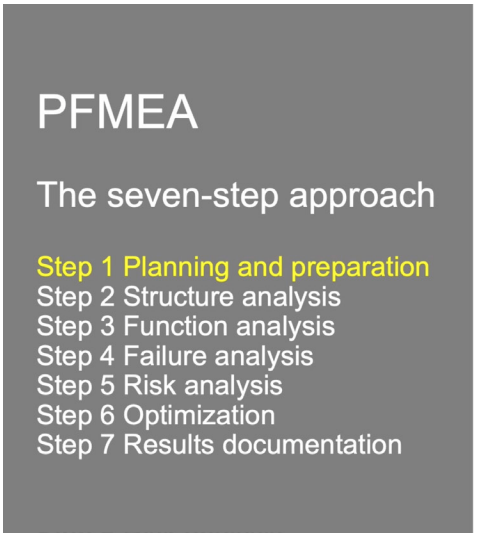
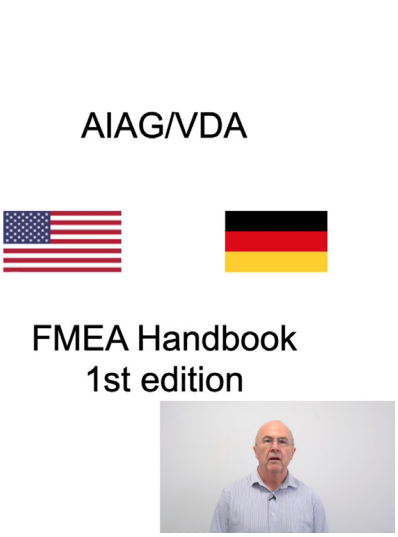
# Quality Partner Newsletter

# September 2019

**Issue date: September 2019**




**Welcome to the Sixteenth 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.

Since the publication of the last newsletter in April 2019 we have final seen the publication of the new AIAG-VDA FMEA handbook. In this newsletter we look at the implications of this change and practical ways to approach implementing the new requirements.

I have also continued to receive many questions on the interpretation and practical implementation of the IATF 16949 requirements.

In addition, this issue focuses on:

- Practical approach to developing a FMEA in accordance with the VDA-AIAG FMEA reference manual
- Questions and answers

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

**IAOB-SMMT You Tube channel**

September saw the launch of the IAOB and SMMT You Tube channel.

The objective is to promote discussion on best practice auditing techniques and practical application of the IATF 16949 requirements.

Each week a short video will be released, some related to auditing processes in an office environment and some related to auditing manufacturing on the shop floor. After each video there is a summary of key learning points and an invitation to post comments and to give feedback.

More information on the You Tube channel can be found on page 2 of this newsletter.

For More Information Visit www.qualitypartner.co.uk

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## IAOB-SMMT You Tube channel


To visit the channel and subscribe visit: https://www.youtube.com/channel/UCocqSC84cx_Bs-xEbhQr9pQ

Each week there will be a new video posted, either from an audit of an aspect of the production process, or a management or support processes.

Each video will include an opening introduction, a video of an audit situation and a summary with key learning points. Viewers will be able to post comments or questions related to the subject matter.

If you have ideas for future videos or if you would be prepared to allow future filming in your company, please let me know.

## Update on the VDA-AIAG FMEA handbook

The new AIAG-VDA FMEA handbook was issued in June 2019.

In the last edition we discussed some of the implications of the change. The conclusions we drew were:

- The handbook promotes a 7- Step approach
- Compliance with the new FMEA handbook may be mandated by customers for new programmes
- The handbook will NOT be an IATF reference manual
- The new approach uses 4M analysis as an input to understand the detailed activities within a manufacturing process step and the associated potential risks
- An Action Priority (AP) ranking is used rather than a Risk Priority Number (RPN) as a way to identify areas for risk reduction
- There is more focus on measuring the effectiveness of the FMEA process by focusing on the cost of poor quality

Since the issue of the handbook I have delivered several training sessions to suppliers in the automotive supply chain around the world.

The conclusions I have drawn so far are:

**Management support**
While organizations see the benefits in the new approach, many are concerned that, unless Top Management are engaged and understand the benefits in investing time with a true multidisciplinary team in developing FMEA's, it will fail.

So how can we get Top Management attention?
In the 20 years I have been involved in training, I can count on one hand the number of senior managers I have had on FMEA training courses!

So, let's think about what Top Management want to achieve.

