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Firstly, I hope you are all safe and well. Wishing you all a happy and successful 2022.

Welcome to the twenty fourth 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

Many of you will know my view that I believe the situation with Customer Specific Requirements (CSR's) is out of control. At the moment any IATF 16949 certified organization, anywhere in the supply chain, can interpret or add requirements, that then have to be sampled in 3rd party IATF 16949 audits.

We must continue to challenge this in 2022!
One area that the IATF OEMs are showing increasing interest in is Reverse FMEA.

This issue focuses on the CSR's related to Reverse FMEA, and discussion on their expectations. There is also the usual Question and Answers section.

If you have any questions or topics for future editions, please feel free to mail to:

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2022 looks to be an interesting year from an IATF perspective. There is still the ongoing challenge of Covid 19 which is continuing to make onsite auditing a challenge in many countries.

It is likely the IATF Covid response, allowing remote audits when onsite audits are not possible, is set to continue.

IATF continue to work on the Rules for achieving IATF recognition 6th edition, which are due for release in the 3rd quarter 2022. Although the changes are more applicable to IATF 16949 certification bodies, the changes will affect certified organizations.

Work has also started on the next revision of IATF 16949, possibly due for release in 2024. Watch this space for more details!

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:
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Reverse FMEA

It seems that the IATF OEMs are taking an increasing interest in Reverse FMEA, with four of the IATF members including reference in their customer specific requirements.

Firstly, let's look at the customer specific requirements (CSR's) stated:

Ford
Ford added a requirement under 8.3.2.1 Design and development planning — supplemental

*"Reverse FMEA Process (RFMEA) Organizations **are required** to have a process in place that ensures all new launches complete an RFMEA event once the equipment is installed and running. This process **should** be first completed at the equipment manufacturer and then after final installation on the organization's plant floor. The reverse FMEA involves design and process engineers working with operators and attempting to make bad parts, beat the error proofing and find new failure modes, causes, and develop controls. The goal is to discover opportunities and implement improvements in the FMEA that were not previously discovered. Evidence of Reverse FMEA events **must** be available starting July 1, 2022, for forward model programs which have not yet completed Job 1".*

GM
GM added a requirement under 10.3.1 Continual improvement – supplemental

*"The organization shall incorporate tools **such as** reverse PFMEA or other similar methods to assist in the PFMEA review."*

Renault
Renault requirement 4.6 added the requirement under Control of non-conforming output (IATF 16949 requirements 8.7.1.2-8.7.1.7 and 10.2.3-10.2.4).

*"The organizations **shall** review FMEA by using Reverse FMEA (R-FMEA) tool. In order to switch from corrective to preventive actions, the organizations **shall** check at shop floor level their existing FMEA and provide necessary activities to avoid occurrence or at minimum to improve detection of non-conformity."*

Stellantis PSA
Stellantis PSA 9.1.1.1 Monitoring and measurement of manufacturing processes.

*"The **supplier must** implement "Reverse PFMEA" to:*

- identify new potential failure modes in shop floor (Proactive Risk Reduction Process),
- confirm or update current Occurrence/Detection levels (Process optimization).

The Reverse PFMEA is an "on-station review" by a cross-functional team."

Clear on the requirements?

Firstly, it is disappointing that four of the IATF members have added a requirement for Reverse FMEA but cannot even agree on the relevant IATF 16949 requirement! and whether they are focused on the use of Reverse FMEA as a tool for corrective action or continual improvement (or both).

Also, with reference to the words highlighted in their requirements above in bold they also cannot agree on common terminology.

The Ford requirement is more written like a definition of reverse FMEA and uses terms like "should" (used 16 times in the Ford requirements).

According to the ISO website under Foreword- Supplementary information it states:

"shall" indicates a requirement.

"should" indicates a recommendation.

"may" is used to indicate that something is permitted.

"can" is used to indicate that something is possible, for example, that an organization or individual is able to do something.

A generally accepted legal definition of should is: "*Should means that a certain feature, component and/or action is desirable but not mandatory."*

Also, Ford use the term *"must"* and *"are required"* for which there is no ISO or IATF definitions.

In the GM requirement, the term "such as" is used related to the use of Reverse FMEA, which is again not an ISO defined term. However, the use of Reverse FMEA is not mandated under the term "such as"

In the Renault requirement they at least use "shall", mandating the use of Reverse FMEA, but three of the four IATF 16949 requirements selected as relevant focus more on reactive rather than proactive use of Reverse FMEA.

