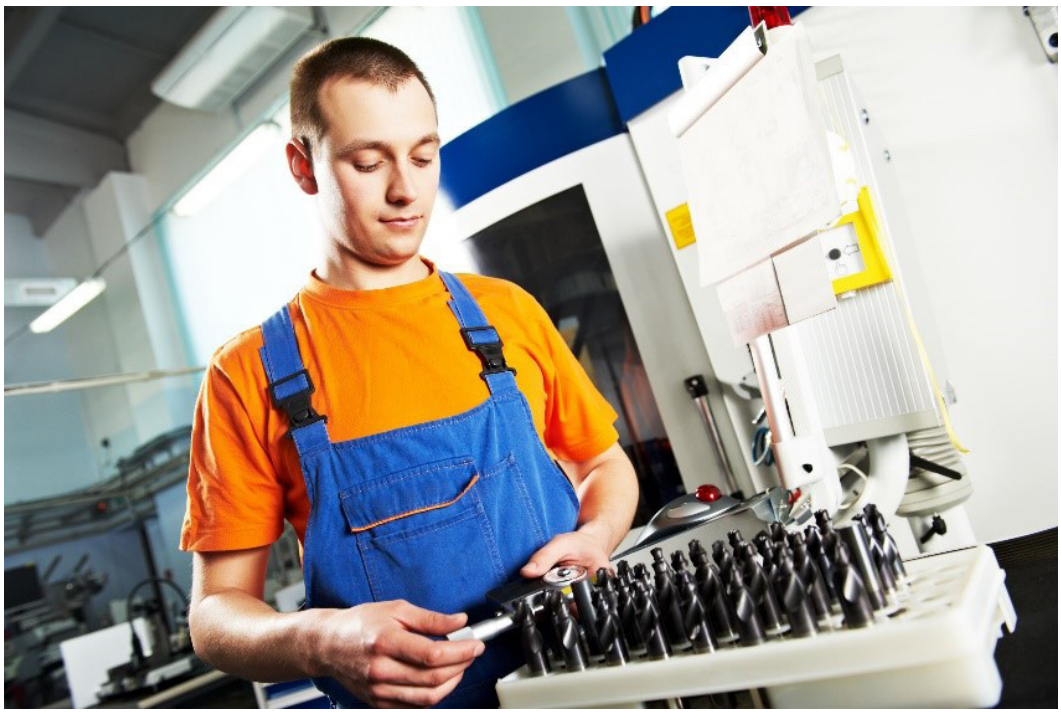
However, the requirement is tougher than in ISO/TS16949. There is more emphasis on setting clear maintenance objectives, providing sufficient maintenance resources, and where maintenance objectives are not met, the process owner should be able to show a clear action plan to address any shortfall in performance.

Also, in requirement 8.5.1.7, it now makes it clear that planned maintenance must be included in the production planning process (in many company's maintenance has the resource, but production will not let them have access to the machines!)





Paul Hardiman was the first person outside Japan to be qualified by the Japan Institute of Plant Maintenance (JIPM) to undertake assessments against the JIPM TPM award scheme. If you are interested in implementing TPM using the proven "pillar" step by step approach contact paul.hardiman@qualitypartner.co.uk to discuss support including gap analysis, training or coaching support.



7.1.5.1.1 Measurement System Analysis

Even 20 years on, I believe MSA is still one of the requirements in IATF 16949 least understood by organizations! Many organizations have a Gauge R &R excel spreadsheet (often given to them by a consultant or downloaded from the internet), where they measure some parts (often not the normal people

doing the measurement), input the data, but have no idea how to interpret the data. Also, I seen many corrupt spreadsheets with wrong formula that make the data worthless anyway!
IATF have put a lot of pressure on the certification bodies to improve auditor knowledge in this area and know how to undertake an effective audit of MSA within the relevant processes, and hence it is now in the top 10 major nonconformity listing.
Many organizations need to increase the skills in this core tool and understand that MSA does not only = gauge R & R, but also value can be gained by understanding bias, linearity and stability for variable equipment, and equipment attribute agreement analysis for attribute measuring systems (e.g. Visual, go-no go gauges etc.)

In the core tool video and exam series produced by Quality Partner, are included 4 on MSA, that can help educate and upskill in this area. For more information contact paul.hardiman@qualitypartner.co.uk

ISO19011: 2018 Guidelines for auditing management systems

In July 2018, after a long drafting and consultation period, ISO published the 3rd edition of ISO19011, the internationally recognised guidelines for auditing management systems. This replaces the previous version (2011) which is now superseded.

Let's now look at some of the key changes:

What are the key changes?

Not surprisingly, with the increased emphasis on Risk Management in ISO9001, ISO14001 and ISO45001, many of the changes in ISO19011 relate to understanding and auditing risk using the process approach to auditing.