Firstly, they should be focused on ensuring the organization meets customer expectations, by delivering conforming products on time, that will meet the product lifecycle expectations. In an era when many vehicle manufacturers are expecting suppliers to sign unlimited liability contracts, that would be enacted in the case of product field failures, there is a lot at stake if an organization does not effectively manage risk.

Secondly, they want to ensure their organization meets their internal objectives, and ultimately make a profit. This can be achieved by supporting initiatives to minimize the cost of poor quality, which is a mandatory IATF 16949 requirement to monitor.

So maybe we should engage Top Management by trying to convince them that if they invest the time in ensuring adequately qualified resources are allocated to consider product and process risk using FMEA, they will see measurable benefits in improvement in customer satisfaction and the reduction of the cost of non-quality.

Also, if there was a serious field failure, I am sure Top Management would feel much happier if a robust FMEA was in place that had been created and maintained by a multidisciplinary team. This could be used in a defence to show that all efforts had been made to understand and try to mitigate risk.

If I was a member of Top Management in an organization, my question could be to the process owner (s) responsible for FMEA:

*"Ok, if I invest in doing FMEA correctly, let's say by investing 50-man days of resource in the FMEA teams to develop/improve FMEA's, what will this deliver?"*

I think the person (s) accountable for creating and maintaining effective FMEA's should be given measurable targets to be achieved, for example a 10% reduction in the cost of non-quality.

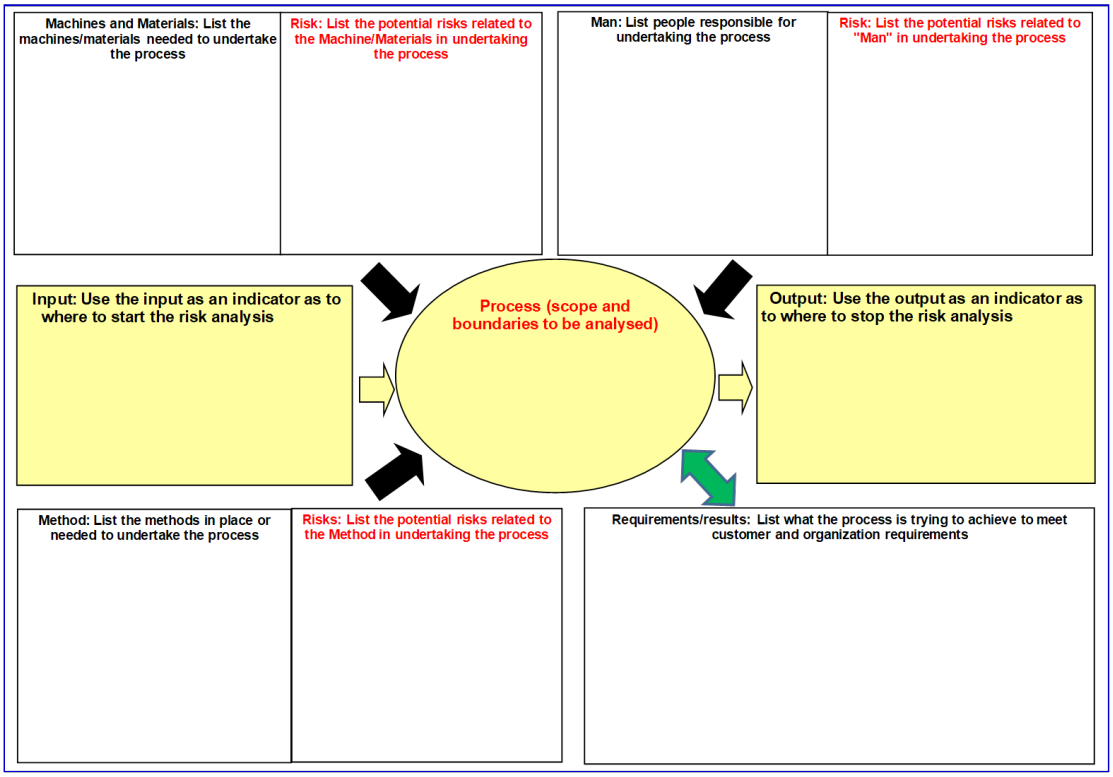
Then, in Management Review, progress against the target could be monitored, and if the target is not

achieved the question should be asked why is the use of FMEA as a risk reduction tool not delivering results?

**Shop floor input into FMEA**
There is the need to get more input from shop floor employees on the 4M influences on the process steps and work elements before developing any PFMEA in the revised format.

