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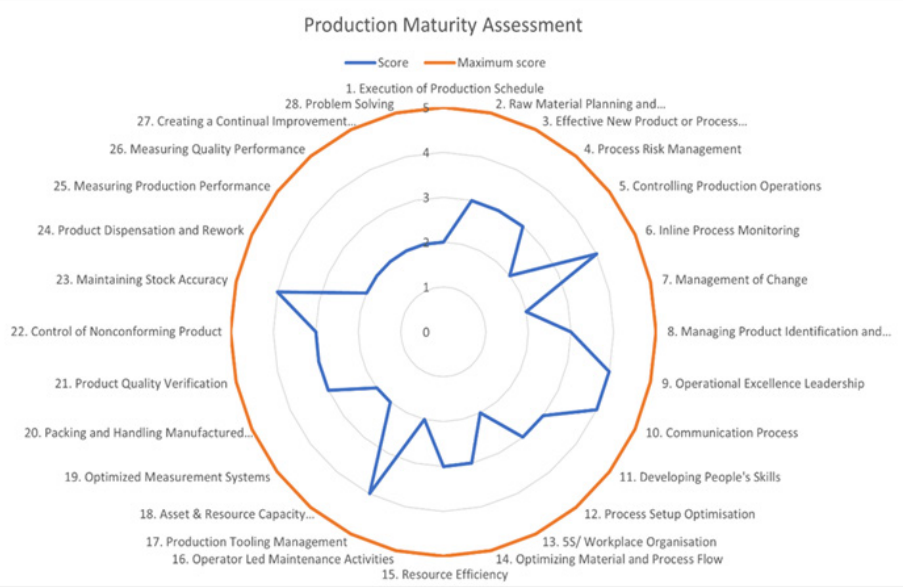


Firstly, I hope you are all safe and well.

Welcome to the twenty fifth edition of the Quality Partner newsletter. The newsletter is designed to keep readers up to date with developments in Quality Management Systems, in particular related to the Automotive Quality Management Standard IATF 16949: 2016

In this edition we focus on:

- Auditing embedded software in the context of IATF 16949
- Use of the Production Maturity Assessment to help develop a manufacturing process improvement plan
- Auditing shifts

Along with the regular question and answers section.

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

Covid 19

Although the global situation with Covid 19 seems to be improving, in some regions of the world doing IATF 16949 audits on site continues to be a challenge.

Since the last edition of the newsletter, IATF have updated the Covid response document, now at revision 7. This is freely available to download from www.iatfglobaloversight.org

IATF certification numbers

There are now over 83500 IATF certified sites around the world, and many more remote support functions that support the sites.

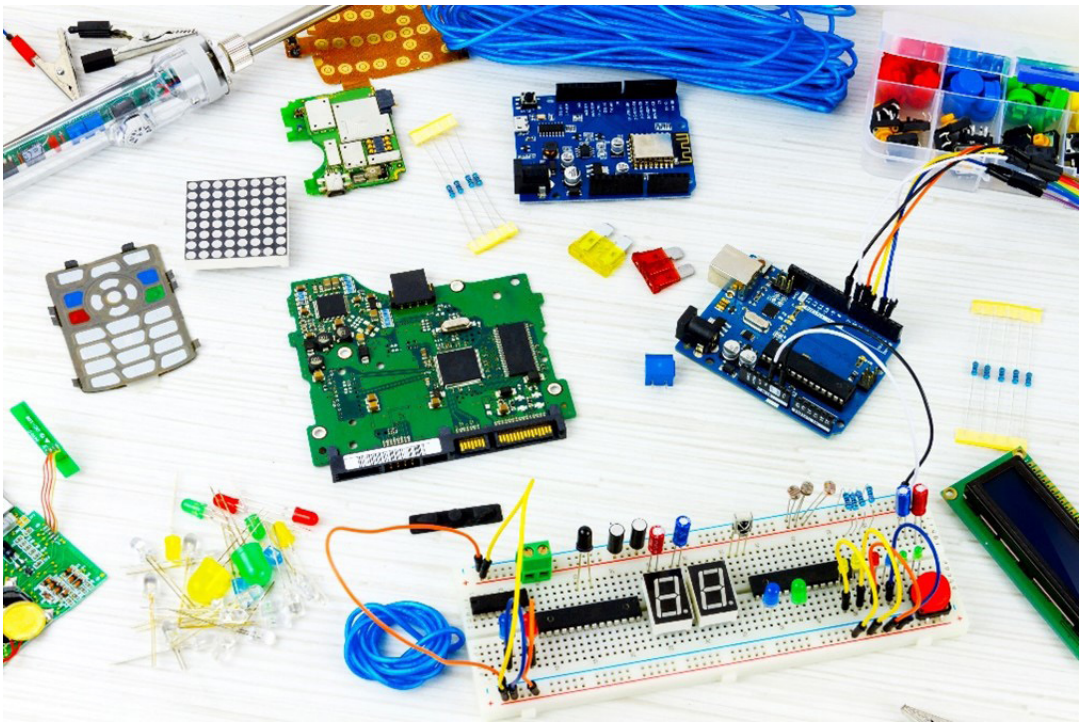
China continues to be number 1 in relation to the number of certificates, followed by India as number 2 and The Republic of Korea number 3.

