Quality Partner Newsletter

April 2019

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Welcome to the Fifteenth edition of the Quality Partner newsletter

Previous editions can be downloaded free of charge at https://qualitypartner.co.uk/news-events/

The newsletter is designed to keep readers up to date with developments in Quality Management Systems, focused on IATF 16949.

I am really pleased that since the last edition I have been asked some great questions on the practical application of IATF 16949 requirements and related rules. I have therefore decided the major content of this edition is sharing the questions and related answers.

In addition, this issue focuses on:

- Update on the development of the VDA-AIAG FMEA reference manual
- Review of IATF 16949 Clause 8.3.2.3: Development of products with embedded software

If you have any questions or topics for future editions, or have any training needs related to IATF 16949, VDA6.3 or the automotive core tools please feel free to mail to: paul.hardiman@qualitypartner.co.uk

IATF I6949 certification status
At the end of March 2019 there were 69758 IATF 16949 certified sites globally. (not including remote support functions).

Of this, 71.5% of these were issued to organizations in the Asia Pacific region, 16% in Europe, 9% in North America and 4.5% in the rest of the world.

China, India and South Korea continue to be the top 3 countries for certification.

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Author: Paul Hardiman

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Update on the VDA-AIAG FMEA handbook

After long delays in the project, there finally seems to be agreement that the new handbook will be issued soon, at the latest by the end July 2019.

Below are some of the questions that you make be asking, with my answers, based on the information currently available.

Question: Will the new handbook be mandated by IATF 16949?
Answer: No, this will not be an IATF reference manual and therefore compliance to the requirements will not be mandated by IATF 16949. However, compliance will be mandated by certain customers, linked to customer specific requirements.

Question: What will happen to the current reference manuals? (AIAG Potential Failure Mode & Effects Analysis 4th edition, Volume 4 Chapter Product and Process FMEA)
Answer: The probability is these will be replaced by the new harmonised handbook. (AIAG have already committed to this in a published white paper).

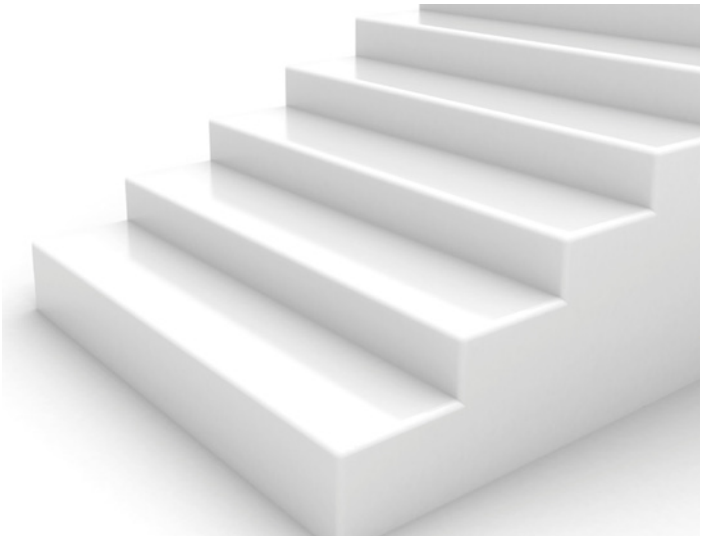
Question: If the handbook is mandated by our customers, will we have to redo all our existing FMEA's?
Answer: The likelihood is compliance will only be required for new programmes (new products, new manufacturing processes etc.), but this could depend on customer specific requirements.

Question: What are the key differences with the existing FMEA approaches?
Answer: Firstly, let's think about effectiveness of the use of FMEA within the automotive supply chain.

In 2017 alone there were over 64 million cars recalled globally and this is only the tip of the iceberg, where problems have escaped into the field. In addition, a massive cost is incurred in the supply chain in the cost of poor quality (cost of internal and external nonconformance).