While it is accepted it is not possible to take operators away from their daily production tasks, spending a few minutes with them can often give some valuable insights into the potential or actual risks they are facing each day, many that management or supervision will not be aware of.

From the training sessions I have delivered, to get this shop floor input, I have used A0 versions of the 4M risk analysis diagram below:




To use this approach, it does not require complex training, just a brief explanation to the shop floor employees that the purpose is to get their input on the actual or potential risks in the production process. This can be done at the process step level (for example injection moulding) or at the work element level (Robot transfers insert into mould tool). The key thing is to clearly define the scope (by clearly stating the input and output) before starting the analysis.

Once the scope is confirmed, ask the people involved what they are trying to achieve (requirements) at the process step of work element level. These could relate to internal or customer requirements.

Then confirm what people are involved (Man), what physical things are required (Man, Material and Environment) and what methods are in place. Then get ideas on the actual or potential risks that could affect meeting the defined requirements. Use the rules of brainstorming, do not discount any ideas!

This input can then be used by the FMEA team in developing or updating the process FMEA. The team should ensure that the risks identified in the 4M analysis are all covered in the FMEA, and the appropriate controls are in place based on the action priority rankings determined.

**Competency of the FMEA multidisciplinary teams**
For FMEA to be effective the team, whether involved in DFMEA or PFMEA, must be competent in understanding the details in the relevant reference manual, which could be the AIAG 4th edition manual, or the new AIAG-VDA FMEA handbook.

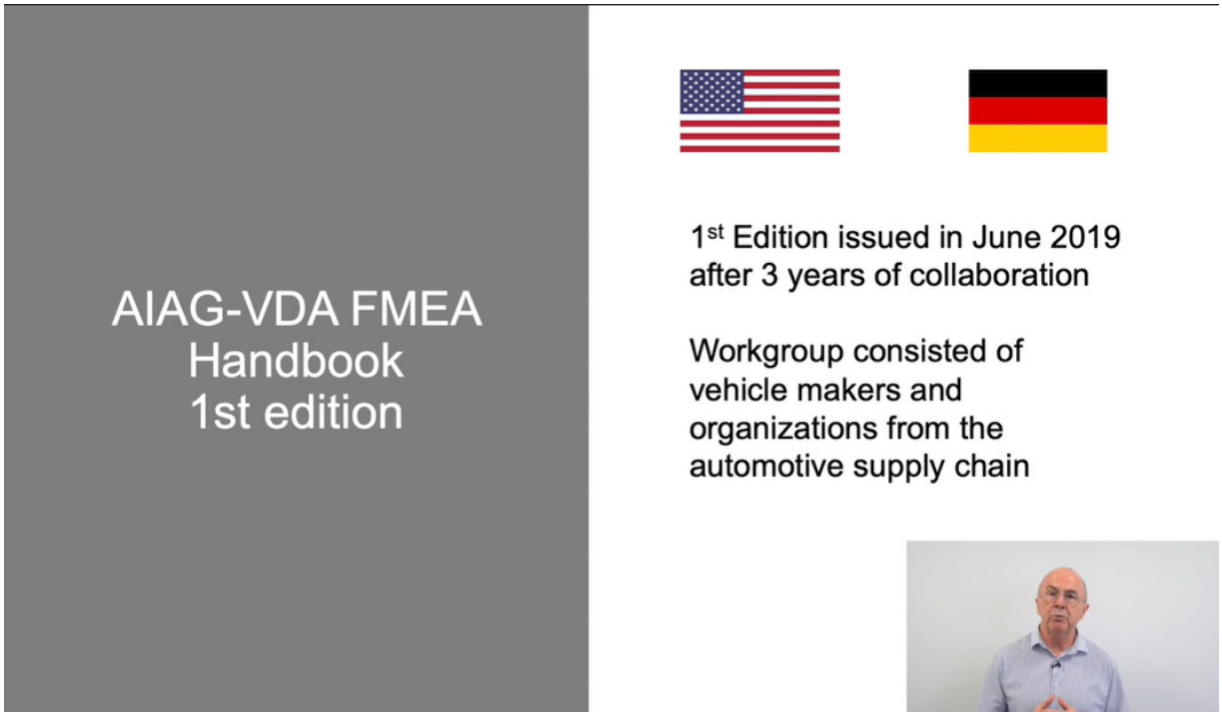
To train many people in FMEA can often be very expensive, and in a day when resources are very “lean”, to release people for days of training can often prove difficult.