Quality Partner training

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

Auditing embedded software in the context of IATF 16949

Many of us will know that in the 2016 edition of IATF 16949 there were requirements added related to products with embedded software.



Firstly, we must understand the meaning of “embedded software”

A definition was added through SI 15 “embedded software”

“Embedded software is a specialized programme stored in an automotive component (typically computer chip or other non-volatile memory storage) specified by the customer, or as part of the system design, to control its function(s).

To be relevant in the scope of IATF 16949 certification, the part that is controlled by embedded software must be developed for an automotive application (i.e., passenger cars, light commercial vehicles, heavy trucks, buses, and motorcycles; see Rules for achieving and maintaining IATF Recognition, 5th Edition, Section 1.0 Eligibility for Certification to IATF 16949, for what is eligible for “Automotive”). “

NOTE: Software to control any aspect of the manufacturing process (e.g., machine to manufacture a component or material) is not included in the definition of embedded software.

The first key learning point is the software must end up in an automotive application, otherwise it is not eligible under the scope of IATF 16949. Although it is important, for example, for an organization to control machine or measuring and test equipment software version control, this is not in the scope of the “embedded software” requirements.

Out of the 83,500 IATF certified organizations, for the majority the requirements related to embedded software will not be applicable. However, under the IATF rules, these requirements cannot be included in the quality manual as permissible exclusions. An organization would need to define these as not applicable to their scope of activities at the time of any audit.

If applicable, the organization needs to be very clear on whether they, or the customer are responsible for the embedded software design., considering any customer specific requirements (CSR’s)
Let’s first consider an organization that has product design responsibility.

All the requirements in 8.3 Design and development of products and services will apply, meaning the organization will need to apply a P-D-C-A documented design control process.

IATF requirements added to the design requirements related to embedded software are:

8.3.3.1 Product design input
"The organization shall identify, document, and review product design input requirements as a result of contract review. Product design input requirements include but are not limited to the following:

h) embedded software requirements."

As with any product design it is important that the organization understands the requirements the software is expected to meet, including customer requirements.

Once the software is designed, considering the potential risks identified in the DFMEA, the next additional requirement relates to validation:

8.3.4.2 Design and development validation

"Design and development validation shall be performed in accordance with customer requirements, including any applicable industry and governmental agency-issued regulatory standards. The timing of design and development validation shall be planned in alignment with customer-specified timing, as applicable.

Where contractually agreed with the customer, this shall include evaluation of the interaction of the organization's product, including embedded software, within the system of the final customer's product." Although managing change control while the software is under development is obviously important, there are additional requirements defined after the software is released.

8.3.6.1 Design and development changes — supplemental

"For products with embedded software, the organization shall document the revision level of software and hardware as part of the change record."

As part of their internal audit programme, an organization must undertake assessments to verify the effectiveness of their software development process, defined in the IATF requirement:

8.3.2.3 Development of products with embedded software

"The organization shall use a process for quality assurance for their products with internally developed embedded software. A software development assessment methodology shall be utilized to assess the organization's software development process. Using prioritization based on risk and potential impact to the customer, the organization shall retain documented information of a software development capability self-assessment.

The organization shall include software development within the scope of their internal audit programme (see Section 9.2.2.1)."