Given that FMEA is a technique that focuses on defect prevention maybe it is not surprizing that the new handbook will focus more on measuring the effectiveness of FMEA as a process. The handbook will focus on comparing the benefits seen through the effective use of FMEA (reduced complaints, reduced warranty cost and reduced cost of poor quality) versus the investments made (time taken by the multidisciplinary team, training costs, improved prevention/detection costs). Ultimately, if FMEA is implemented correctly, with the correct resources provided by Top Management, this should result in the reduction of the cost of poor quality and reduced field concerns.

The next significant change is a seven-step approach to FMEA, broken into three clear phases:



The first phase is titled **System analysis** including:

1st Step: Planning and preparation. This step is focused on ensuring the scope of the FMEA activity is clear, all the relevant performance data is collected (issues with similar products/processes, complaints, internal issues etc.) and that a competent multidisciplinary team is available to perform the FMEA activity.

2nd Step: Structure analysis. This step is focused on understanding specific aspect of the product design or manufacturing process step to be evaluated, the relationship with the higher lever system/process, and an understanding of the 4M (Man, Machine, Method, Material) conditions that could influence the specific aspect of the product design or manufacturing process step that will be evaluated.

3rd Step: Function analysis. This step focuses on understanding the specific functional requirements to be met in the related aspect of the product design or the manufacturing process step being evaluated. These could be defined by the customer, legal or as internal requirements.

The second phase is titled **Failure analysis and risk mitigation** including:

4th Step: Failure analysis. This step focuses on understanding all the potential failure modes (FM), the failure effects (FE) on the next process, the customer or the end user, and the failure causes (linked to the 4M analysis in step 2).

5th Step: Risk analysis. This step uses modified tables for severity, occurrence and detection to generate an action priority ranking (AP). This AP rank is based on looking at the combination of severity, occurrence and detection to give a red, yellow or green rating.

6th Step: Optimisation. The purpose of this step is to determine actions to mitigate risk and assess the effectiveness of these actions.

The main objectives of process optimisation are:
- Identification of actions necessary to reduce risks
- Assignment of responsibilities and target completion times for action implementation
- Implementation and documentation of the actions taken
- Confirmation of the effectiveness of the implemented actions
- Reassessment of the risks after the action is taken
- Continuous improvement of the process
- Basis of refinement of the process requirements and prevention detection controls

The third phase is titles **Risk Communication** including:

7th Step: Results documentation. The purpose of this step is to communicate the results internally (including to Top Management who may have to provide resources to ensure actions are implemented) and to the customer (if required).

This step will link to the management review requirements in IATF 16949 including:

a) cost of poor quality (cost of internal and external nonconformance);

Has FMEA had an impact on reducing cost?

j) identification of potential field failures identified through risk analysis (such as FMEA);

Is the FMEA process effective in preventing field failures?

k) field failures and their impact on safety or the environment.

Why was FMEA process not effective to identify any failures?

Question: Will we have to use any specific software to record the results of the FMEA?
Answer: No. FMEA's can be documented using either a spreadsheet (as most of the organizations now do according to a survey conducted by AIAG) or with integrated software.

Question: Will any specific training be mandated?
Answer: While there may be specific training requirements mandated by the customer, in most cases no. For any training you must ensure you select a suitable, competent training provider.

Quality Partner will have a one and two-day practical, application-based, face to face training courses available after the formal publication of the handbook.

Also, understanding that it difficult for organizations to release large groups of people for face to face training, Quality Partner will also have available a video series, comprised of 8 modules and supporting exam, to provide practical guidance on effectively implementing the new approach. More details will be published in the next newsletter.

In conclusion:

- Compliance with the new FMEA handbook may be mandated by customers for new programmes
- The handbook will NOT be an IATF reference manual
- The handbook will promote a 7- Step approach
- The proposed approach uses 4M analysis as an input to understand potential risks
- An AP ranking is proposed rather than RPN as a tool to identify areas for risk reduction
- There will be more focus on measuring the effectiveness of the FMEA process by focus on the cost of poor quality

However good the manual is in principle, the key to successful implementation is getting the commitment of the Top Management Team in the organization to provide the necessary resources (competent FMEA teams with enough allocated time and physical resources where needed to address potential failures modes) to prevent issues from occurring.