In the last 4 years, Quality Partner has produced several video series related to the automotive core tools, awareness of management system standards, and effective process-based auditing.

Each video is approximately 15 minutes long and is supported by online exams to verify learning. Videos can be viewed individually, or in small teams. One of the benefits of using video technology if the video can be stopped at any time, to allow team discussion before moving on to the next section.

Over 5000 delegates have taken at least one module and exam, many from large multinational organizations, with excellent feedback.

For free access to a 17-minute introduction video on the new handbook visit:
https://qualitypartner.co.uk/core-tools/effective-application-of-the-aiag-vda-fmea-handbook/




**F**or a more detailed understanding of the new handbook Quality Partner is pleased to announce the issue of two new video series:

**Implementing the new AIAG-VDA handbook related to PFMEA**
This series of seven videos explains the seven steps of developing a PFMEA, built around a practical case study example.

To buy this series with a single user licence access for 12 months, the cost is £70.

However, for the **first 100 people** who mail paul.hardiman@qualitypartner.co.uk I will send **a 50% discount** code, reducing the **total cost to £35.**

If you require multi-user unlimited time access to this video series, the cost is £350.

**Implementing the new AIAG-VDA handbook related to DFMEA**
This series of eight videos explains the seven steps of developing a PFMEA, built around a practical case study example, and one video on the FMEA Monitoring and System Response (FMEA MSR).
To buy this series with a single user licence access for 12 months, the cost is £80.

However, for the **first 100 people** who mail paul.hardiman@qualitypartner.co.uk I will send a **50% discount** code, reducing the **total cost to £40.**

If you require multi-user unlimited time access to this video series, the cost is £350.

For more information visit www.qualitypartner.co.uk

Single user licences can be purchased online with a credit card, for multiuser licences contact paul.hardiman@qualitypartner.co.uk

## Ask the expert

*Quality Partner's expert, Paul Hardiman*

**Question**
I am responsible for preparing the internal audit programme in our organization. I have some questions:

1. In manufacturing we are set up in customer cells (we have 12 cells, in each cell have multiple manufacturing processes). In addition, we have some standalone processes that support all the cells (for example heat treatment). Do we have to undertake manufacturing process audits in all the cells on each shift over a three year cycle, or can we sample?

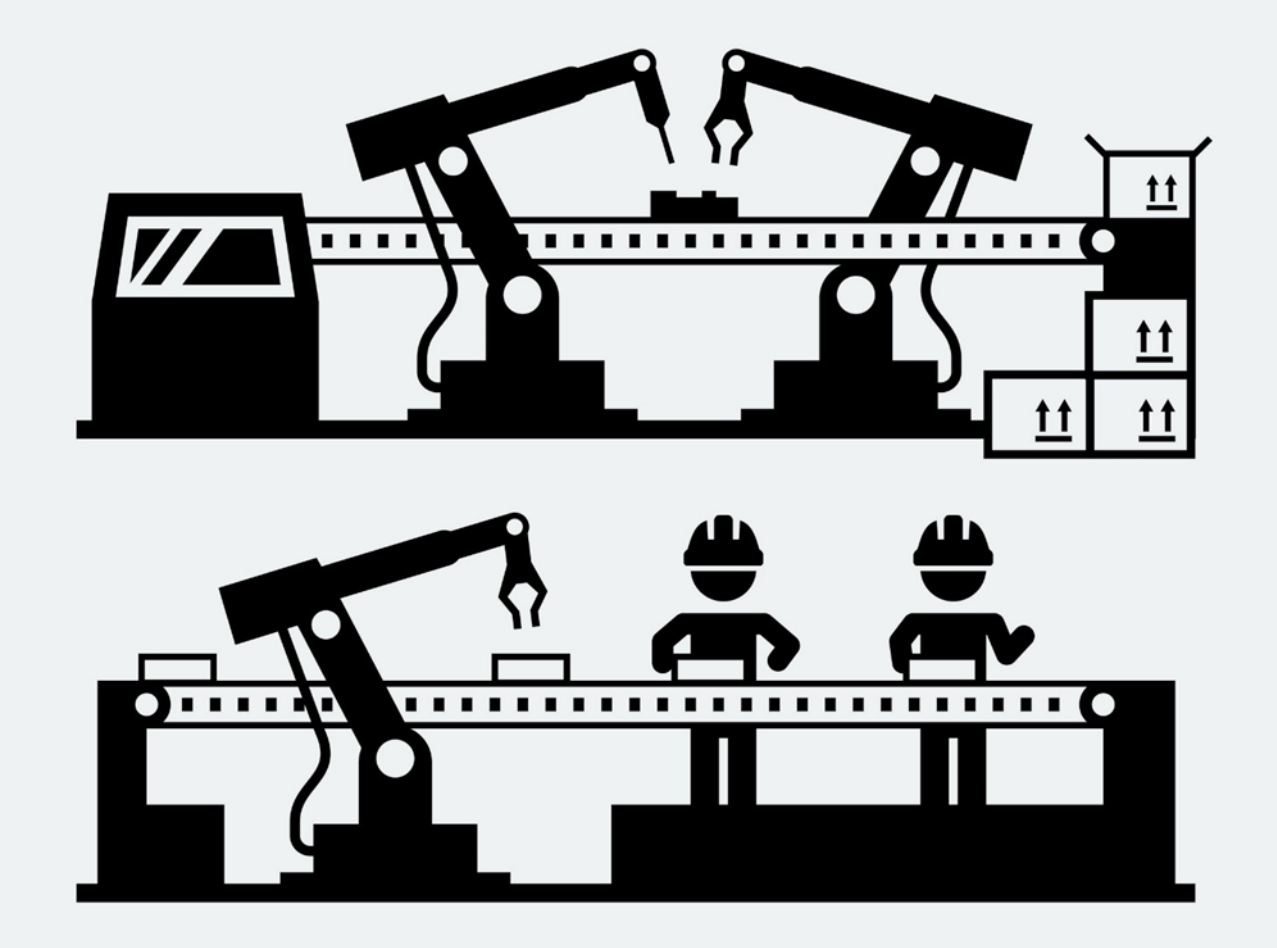
2. If we do manufacturing process audits as above, do we also have to undertake a system audit of the manufacturing process?