The two software process development tools mentioned in Annex B of IATF 16949 are:

- Capability Maturity Model Integration (CMMI)
- Automotive SPICE® (Software Process Improvement and Capability Determination)

Which tool an organization uses will depend on customer specific requirements, or, if there are not, the organizations decision.

As this forms part of the internal audit programme, any auditor undertaking the assessment needs to be competent against the requirements defined in 7.2.3, internal auditor competency, considering customer specific requirements.

If the organization purchases product with embedded software, IATF 16949 requires:

8.4.2.3.1 Automotive product-related software or automotive products with embedded software

"The organization shall require their suppliers of automotive product-related software, or automotive products with embedded software, to implement and maintain a process for software quality assurance for their products.

A software development assessment methodology shall be utilized to assess the supplier's software development process. Using prioritization based on risk and potential impact to the customer, the organization shall require the supplier to retain documented information of a software development capability self-assessment."

If second party audits are undertaken of suppliers either developing embedded software or manufacturing automotive products with embedded software, the auditors need to be competent against the requirements of 7.2.4 Second party auditor competency, again considering any customer specific requirements.

Finally, in the event of any customer concern or field related issue:

10.2.6 Customer complaints and field failure test analysis

"The organization shall perform analysis on customer complaints and field failures, including any returned parts, and shall initiate problem solving and corrective action to prevent recurrence.

Where requested by the customer, this shall include analysis of the interaction of embedded software of the organization's product within the system of the final customer's product.

The organization shall communicate the results of testing/analysis to the customer and also within the organization."

In auditing these requirements, these may be some audit questions to consider:

- Do you have any new products in development, or released products with embedded software?
- Who has the responsibility for the software design?
- If the organization, how is the embedded software development controlled, including validation and change control? (8.3.2.3, 8.3.4.2, 8.3.6.1)
- How are the potential risk of failure in the software assessed? (8.3.5.1)
- If embedded software design is outsourced how is this managed, including defining the input requirements for the software to the supplier? (8.4.2.3.1)
- What software development assessment methodology tool do you mandate the outsourced supplier to use, considering customer specific requirements? (8.4.2.3.1)
- What is the process for validating the embedded software meets the customer and organization requirements? (8.3.4.2)
- Once a product is approved, what is the process for ongoing software version change control? (8.3.6.1)
- If any customer or field related issues with the software, how are these dealt with, including the interaction with any customer systems? (10.2.6)