Finally, the FMEA teams must believe in the process and not just see it as a form filling exercise to show the auditor of the customer. My approach will be to train using brainstorming around the 4M approach, capturing the potential risks and then formatting into the spreadsheet or software.

IATF 16949 Clause 8.3.2.3: Development of products with embedded software

This next article was put together with the help of a friend and regular reader of the newsletter, Morteza Kheirkhah.I thank him for his input, hope you find interesting.

Driven by the rapidly increasing amount of embedded software in automotive applications (for example powertrain control, comfort, and driver assistance), IATF 16949 added new requirements related to an organization's control over the design, sourcing and embedding of software.

This requirement focuses on the requirement related to the embedded software design and development activities.

The first part of 8.3.2.3 states:

"The organization shall use a process for quality assurance for their products with internally developed embedded software."

The first point is that there is no requirement for “documented” process. However, the organization should demonstrate that have a process for quality assurance. This can be shown by including the assurance activities in a product’s development project plan.

If the development of the software is done by an outsourced supplier, clause 8.4.2.3.1 “Automotive product-related software or automotive products with embedded software” applies.

If outsourced, you must require your supplier to have and implement such quality assurance process and the organization shall define and apply necessary controls over supplier and provided software/product (for example reviewing their capability self-assessment, second party audit etc.).

The purpose of a Quality assurance process is to provide independent and objective assurance that products and processes comply with predefined requirements and plans, and that any potential nonconformances are addressed.

Organization’s may have a standard (typical) assurance process which some of its inputs, activities, and outputs may be:

Inputs:
- Project plan
- Available resource
- Reference documents (CSR’s, Standards, organizational documents etc.)
- Available resource
- Lesson learned from previous projects

Activities:
- Developing a quality assurance plan
- Ensuring that the products meet the defined product requirements according to the quality assurance strategy and the project schedule
- Ensuring that the product development processes are implement as planned (according to the quality assurance strategy and the project schedule)
- Ensuring the resolution of nonconformances. Nonconformance found in process and product quality assurance activities should be analysed, tracked, corrected, and further prevented
- Escalation of results of assurance activities to related levels/persons in the organization

Outputs:
- Implemented quality assurance plan
- Design reviews
- Actions to address risks
- Communication records (with the customer and internally)

Automotive SPICE (v3.1), ISO/IEC/IEEE 12207 (2017), IEEE 730 (2014) and ISO 15026-4 (2012) all provide good information on quality assurance process and assurance plans.

The next part of 8.3.2.3 states:

“A software development assessment methodology shall be utilized to assess the organization’s software development process.”

Selecting the assessment methodology is the responsibility of the organization, but some customers may have their requirements on the assessment methods and the maturity/capability level to be attained by the organization.

For example, VOLVO in its supplier quality assurance manual (4th edition) requires suppliers to use SPICE method and level 3 would be minimum acceptable capability level.

The scope of the above requirement is only software development processes, not the overall product or system development processes.

The last part of 8.3.2.2 states:

"Using prioritization based on risk and potential impact to the customer, the organization shall retain documented information of a software development capability self-assessment."

Failures or malfunctions of embedded software and related products have no identical impact on customers or end users. For example, the impact of a failure in a braking system ECU and gearbox TCU would not equal. This requirement requires the organization to retain self-assessment results and related supporting documents for a certain time based on risk and its impact to the customer.

For meeting this requirement, organizations can use DFMEA or a risk matrix.