3. In the last 12 months we planned and undertook 5 product audits. Our external auditor told me this is not enough, is this correct?

**Answer**
Let's answer your questions one at a time:

1. The IATF requirement 9.2.2.3 Manufacturing process audit states:

*"The organization shall audit all manufacturing processes over each three-year calendar period to determine their effectiveness and efficiency using customer-specific required approaches for process audits. Where not defined by the customer, the organization shall determine the approach to be used. 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."*



The key word is all manufacturing processes, not cells. However, when scheduling internal audits, customer specific requirements, internal and external performance data, results of previous audits, risk and changes need to be considered in determining the frequency of manufacturing process audits. The key thing is your audit programme, at minimum, must cover all the manufacturing processes on all shifts over a three-year cycle. (Also notice that this states shifts (periods of time) rather than crews).

So for example if one of the manufacturing processes in each cell is injection moulding, and this is operating on three shifts, say 6.00am-2.00pm, 2.00pm to 10.00pm and 10.00pm to 6.00am, injection moulding must be audited at least once in a three year period on all the shifts.

This could be one audit, for example in cell 1 starting at 12.00pm to 4.00pm, covering the shift handover at 2.00pm and then one audit in cell 5 (again an example) starting at 8.00pm and finishing at 12.00am, again covering the shift handover at 10.00pm. Focusing on cell 1 and 5 could have been influenced by cell performance, risk, or customer specific requirements.

The method used to undertake the manufacturing process audits will depend on customer specific requirements (for example VDA6.3). In all cases the manufacturing process audits should include the effective implementation of the process risk analysis (FMEA) and control plan. This does not mean they have to be 100% checked, but sampled to ensure effective implementation, focused on areas of highest risk (for example Special Characteristics)

Bear in mind that the frequency of all manufacturing process audits over a three-year period is a minimum, in reality the frequency may be higher, influenced by customer specific requirements, changes, performance or risk.

2. The IATF requirement 9.2.2.2 Quality management system audit (incorporating SI 14) states:

“The organization shall audit all quality management system processes over a three-year audit cycle, according to an annual programme, using the process approach to verify compliance with this Automotive QMS Standard. Integrated with these audits, the organization shall sample customer-specific quality management system requirements for effective implementation.”

So, whereas manufacturing process audits verify the effective implementation of the relevant manufacturing process, quality management system audits look at the effective implementation of the overall Quality Management System.

The internal audit schedule should be based on the high level QMS processes defined in your Quality Manual. To be eligible for IATF 16949 certification, organizations must have manufacturing capability, so this would need to be audited as part of the system audit programme. (although the process does not have to be called manufacturing, for example could be called production, etc. in the Quality Manual).