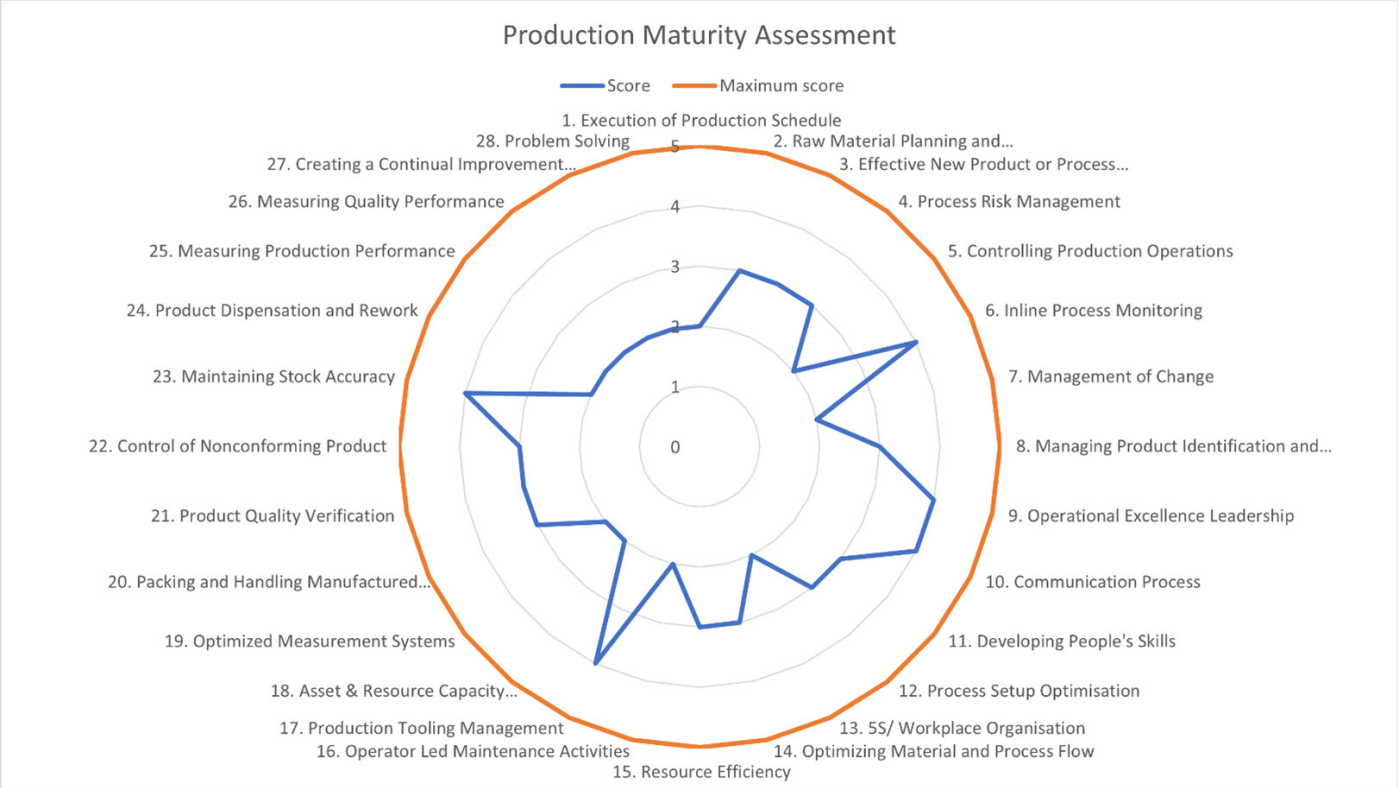
Production Maturity Assessment

Many of you reading this newsletter will work for organizations that are IATF 16949 certified.

The way the IATF scheme is structured is very much based on pass/fail criteria, with organizations having no understanding how their production process maturity matches world class criteria.

I have drafted a “Production Process Maturity Assessment”, facilitating an assessment of:

- The robustness of an organizations manufacturing processes against 28 defined criteria. Each criterion is ranked 1 to 5, with 1 criterion not met, 3 IATF compliant, and 5 being world class. The assessment can be done for an organizations entire manufacturing process, or individual processes/cells/areas.



The output of the assessment could be an input into developing a “Manufacturing process improvement plan” required by IATF 16949 10.3.1.

If you are interested in trialling the assessment, please contact me with your e-mail, and I will send the criteria and scoring sheets for you to trial in your organization. All I ask for in return is your feedback, with the summary score and any opportunities to improve the criteria. All information received will be treated with confidentiality.

Your inputs will be used to refine the assessment prior to formal launch.

Auditing shifts

In IATF requirement 9.2.2.3 Manufacturing process audit it states:

“Within each individual audit plan, each manufacturing process shall be audited on all shifts where it occurs, including the appropriate sampling of the shift handover.”

Due to some differences in interpretation, IATF issued FAQ 19 related to this that states:

"Each audit does not have to cover all shifts in one audit (for example an audit of the pressing process could be done on shift 1 and 2, sampling shift changeover in year 1, and then in year 2 or 3 an audit undertaken on the third shift for pressing). However, all manufacturing processes must be audited on all shifts over a three-year cycle, the frequency depending on risk, performance, changes etc."

So why do IATF put emphasis on auditing shifts, especially in manufacturing, and how should and audit programme be developed and how should the auditor plan and undertake the audit?

Firstly, an organization must prepare an audit programme, In ISO9000 the definition of an audit programme is:

"set of one or more audits planned for a specific time frame and directed towards a specific purpose"

According to IATF 16949 the audit programme should consider criticality of the processes, internal and external performance, changes, and results of previous audits. In planning, the person creating audit programme needs to have a clear understanding of the organization manufacturing processes and shift patterns.

A good source of information to understand the different manufacturing processes is to review the process flow charts for the different types of products manufactured. Remember the requirement is not each manufacturing cell, or each machine, but each manufacturing process on each shift.