ISO 26262, titled Road Vehicles–Functional Safety, is the automotive functional safety standard for passenger vehicle industry, and compliance is mandated by some customers. In order to accomplish the goal of designing and developing dependable automotive systems, ISO 26262 uses the concept of Automotive Safety Integrity Levels (ASILs), the adaptation of Safety Integrity Levels. ASILs are allocated to the components and subsystems that can cause system failure and malfunctions that lead to hazards. They are five levels (QM, A, B, C, D) from the least strict ASIL (A) to the strictest ASIL (D), where QM means no safety requirements. Organizations can use the Automotive Safety Integrity Level for determination of retention time.

Ask the expert

Quality Partner's expert, Paul Hardiman

Question:
We have just done an internal system audit on our Facility & Asset Maintenance Process and have stumbled across a grey area.

We have multi-meters on site that are used to measure voltage and current flow by the maintenance team. These do not measure any products characteristics.
Do these multi-meters need to be calibrated by an ISO/IEC17025 laboratory with an ISO/IEC17025 accredited certificate?

We have received a calibration certificate from the company who carried out the calibration and although it shows traceability and the measured values before and after adjustment, the calibration provider is not ISO/IEC 17025 accredited?

Answer:
It depends whether the multi-meters are being used to verify any aspect of the manufacturing process control.

For example, if the control plan says, under process control, a voltage must be 200+/-10V, then the multi-meter would have to be calibrated by an ISO/IEC 17025 accredited laboratory.

If the multi-meters are not used to measure any aspect of process control specified on the control plan, (maybe, for example, is just used to check if a voltage or current is flowing, but the absolute value is not important) then there is no need for an ISO/IEC17025 laboratory to be used, but it would still make sense to keep them in the calibration system, with records or calibration traceable back to national or international standards.

Question:
My company is IATF 16949 certified. We have one supplier of production parts where their ISO9001 has been suspended by their certification body (for period of 6 months).

With the suspension; Would this still allow the supplier to continue ship the parts to my company? What action would you recommend we take?

Answer:
Firstly, we must understand that under the IATF scheme, if a certificate is in a state of suspension it is still valid. However, in the ISO9001 scheme if a certificate is in suspension it is not valid.

The action you take will depend on the potential risks, what they supply you and why they are to be suspended (for example its poor performance, move of site, falsifying data etc.?)

You must decide:
What level of containment do we need to do to ensure the incoming product meets the specification? (For example, increased inspection/testing).

In the period of suspension, maybe you would need to undertake a second party audit to verify they still have a functioning quality management system.

Depending on criticality and risk you may consider starting the process to find an alternative supplier. During this period of suspension, you would need to inform the relevant customer (s) of these planned actions, as under IATF 16949 8.4.2.3 (including sanctioned interpretation 8), states:

“Unless otherwise authorized by the customer a QMS certified to ISO 9001 is the initial minimum acceptable level of development.”

Question:
We have implemented a management review process, that, rather than based on one big annual meeting, each of the senior management team members hold a monthly meeting with their teams to review process performance and act when targets are not met.

I have two questions:
1. Does this management review structure meet the requirements of IATF 16949?
2. If all the process targets under the responsibility of a department are all being met, do they have to still show evidence of continual improvement?

Answer:
1. Management review can be regarded as a process and can comprise of several meetings. However, looking at the overall process, you need to ensure than, at minimum, you ensure coverage of all the management review input requirements defined in 9.3.2 in ISO9001 and 9.3.2.1 in IATF 16949. Reviewing performance alone would not meet the requirement.

Also, my audit question would be: “How does the Top Management team review the overall effectiveness of the quality management system, review the strategic direction and set targets for the next period?” (maybe annual objectives). This could be fulfilled by an annual review, that does not look at all the input requirements defined in the standards but is more a strategic review meeting.

2. There is nothing in IATF 16949 that says every process must show evidence of improvement, it is the responsibility of Top Management to decide where to focus resources on improvement activities.

   You must ensure that you meet the intent of IATF 16949 10.3.1 continual improvement, namely:

   “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)”

So, for the manufacturing process, it is mandated a manufacturing improvement plan is in place, but again this does not say every aspect of the manufacturing process (for example all customer cells, all sub-processes etc.) have to be improved within the plan, this would be based on criticality, performance and risk.