The Quality Management System audit of manufacturing would be undertaken with the process owner, for example the production manager. The audit would focus on the process, the process performance, the process risks, and how the process is monitored on an ongoing basis for effective implementation. It would not need to include a detailed audit on the shop floor as this would be covered in the programme of manufacturing process audits.

3. The relevant requirement for product audit is 9.2.2.4 Product audit which states:

The organization shall audit products using customer-specific required approaches at appropriate stages of production and delivery to verify conformity to specified requirements. Where not defined by the customer, the organization shall define the approach to be used.

This is less prescriptive than for system and manufacturing process audits. Unless there are customer specific requirements (for example VDA 6.5), it is up to the organization to define how the audits are undertaken, and at what frequency. Again, like for manufacturing process audits, the frequency should depend on performance, criticality (for example products with safety critical characteristics) and risk. What is checked on the product audit needs to be determined during the audit planning.

For example, in the table below there are many product characteristics referenced on the drawing, not all need to be checked. In this example the auditor may decide, based on risk, to focus on the shaft diameter OD1 and the surface roughness, as these are both special characteristics.

| Characteristic number | Characteristic | Specification | Special characteristic | Proposed measurement technique |
|---|---|---|---|---|
| | | | | |
| 1 | Incoming Shaft Part No. | A345680 | | Visual |
| | | | | |
| 2 | Shaft OD 1 | 29 ± .025 | Yes | Micrometers |
| | | | | |
| 3 | Shaft OD 2 | 20.5 ± .05 | | Ring Gage |
| | | | | |
| 4 | Shaft OD 3 | 30.3 ± .05 | | Micrometers |
| | | | | |
| 5 | Chamfer Position | OK / NG | | Master Part |
| | | | | |
| 6 | Roundness | 0.02 max | | CMM |
| | | | | |
| 7 | Surface Roughness | OK / NG | | Master Part |
| | | | | |
| 8 | Surface Roughness | Ra 3.2 | Yes | Roughness Tester |

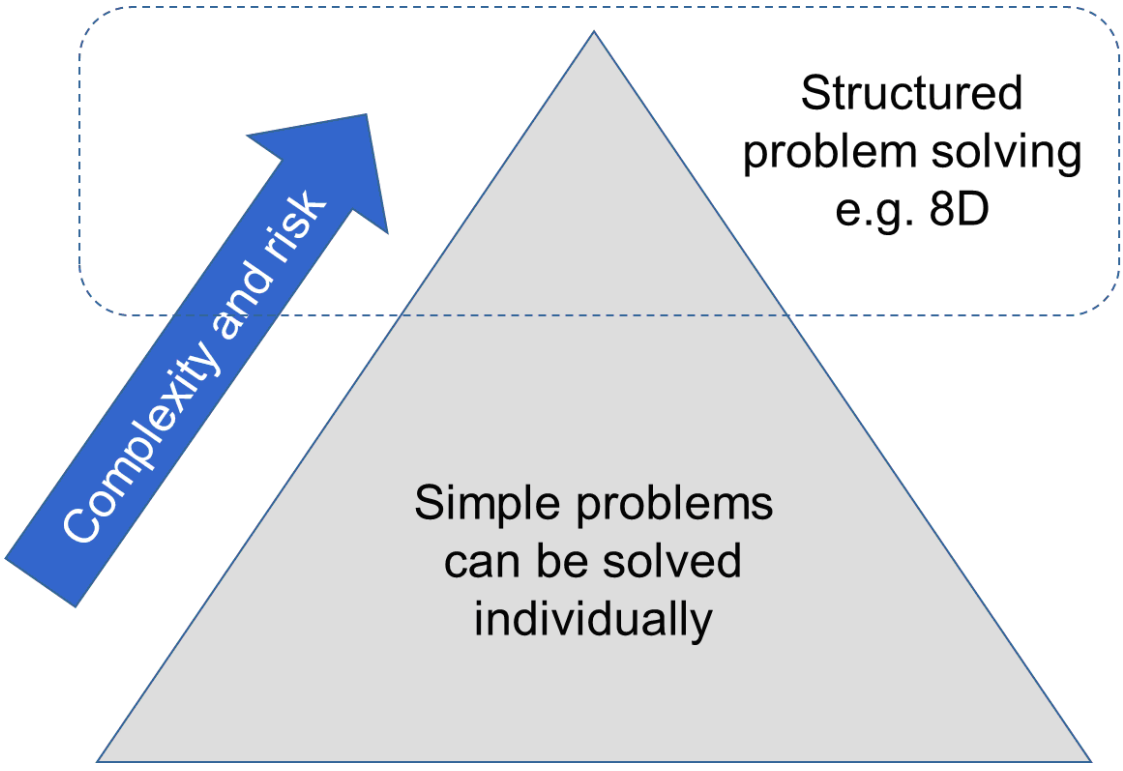
The auditor was wrong to state 5 product audits is not enough, unless he found evidence that the product audit programme was not effectively implemented (for example you planned 10 and only undertook 5) or that the programme did not meet customer specific requirements, or the programme was not based on performance, changes and risk.