The key changes are outlined below:

Risk-based approach to auditing:

- Auditors should be focused on the intended result of the management system throughout the audit process. While processes and what they achieve are important, the result of the management system and its performance are what counts. This means that when preparing and undertaking an audit, the auditor should focus not only on compliance to the relevant management system documentation, but the process objectives (KPI's), whether the objectives are being met, and if not, what action is being taken to address the issue(s).

- Audit planning should address or reference: the processes to be audited, the locations (physical and virtual), the need to familiarise themselves with the auditee's facilities and processes. This may include, before the start of the audit, the auditor going to visit the area where the process is performed, which will help in ensuring the effective planning for the audit.

- When auditing the Management processes, auditors should interview top management to confirm that they have an adequate understanding of the management system, the context their organization operates within and the strategic direction, so that they can ensure that the management system achieves its intended results. Auditors should not only focus on leadership at the Top Management level but should also audit leadership and commitment at other levels of management, as appropriate.

- An audit of an organization's approach to the determination of risks and opportunities should not be performed as a stand-alone activity. It should be implicit during the entire audit of all processes in the management system, including when interviewing Top Management. The organization's treatment of its risks and opportunities, including the level of risk it wishes to accept and how it is controlled, will require the application of professional judgement by the auditor, as this is not defined in any standard.

- Auditors should have relevant sector-specific knowledge and understanding of the management tools that organizations can use to make a judgement regarding the effectiveness of the processes. This is in line with the IATF requirement 7.2.3 which requires audits to have a technical understanding of the process to be audited. For example, if the auditor is going to undertake an audit of a plating process, they need to understand some of the critical things that need to be controlled to ensure the process meets the defined requirements.

- When preparing the audit report, this should include issues such as the identification of risks and effectiveness of actions taken by the auditee to address risks;

Expansion of the guidance on managing an audit programme, including audit programme risk.

In many organizations very little time is spent on preparing a risk based internal audit programme, often with a programme showing that all processes are audited once per year (often in one big audit) without any prioritization. In ISO19011: 2018 there is much more guidance on preparing an audit programme including:

- Focusing on the design, planning and validation of the audit programme, including where multiple locations/sites or where important functions are outsourced.

- Ensuring the audit programme includes information relating to risks and opportunities associated with the audit programme, and the actions to address them (for example providing enough resources to ensure the programme is implemented)

Expansion of Annex A to provide guidance on auditing the new concepts such as organizational context and leadership and commitment

- The expanded annex gives guidance on the competence and evaluation of auditors including:
    - understanding the types of risks and opportunities associated with auditing and the principles of the risk-based approach to auditing, auditing a process from start to finish, including the interrelations with other processes and different functions, where appropriate;
    - understanding the relationships and interactions between the management system(s) processes;
    - understanding the needs and expectations of relevant interested parties that impact the Management System;
    - Having the competence to discuss strategic issues with Top Management to determine whether they have considered the issues when evaluating their risks and opportunities;
    - Ensuring maintenance and improvement of auditor competence including continual professional development (e.g. could include new process technology etc.)

As explained in the article above one of the top 10 major nonconformities being found related to internal auditor competency. Quality Partner has developed a cost-effective solution, not only to train and qualify new management system auditors, but also to help in the continued professional development of existing auditors. The videos series on auditing, which includes a comprehensive exam to verify understanding has just been released. For more information contact paul.hardiman@qualitypartner.co.uk

Incorporating occupational health and safety requirements into a process-based management system audit

In March 2018 we saw the publication of ISO45001: 2015 related to Occupational Health and Safety management system requirements. This standard, which will replace OHSAS 18001, is based on the framework of Annex SL and is structured around a Plan-Do-Check-Act approach.

One key requirement, in section 5.1 Leadership and commitment states “Top management shall demonstrate leadership and commitment with respect to the OH&S management system by:

c) “ensuring the integration of the OH&S management system requirements into the organization’s business processes;”

Historically many organizations have built an Occupational Health and Safety management system based on a series of procedures to address the relevant requirements (e.g. OHSAS 18001), led by an OH&S/ Safety Manager, rather than integrating the standard requirements into the business processes.