Question
In a recent audit in our Scan & Pack area (shipment area), one of the observations found that the operator used the “QA stamp” on each box after they had packed the units in the box.

There was no traceability as to who had packed the product and who had applied the “QA stamp”. There was also no “control” over the stamps (not allocated to any individual).

When we checked through our Control Plan, Work Instructions and other documents, there is no such requirement to apply the “QA stamp” to every box.

Can we remove from our process the application of the QA stamp?

Answer:
Firstly, let's look at the ISO9001 requirement 8.6 Release of products and services.

"The release of the product or service shall not proceed until the planned requirements have been satisfactorily completed..."

IATF 16949 8.6.1 adds "The organization shall ensure that the planned arrangements to verify that the product and service requirements have been met encompass the control plan and are documented as specified in the control plan"

So, neither of these requirements state that this has to be by applying any form of "QA stamp" or marking to each box (although check that this is not a customer specific requirement), but it should be evident in the control plan what checks are performed to verify that the final product ready for shipment conforms to all the customer and internal requirements and who has the authority to make the decision to release the product to the customer.

This evidence could be maintained by hard copy or electronic records, but the record must be traceable to the person (s) making the release decision.

This also links to IATF 16949 requirement 8.5.2.1 Identification and traceability — supplemental. I would question what the relevant traceability plan says (for example if there was a customer issue related to the product or the related packaging what records would be available to help define the scope of the issue).

Question:
At the end of the clause 9.2.2.1 Internal Audit programme, it is written that:

"The effectiveness of the audit programme shall be reviewed as a part of management review"

What is the meaning of audit programme effectiveness?

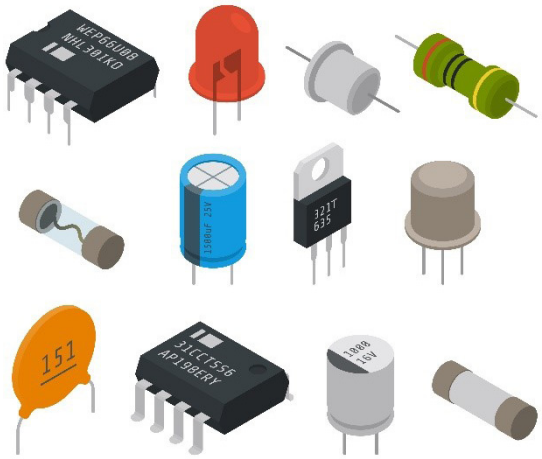
How can we say that the audit programme of the last 12 months is effective or not?

Answer:
Firstly, the ISO9000 definition of effectiveness is "Planned results achieved".

You could measure effectiveness of the audit process by one or more of the following:

- Audits completed to schedule
- Nonconformities closed within agreed timescales
- Number of improvement opportunities identified
- Number of repeat nonconformities
- Comparison of internal audit findings with those in external audits (if the internal audit process is effective, this should reduce the number of external audit findings)

Question:
We buy electrical components from different types of distributors. According to our ordering/payment system, these distributors are treated as our supplier, not the component manufacturer.



My question is what types of distributors need to have ISO9001 certification?

Our current stand point is that if they add value or potential risk, they should be certified, (e.g. warehousing or re-labelling activity), but if all they do is buy and sell from manufacturers (e.g. sales office) we would not mandate ISO9001 certification.

Answer:
I agree with you; it depends on risk and what the distributor you are purchasing from is doing.

If they are buying in, storing, picking and distributing to you, ISO9001 certification by an IAF accredited certification body would be required under IATF 16949 requirement 8.4.2.3 Supplier quality management system development.

If they are only a “post box” and then do not physically see the product, then the risk is lower and therefore you could argue ISO9001 certification is not mandatory.

In either case you need to make clear in your purchase order to the distributor the full specification of the components you require, the manufacturer they should come from (which could be mandated by the customer), along with any relevant product certification or certificate of conformity requirements.