Let's look at an example. An organization manufacture's a range of injection moulded components, on machines ranging from 50 tonnes to 500 tonnes, some parts are shipped direct to the customer, and some go to assembly cells for assembly to meet customer requirements. In one of the assembly cells, mating parts are joined together by ultrasonic welding, before final assembly. For some parts, after assembly they are sent to an outsourced supplier for painting, returned for final inspection, and then dispatched.

In injection moulding there are three shifts, working 5 days a week, starting on Sunday at 12.00 midnight until 8.00am, and then 8.00am to 4.00pm and 4.00pm until midnight.

There is also a dedicated weekend shift with two crews in injection moulding, starting at 8.00pm Friday until 8.00am Saturday, 8.00am to 8.00pm, 8.00pm to 8.00am and 8.00am to 8.00pm Sunday.

In assembly, they only work days, with overtime when needed, 8.00am to 5.00pm.

So, at minimum, the following must be covered in the three-year audit cycle:

- Injection moulding, 3 shifts, Monday to Friday (00.00-08.00, 08.00 -16.00, 16.00 – 00.00)
- Injection moulding 2 shifts, Friday to Sunday (20.00 – 08.00, 08.00 – 20.00)
- Assembly day shift
- Ultrasonic welding day shift

An example of an audit programme for manufacturing process audits is shown below. In this example the organization is doing more than the minimum requirement of auditing each manufacturing process on all shifts every 3 years.

Manufacturing process	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec
Injection Moulding Weekday shifts		Shift 1 and shift 2				Shift 2 and shift 3						
Injection Moulding Weekend shift			Shift 1 and shift 2									
Assembly day shift				Day shift							Day shift	
Ultrasonic welding day shift						Day shift						

- Auditor should verify effectiveness of shift handover
- Each audit should verify effective implementation of PFMEA and control plan
- Each audit should sample applicable customer specific requirements

In undertaking these audits, auditors must also sample shift handovers.

So, it is important when planning an individual audit, to consider timing to ensure appropriate sampling of shift handover. For example, if auditing in injection moulding, the auditor could plan to start the audit at 6.00am to 10.00am and would then be there during the handover at 8.00am.

Next let's consider the audit planning for a specific manufacturing process audit. The definition in ISO9000 of audit plan is:

"Description of the activities and arrangements for an audit"

Like any process approach audit, the key to undertaking an effective audit is good planning. Whereas the audit programme may say to the auditor they must audit injection moulding shift 1 and 2, the programme would normally not say which machine/cell/product to audit.

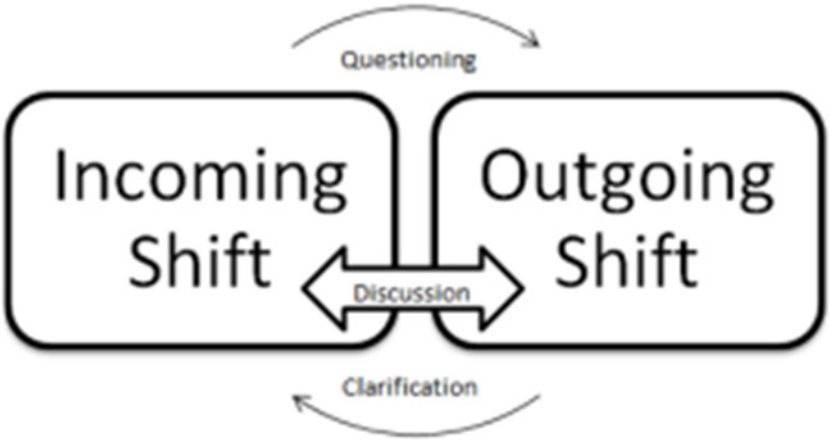
As part of the preparation, the auditor should review internal and external performance data, which could include customer complaints, internal ppm, OEE and other relevant data to determine the specific machine/ cell or product to cover in the scope of the audit.

The next task would be to retrieve the relevant PFMEA and control plan, customer specific requirements and performance data, and use these to define specific questions/focuses areas for the audit.
When undertaking the audit, what should the auditor look for at shift change?

The key thing is observation. The purpose of observing the shift change is to verify the effectiveness of the internal communication process.