**Question**
We are currently reviewing and updating our problem-solving process. The process covers dealing with customer complaints, internal performance issue and internal and external audit findings. Is it a requirement that to solve all problems we must have a multidisciplinary team and use structured problem solving?

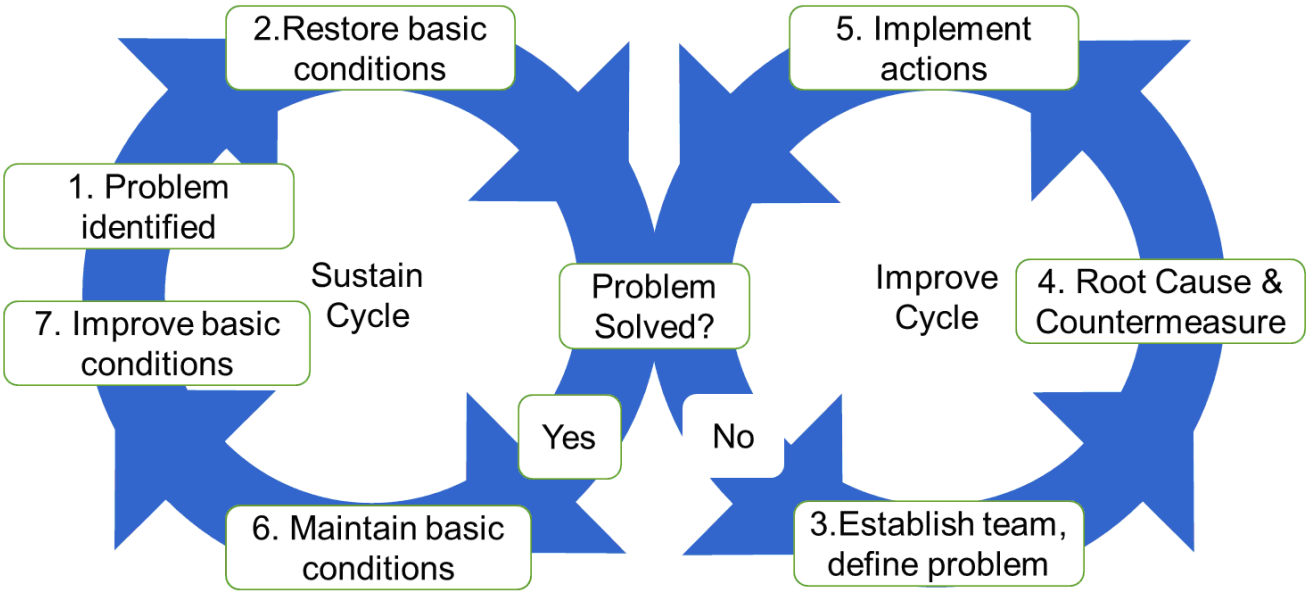
**Answer**
Good question, Firstly, in 10.2.3 it does not mandate a multidisciplinary team is used, but this could be mandated in some customer specific requirements.

In the IATF requirement 10.2.3 it states a) defined approaches for various types and scale of problems (e.g., new product development, current manufacturing issues, field failures, audit findings);

To meet this requirement it makes it clear that you do not have to have one problem solving methodology, you can have different approaches for different types of problems.




For simple problems I would suggest you consider “figure of 8” the approach on the next page.




Many small problems in processes are caused by people not working to the defined standards/instructions. For these the initial action can be to restore “basic” conditions and then monitor to see if there is any repeat of the problem. This action can be taken locally within the process and does not necessarily need a full cross functional team.

Using data, if the issue becomes a recurring problem, a multidisciplinary team can be formed, the problem statement defined, and a structured problem-solving process initiated (for example 8D).