You should seek evidence that the components you purchase have been procured from a manufacturer who has at minimum ISO9001 certification by an IAF accredited certification body for the manufacturing site where the components are manufactured. You could place this as a purchase order requirement to your distributor to source this information for you.

You must then monitor the performance of the distributors (including any quality problems you get related to the product and delivery issues) and then demonstrate effective corrective action with either the distributor or direct with the manufacturer if you have contact.

The degree of supplier development activities (if any) you need to undertake would be based on criticality, risk and performance. (Distributors that have no manufacturing capability are not eligible for IATF 16949 certification)

I would also document in your supplier listing/records how you made the risk-based decision on the need for ISO9001 certification of distributors.

Question:
Please can you give me some advice.

We are currently undergoing our IATF 16949 surveillance audit and an issue has come up concerning an MSA study conducted on a specialised piece of equipment (angle measuring machine).

We have 2 operators who have been certified to use this equipment and we conducted a 2 operator, 4 sample, 5 trial gauge R&R MSA study.

The reason for this study is as follows:

- Only 2 certified trained operators
- Only 4 reference standards available for measurement
- Only 5 trials done due to the extensive time taken to conduct each trial.

We have checked and none of our customers have specific requirements related to MSA.

Previously there was no MSA study conducted on this equipment, so last year a minor NC was raised against this subject.

The auditor is threatening to raise a major non-conformance as a 3 operator, 3 trial,10-part MSA study has not been conducted.

The costs involved with sending another operator to Japan for training/certification and the availability of training course place means that if a nonconformity is raised, we would not be able to close within 90 days. Please can you suggest the best way forward on this issue.

Answer:
Firstly, there is no requirement in IATF 16949 to do Gauge R&R studies unless mandated in customer specific requirements. The requirement is to undertake MSA studies which could include bias, linearity and stability, Attribute agreement analysis etc., not only gauge R&R.

You must define which reference manual and acceptance criteria you use, for example there are three options in IATF 16949, annex B.

I would challenge the auditor on the where the source of the requirement to do a Gauge R&R study using 3 operators, 3 trials and 10 parts has come from.

If I was auditing I would more focus on:

- What is the frequency of calibration of the angle measuring machine? (and how has the frequency been established based on criticality, risk and usage)
- Based on risk, in between the calibration intervals are any checks done on the machine using the reference standards (bias, linearity and stability) and if so, how are these recorded/analysed?
- Which reference manual did you refer to in deciding the type of study to undertake and how many parts/appraisers/trials to undertake?
- What was the result of the MSA study you undertook, what was the acceptance criteria, and what action did you take if the acceptance criteria was not met?
- How do you manage the risk of only having 2 qualified operators of the machine?

Question:
I have an IATF query relating to change control.

We categorise any change as a either a Class 'A' change or a Class 'B' change;

Class 'A' change being a change that affects the product build/test/spec (Fit/form/function).

Class 'B' change being any other type of change (correcting typo's, clarifying wording, restructuring BOM format etc.).

Now we are playing it safe, that whenever an Engineering Change Request (ECR) is raised we insist on obtaining full cross functional team (CFT) approval (for both class A and B changes). This causes additional workload and delays in the process to implement changes.

What are the requirements for CFT approval of changes?

Could we designate that CFT approval is only required for class 'A' changes?

Answer
Let's look first at the relevant IATF 16949 requirements where a multidisciplinary approach is mandated:

7.1.3.1 Plant, facility, and equipment planning.

This requires a multidisciplinary approach, including "evaluating proposed changes to existing operations". If the change relates to a proposal to change any aspect of the plant or facility layout a CFT must be used.

8.2.3.1.3 Organization manufacturing feasibility

"The organization shall utilize a multidisciplinary approach to conduct an analysis to determine if it is feasible that the organization's manufacturing processes are capable of consistently producing product that meets all of the engineering and capacity requirements specified by the customer. The organization shall conduct this feasibility analysis for any manufacturing or product technology new to the organization and for any changed manufacturing process or product design."