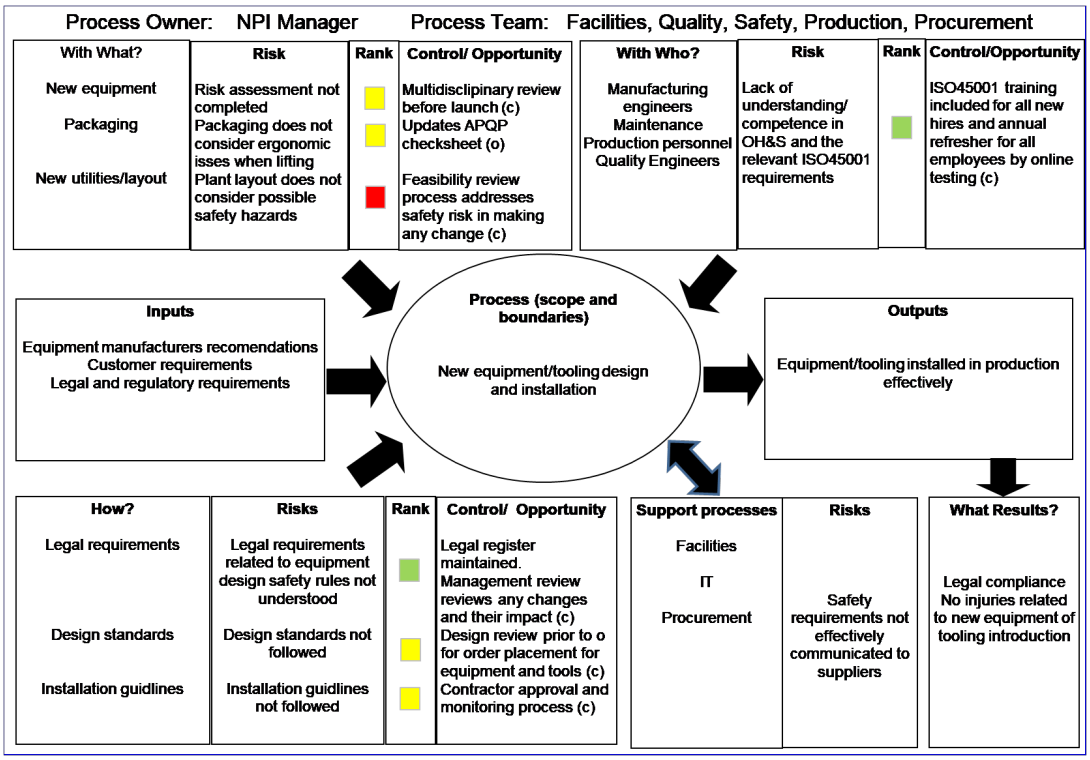
This must change for organizations seeking certification to ISO45001 (or indeed ISO9001 or ISO14001).

IATF 16949: 2016 makes it clear that each management system process must have a clearly defined, competent, process owner, who has the responsibility to manage the process to ensure it meets the desired outputs.

So, thinking about an integrated approach, it would make sense for the relevant Occupational Health and Safety requirements are incorporated into the relevant process, under the ownership of the process owner.

Let's look at an example. One process that can have a significant impact of occupational health and safety is the new product/process introduction process, for example for a new product there is the need for new manufacturing equipment to be designed and installed within the production process.

An example of a risk-based turtle diagram is below:



In this example the process owner, the NPI Manager, with a team of people involved in the process, evaluate the process and discuss the potential/actual OH&S risks that could affect achieving the desired process results, rank the risk (in this case they have opted to use a traffic light ranking, but also could be done based on severity x occurrence). The team then discuss if systems are in place to control the risks (c) or whether there is an opportunity to improve the process (o).

Taking this approach helps demonstrate that OH&S considerations are integrated into each of the relevant processes in the business, and that the relevant process owners are accountable for ensuring the process compliance and meeting the relevant ISO45001 requirements.
Also, taking this approach, it provides a framework for developing an integrated management system, and the risk-based turtle diagrams provide valuable information in preparing and undertaking integrated audits.

Quality Partner has developed a one-day ISO45001: 2018 awareness course, and a two or three-day ISO45001: 2018 internal auditor course. Both courses use practical exercises and case studies to ensure delegate understanding. For more information contact paul.hardiman@qualitypartner.co.uk

Appeal process in the event of non-agreement with audit findings

Many organizations subject to third party audits to IATF 16949 have nonconformities raised against them that they feel are not justified or not traceable to any requirement in IATF 16949 or customer specific requirements. However, many accept these without knowing, that under the Rules for Achieving IATF 16949 recognition, that they can make an appeal to the relevant certification body.

The rules for achieving IATF recognition, 5th edition requirement 2.9 states:

Appeals and complaints

"The certification body shall have a process for addressing appeals from the client and complaints from any interested parties. The process shall include the following activities where appropriate:
a) receiving, validating, investigating;
b) determining the root cause;
c) ensuring that any appropriate correction and systemic corrective actions are taken;
d) providing progress reports and the outcome; e) maintaining the records of appeals, claims, and actions taken.

The appeals process shall not impact the timings related to nonconformity management (see section 5.11) or the certificate decertification process (see section 8.0).