Obviously in making the decision on whether structured problem solving using a multidisciplinary team is required, customer specific and interested party (for example certification body) requirements must be taken into account
CQI CQI-20 Effective Problem-Solving Practitioner Guide provides some valuable guidance.
The method used to identify root cause is not defined in IATF 16949, but the key thing is the team must record the methodology used in the problem solving documentation.

**Question**
We are currently considering moving from having hard copy work instructions at the production workstation to having computer terminals in the work cells where operators would access the instructions electronically. Would this cause any problems in meeting the IATF requirement 8.5.1.2?

**Answer**
The IATF requirement 8.5.1.2 Standardised work — operator instructions and visual standards states

a) accessible for use at the designated work area(s).

So, the requirement does not state hard copies need to be available. The key word is “accessible”.

The access terminals need to be on the shop floor, not for example in a supervisor’s office and operators need to be competent to know where and how to access the relevant documents to perform their tasks. There would need to be protection to stop unauthorised amending or printing of copies, which could lead to document control issues.

There also needs to be an effective contingency plan in place in the event of computer breakdown, cyber-attack etc to allow the relevant documents to be accessed.

Finally, in making the decision, customer specific requirements must be considered, some may mandate that instructions must be at the specific workstations.

**Question**
In my company, there is some confusion about ISO9001 and IATF 16949 requirements related to clause 10.2 Non-conformity and corrective actions, especially the effectiveness of corrective action.

Some people have said that to check the effectiveness of a corrective action is just a check the corrective action has been implemented. I disagree but would like your view.

**Answer**
In CQI-20 problem solving, it states "*Verification of corrective actions is the final gate to ensure that all the actions taken have been successful in permanently resolving the issue and preventing it's reoccurrence. The team needs to be mindful of addressing the root causes verses eliminating the symptoms. Success of the corrective action is to be validated by gathering and analysing quantifiable data."*

So, effectiveness of corrective actions is not just implementing the corrective action but ensuring it has addressed the root cause(s) identified.

This could be done by monitoring the process output (for example the process KPI) to see if the process performance has improved and the problem eliminated or monitoring by audits (system, manufacturing process or product). To do this often takes time, being solved should not be closed until the effectiveness is verified and evidence seem to demonstrate effectiveness.

**Question**
I would like to seek clarification in ISO9001 8.7.1 b.

*The organization shall deal with nonconforming outputs in one or more of the following ways:*

*b) segregation, containment, return or suspension of provision of products or services*

Does the term 'segregation' here mean that if you hold and tag the nonconforming material by the shop floor system this is compliant or is the segregation in both the system and the physical lots?

**Answer**
The key thing is to demonstrate a system to prevent the inadvertent use of any nonconforming product.

This does not necessarily mean that the nonconforming product must be in a separate segregated area, but you need to ensure your system is fool-proofed and that nonconforming product cannot be taken and used by mistake. (For example, bar code scanning that would show if the product is nonconforming that it cannot be taken and used in further processes).

The only thing that would change this is if there was any specific customer requirement. In VDA 6.3 the requirement in question 6.2.4 states:

*"Storage areas for blocked stock and restricted areas must be clearly labelled."*

Question 5.6 states *"Suspect or quarantined products must be stored securely to prevent unauthorised access to them".*

**Question**
I see in the new AIAG-VDA FMEA manual, it seems that it is not a requirement to identify special characteristics in the DFMEA and in PFMEA special characteristics are not mentioned until step 5. Can you explain?

**Answer**
As an input to creating a DFMEA, an organization must understand any customer requirements related to special characteristics, including designation and any criteria of the design that is critical to the customer (in the interface with their higher-level system). This forms an assessment into the design risk analysis.

The team may use the DFMEA to highlight where process controls may be needed to ensure conformance to specification. The design FMEA form sheet has a column “Filter code” that may be used to document this information.

On completion of the DFMEA the organizations pass the results of the risk analysis and any actions to either external suppliers (for example tier 2) who may be designing part of the overall system, or to the internal team responsible for creating the PFMEA.

The PFMEA form sheets contains a column called “Classification”. This may be used to specify special characteristics (e.g. critical, key, major, significant, considering customer specific requirements) that require additional process controls.

Although this column shows in step 5, risk analysis, this does not mean the team do not consider special characteristics until then. As stated above the team would receive inputs from the DFMEA and or the customer requirements/specifications, these would be considered when doing the scoring of severity, occurrence and detection, which in turn may identify additional special process characteristics.