8.3.2.1 Design and development planning — supplemental

Although this requirement does not specifically mention change, a note states:

"A multidisciplinary approach typically includes the organization's design, manufacturing, engineering,

quality, production, purchasing, supplier, maintenance, and other appropriate functions."

So, in conclusion, you must apply a multidisciplinary approach (CFT) when planning any change that affect the manufacturing process or product design, (in your terminology class A change).

For class B, you can determine the level of authority and degree of cross functional approval based on risk, but at minimum would recommend it is done with more than one person (for example however minor the proposed change (for example clarifying wording), there is benefit in a second person reviewing to see if any potential impacts in making the change the initial reviewer may have missed).

Finally, you need to ensure that any customer specific requirements related to change control are met.

Question:
We had a minor nonconformity raised in our recent third-party audit against clause 8.4.2.3 regarding our supplier quality management system development process not being fully effective.

We have a supplier who do not have ISO9001 certification.

Originally IATF16949 8.4.2.3 Supplier quality management system development requirement allowed us to undertake a second party audit (which we did of this supplier and then give us good quality and delivery performance) but this was removed in SI 8.

We have looked at re-sourcing, but this would take longer than the 30 days we have left to send the corrective action to our certification body, and we are unable to invest £400,000 in new equipment that would be required to manufacture the component internally.

We have asked our customer for a waiver to allow us to continue to use this supplier, but they have declined.

The supplier in question is planning to seek ISO9001 and IATF16949 certification.

Our understanding is that if we cannot close this nonconformity in 90 days from the end of the onsite audit, we will lose our IATF certification.

Is there anything we can do to prevent this?

Answer
This is a difficult one.

Firstly, I would seek a specific timing plan with supporting evidence from the supplier related to their plan to achieve ISO9001 certification.

I would then provide this to the certification body, with other related supporting evidence, indicating containment, root cause analysis and a detailed corrective action plan (performance data, incoming controls, second party audit reports and evidence of communication with customer) and ask them to consider 100% resolving this minor nonconformity.

This term is referenced in the rules for achieving IATF recognition 5th edition 5.11.3:

*"In **exceptional case(s)** where the implementation of corrective actions cannot be completed within a maximum of ninety (90) calendar days from the closing meeting of the site audit, the certification body shall consider the nonconformity open but 100% resolved when the following conditions have been met:*

a) containment of the condition to prevent risk to the customer has been taken, including a review of the systemic impact on the client's process;

b) documented evidence of an acceptable action plan, instructions, and records to demonstrate the elimination of the nonconformity condition, including a review of the systemic impact on the client's process;

c) scheduled onsite special audit based on the accepted action plan and prior to the next audit (see section 7.2);
d) in situations where 100% resolution has been determined, the certification body shall maintain records of the justification.

Hopefully, if the certification body agrees to this, this will allow you to maintain your certification and time to close and verify the effective implementation of the actions to address the nonconformity.

Question
Could you please help me to understand the mandatory requirements for internal audit of a corporate quality management system?

We have a central R&D function (Technical centre) where all the product design activities are co-ordinated from.

In addition, we also have small teams of people in some of our manufacturing sites involved in R&D activities.

We have a corporate internal audit programme, within which R&D activities at the Technical Centre are audited every year.

We have just had a non-conformity for not carrying out internal audits of our R&D activities at our manufacturing sites.

Clause 9.2.2.2 (including SI 14) of the IATF standard states that "The organization shall audit all quality management system processes over a three-year cycle".

Is the auditor correct in their finding?

Answer
While I agree the requirement is not 100% clear, my understanding of the requirement has always been that each quality management system process at each site or remote location needs to be internally audited at least once in each three-year cycle.

Whereas you are verifying the effective implementation of the R&D process at the central function, you need to ensure the same process is effectively implemented at each of the other locations R&D is performed. This need not be annually but must be covered over the three-year cycle.