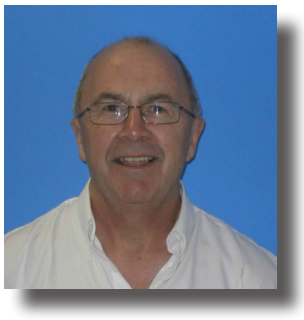
The certification body shall ensure that adequate resources are available and that the persons engaged in the appeal and complaint process are different from those who carried out the audits and made the relevant certification decisions."

If you are unaware of the relevant certification body contact person, details can be found at: http://www.iatfglobaloversight.org/certification-bodies/under-contract/

Ask the expert

Question:
We have a key supplier of a chemical used for washing our products and this is critical to product quality. We instructed the supplier, that, as part of supplier development that we want them to supply us a plan to move for ISO9001: 2015 certification to certification to IATF 16949: 2016.

They have replied to us that they approached an IATF recognised certification body and they have been told they are not eligible for certification. Is this correct?



Quality Partner's expert, Paul Hardiman

Answer:
The certification body is correct. Under the rules for achieving IATF recognition, the requirement states:

"IATF 16949 is applicable to all sites of a client where customer-specified production parts, service parts, and/or accessory parts are manufactured. "Customer-specified production parts" shall be understood as parts that are an integral part of a vehicle."

As the chemical is only used for cleaning and does not stay with the product, this organization is not eligible for certification. However, as part of supplier development, you can state they should develop a system compliant with IATF 16949: 2016, and that you could/will undertake a second party audit (s) to verify effective implementation (priority and frequency of second party audit will depend on risk, criticality and performance).

Question:
Our manufacturing site has several remote support functions, based around the world, listed on our IATF 16949 certificate. I am responsible for coordinating the internal audit programme for the site and the remote support functions. Due to the size of the remote support functions (5 to 10 people), it is not practical to have a qualified internal auditor at each location, and even if there was, keeping objectivity of the audit process is difficult. However due to budget constraints it is not practical for me to visit each location every 3 years to undertake the internal audits. I want to do "remote" audits, there the audit is undertaken via video conference, is this allowed by IATF?

Answer
Interesting question. IATF does not specifically state that "remote" audits cannot be done.

The newly published ISO19011: 2018 has a section related to this:

Auditing virtual activities and locations

"Virtual audits are conducted when an organization performs work or provides a service using an online environment allowing persons irrespective of physical locations to execute processes (e.g. company intranet, a "computing cloud"). Auditing of a virtual location is sometimes referred to as virtual auditing. Remote audits refer to using technology to gather information, interview an auditee, etc. when "face-to face" methods are not possible or desired.

A virtual audit follows the standard audit process while using technology to verify objective evidence. The auditee and audit team should ensure appropriate technology requirements for virtual audits which can include:

- ensuring the audit team is using agreed remote access protocols, including requested devices, software, etc.
- conducting technical checks ahead of the audit to resolve technical issues;
- ensuring contingency plans are available and communicated (e.g. interruption of access, use of alternative technology), including provision for extra audit time if necessary.

Auditor competence should include:

- technical skills to use the appropriate electronic equipment and other technology while auditing;
- experience in facilitating meetings virtually to conduct the audit remotely.

When conducting the opening meeting or auditing virtually, the auditor should consider and the following items:

- risks associated with virtual or remote audits;
- using floor plans/diagrams of remote locations for reference or mapping of electronic information;
- facilitating for the prevention of background noise disruptions and interruptions;
- asking for permission in advance to take screen shot copies of documents or any kind of recordings, and considering confidentiality and security matters;
- ensuring confidentiality and privacy during audit breaks e.g. by muting microphones, pausing cameras"

Other things to consider are:

Avoid the auditee selecting the samples to audit. As an auditor you must control the audit and ensure you are auditing the process for effective implementation.

In preparation to do the audit you could ask them to supply lists etc of projects/contracts etc. so you can select at random things to check during the interviews.

Question
I need clarification on IATF clause 8.5.5.1

It is confusing whether requirements are applicable for service organization or manufacturer.

Answer
The requirement states:

"The organization shall ensure that a process for communication of information on service concerns to manufacturing, material handling, logistics, engineering, and design activities is established, implemented, and maintained".

This is applicable to organizations certified to IATF. The requirement means that if the organization gets feedback on any service concerns (feedback from their Customer/ OEM on problems being found in the customer /OEM plant, dealerships or in the field, these are effectively communicated internally within the organization and effective problem solving applied.

In an organization lower down the supply chain they may not get any direct feedback, but this requirement cannot be excluded from the scope of certification (the only permissible exclusion is product design where an organization is not design responsible)

In this case they would explain in an audit that the requirement is not applicable at this time.