A typical practice is, maybe 15 minutes before the end of the shift, is for the team leader/supervisor to meet with the incoming team leader/supervisor to exchange information, that could include but not limited to

- Performance against KPI's
- Progress against the production plan
- Quality issues encountered
- Machine issues encountered
- Machine/material changeovers planned



By observing and listening, the auditor can pick up audit trails to follow on the next shift. If needed the auditor can question the outgoing or incoming shift leader/supervisor, seeking clarification on any issues discussed.

There is no requirement in IATF 16949 that the shift communication is documented, but in many organizations a record of the communication is maintained in a shift logbook or communication board.

In the audit report, the timing of the audit (for example 6.00am to 10.00am) needs to be clearly reported, along with notes to give evidence of the auditing of the shift changeover. If allowed by the organization policies, a photograph/video of the handover can be retained as evidence as part of the audit evidence.

Questions and answers

Quality Patrner's expert, Paul Hardiman

Supplier development

Question
We are looking to develop our supplier development process and looking to MAQMSR. Is this still available and is Rev 2 the latest version?


AUTOMOTIVE
QUALITY MANAGEMENT
SYSTEM DOCUMENT

MAQMSR

Second Edition
September, 2017

Minimum Automotive Quality Management System Requirements for Sub-Tier Suppliers

Sections of IATF 16949 selected for supplier QMS development

International
Automotive
Task Force

Answer
Yes, MAQMSR is still available and can be accessed from the IATF Global Oversight website under customer specific requirements

https://www.iatfglobaloversight.org/oem-requirements/customer-specific-requirements/

The document is included in both the Ford and Stellantis (ex FCA) headings.

The initial intent of this document was as a steppingstone for ISO9001 certified organizations to demonstrate they were developing their management systems towards IATF compliance/certification. For some ISO9001 certified organizations, especially smaller in size with limited resources, meeting all the additional IATF requirements can appear daunting,

Using MAQMSR, which defines some key initial IATF requirements to focus on, this, coupled with support from their automotive customers, can appear to be a practical approach that can be achieved in a shorter timescale than full compliance with IATF 16949.

An IATF certified organization can promote the use of MAQMSR to its ISO9001 certified suppliers, maybe initially requiring then to undertake a gap analysis using the requirements and develop an implementation plan.

They could then either audit the suppliers to monitor the suppliers progress or provide supplier development support in understanding and meeting the requirements.

Supplier certification

Question
I just wanted to pull on your knowledge regarding certification. It appears that one of our suppliers has IATF 16949, however they are stating that they do not have ISO9001?

We have an approved supplier list, and in every case, we have (2) certificates, ISO 9001 & IATF16949
I have checked the certificate number of the supplier on the Global oversight weblink, and it is valid certificate.

Just wondered how they can have one but not the other.

Answer
For an organization to be certified to IATF 16949 they must have an implemented process-based Quality Management System (QMS) that meets all the requirements of ISO9001 and IATF 16949.

In the foreword to IATF 16949 it states “This automotive QMS Standard cannot be considered a stand-alone QMS Standard but has to be comprehended as a supplement to and used in conjunction with ISO 9001:2015”

It is the organizations decision on whether they ask the certification body, not only for an IATF 16949 certificate, but also an ISO9001 certificate.

This decision could be influenced by factors such as if they manufacture non-automotive products, which, according to the IATF rules, would not be covered/audited in any IATF 16949 third party audit.

To obtain the additional ISO9001 certificate, the certification body, to satisfy accreditation rules, will add additional audit time and normally charge an additional certificate fee.

This is normally for this reason that organizations, who only supply automotive products, elect only to have

an IATF 16949 certificate, and not an additional ISO9001 certificate.

Control of special characteristics

Question
We have several special characteristics defined in our control plans. Some have been identified by the customer, and some as part of our risk analysis (PFMEA), including both product and process characteristics. Do we have to use SPC and calculate process capability for all special characteristics?

Answer
The first thing we need to understand are customer specific requirements related to identification and control of special characteristics.

This relates to the IATF requirement:

8.2.3.1.2 Customer-designated special characteristics

The organization shall conform to customer requirements for designation, approval documentation, and control of special characteristics.

Next let's look at other relevant IATF 16949 requirements:

8.3.3.3 Special characteristics

"The organization shall use a multidisciplinary approach to establish, document, and implement its process(es) to identify special characteristics, including those determined by the customer and the risk analysis performed by the organization, and shall include the following:

b) development of control and monitoring strategies for special characteristics of products and production processes;"

This is further reemphasised in IATF requirement 8.5.1.1. Control Plan:

"c) methods for monitoring of control exercised over special characteristics (see Annex A) defined by both the customer and the organization;"

Finally in 9.1.1.1 Monitoring and measurement of manufacturing processes:

9.1.1.1 Monitoring and measurement of manufacturing processes

"The organization shall perform process studies on all new manufacturing (including assembly or sequencing) processes to verify process capability and to provide additional input for process control, including those for special characteristics."

So, to summarise:

- An organization must use a multidisciplinary team to identify special characteristics, considering any customer specific requirements
- The criteria used for identifying special characteristics as part of the risk analysis (FMEA) needs to be defined (e.g., Severity, Severity x Occurrence etc.)
- A monitoring strategy needs to be defined for each special characteristic, whether product or process characteristics
- SPC could be a monitoring strategy, but is not mandated unless defined in agreed customer specific requirements
- An organization must perform process capability studies for new products/processes, focused on special characteristics. The capability indices (e.g., Ppk, Cpk) used, and acceptance criteria will depend on either customer specific requirements, or the organization's own defined criteria

Customer specific requirements

Question
An organization at tier 3 in the supply chain is aware that some of their supplied products ends up being used in a Ford car. Do they have to meet all the Ford customer specific requirements?

Answer
The answer is a definite no!

IATF 16949 requirement 4.3.2 states:

"Customer-specific requirements shall be evaluated and included in the scope of the organization's quality management system."

The definition of customer in ISO9000: 2015 is:

"person or organization that could or does receive a product or a service that is intended for or required by this person or organization."

So, in this case, the customer is the second-tier supplier. The organization must understand and meet their requirements (customer and customer specific requirements)

Foundation FMEA

Question
I have been asked about this and have struggled to find much information. Can you tell me whether it is now a requirement to implement a Foundation FMEA for achieving certification to IATF 16949? If so what format/scoring method is acceptable to meet the standard?

Answer
There is no specific reference to Foundation FMEA in IATF 16949, so, as such, it is not a requirement. However, firstly we need to understand customer specific requirements.

Some OEM's mandate the use of Foundation FMEA, such as Ford, stating in their CSR's:

Foundation FMEAs

"Organizations are required to have foundation FMEAs. Foundation FMEAs are typically created for each process type (e.g., stamping, riveting, injection molding, etc.). See the AIAG/VDA FMEA manual for more information. Foundation FMEAs are also known as corporate, generic, baseline, core, master, or best practice FMEAs and contain knowledge of the organization from prior developments and problem-solving activities. They play a critical role in the Prevent Recurrence process by capturing knowledge from problem solving and making sure the errors are not repeated in future launches. Knowledge gained from problem solving processes (8D, 6-Sigma, Shanin, etc.) shall be documented in both the part and the foundation FMEAs. The foundation FMEAs are not a replacement for the part FMEA but are a starting point for a part FMEA on a new launch."

Whether a customer specific requirement or not, I believe there is a benefit in organizations investigating the use of this approach.

Let's look at an example. An organisation manufactures a range of injection moulded components (e.g., 100-part numbers), of various shapes and sizes, manufactured on a range of size machines (50-500 tonne)

Historically, many such organizations would have 100 PFMEA's, one for each part number. If a failure mode occurred, maybe resulting in a customer complaint, they would have to, as part of prevention control, have to go back and review the failure mode for the other 99 PFMEA's.

Now is a good opportunity to review this structure. Many organizations are either having to, or are choosing to adopt the FMEA seven step approach defined in the AIAG-VDA FMEA handbook for new projects.

In the case above the organization could develop a Foundation PFMEA for Injection moulding, identifying the common failure modes, effects, and causes, irrespective of the size of the part or the machine size it is moulded in.

The organization could then consider whether, based on the Foundation PFMEA, to develop Family PFMEA's for different product sizes, different machine groups etc.

Then, if it is a customer specific requirement, part specific PFMEA's could be developed, using the Foundation and relevant Family FMEA as an input.