In Stellantis PSA requirement the term "must" is used, which seems to indicate reverse FMEA is a mandatory requirement (why was "shall" not used?).

While this may seem like nit-picking, 3rd party auditors are mandated to sample customer specific requirements to verify effective implementation during IATF 16949 audits, and if the requirements are not clear this will lead to inconsistencies.

Also, if nearly 50% of IATF members are adding requirements related to Reverse FMEA, why has this not been discussed in the IATF group, and if there is consensus that it is a good tool, it added as an IATF 16949 requirement through a sanctioned interpretation?

Finally, before we review the meaning of reverse FMEA, why is there no reference to Reverse FMEA in the AIAG-VDA handbook, that took over 3 years to develop by collaboration between the American and German automotive industry?

What is Reverse FMEA?

Reverse FMEA is a structured process of continuous improvement that aims to help ensure the effective implementation on the PFMEA. The Reverse FMEA is a review, done at the shop floor (reality), of all failure modes included in the Process FMEA, conducted by a multifunctional team, to verify that all failure modes have been identified and any identified prevention/detection controls effectively implemented.

The main activities to be performed for a Reverse FMEA are:

• Collect and analyse the actual performance results
• Review the current process at the workstations
• Diagnose the actual situation and the implementation of any PFMEA improvement actions
• Test the actual effectiveness of the prevention and detection controls
• Identify any missing failure modes
• PFMEA revision and new improvement actions defined

Is Reverse FMEA an IATF 16949 requirement?

The short answer is no unless it is a customer specific requirement. There is also no clear requirement in IATF 16949 related to how often FMEA's should be reviewed.

Requirement 8.5.1.1 states:

The organization shall review control plans, and update as required, for any of the following:

f) the organization determines it has shipped nonconforming product to the customer;

g) when any change occurs affecting product, manufacturing process, measurement, logistics, supply sources, production volume changes, or risk analysis (FMEA) (see Annex A);

h) after a customer complaint and implementation of the associated corrective action, when applicable;

i) at a set frequency based on a risk analysis.

10.2.3 Problem solving requirement states:

The organization shall have a documented process(es) for problem solving SI20 which prevent(s) recurrence, including:

f) reviewing and, where necessary, updating the appropriate documented information (e.g., PFMEA, control plan).

Also 10.3.1 Continual improvement supplemental states:

The organization shall have a documented process for continual improvement. The organization shall

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include in this process the following:

c) risk analysis (such as FMEA)

So, we can conclude from these requirements that PFMEA and control plans:

*   Shall be "live" documents
*   Shall be reviewed at a frequency based on risk analysis
*   Shall be reviewed by a multidisciplinary team
*   Shall be reviewed as part of the problem-solving process
*   Shall be an input into developing a manufacturing process improvement plan

So, even if not mandated by the customer, Reverse FMEA can be a tool that any organization can use as part of their problem solving or continual improvement process.

When does the use of a Reverse FMEA become applicable?

To conduct a reverse FMEA, the key point is there needs to be a physical manufacturing process, it cannot be based on theory. In the Ford requirement it states: "once the equipment is installed and running", which could be at the equipment supplier as part of the equipment sign off process and when the equipment is installed in the manufacturing plant. After installation reverse FMEA can be done at any time.

Who should be involved in the Reverse FMEA process?

In 8.3.2.1 Design and development planning — supplemental

"Examples of areas for using such a multidisciplinary approach include but are not limited to the following: c) development and review of product design risk analysis (FMEAs), including actions to reduce potential risks;"

The note states "A multidisciplinary approach typically includes the organization's design, manufacturing, engineering, quality, production, purchasing, supplier, maintenance, and other appropriate functions."

In the Ford requirement it states:

"The reverse FMEA involves design and process engineers working with operators….."

So, in conclusion, it is the responsibility of the organization to identify a multidisciplinary team, the key thing is it cannot be done by an individual, and must include people working close to the process (operators, inspectors, setters etc.).

Is training in Reverse FMEA mandated?

No, but it is a requirement, stated in IATF 16949 7.2.1 Competence — supplemental.

"Personnel performing specific assigned tasks shall be qualified, as required, with particular attention to the satisfaction of customer requirements."

Competence could be demonstrated by education, experience, training, or a combination.

How should we prioritize which manufacturing processes to trial or use Reverse FMEA?

Reverse FMEA can be used:

*   For a new manufacturing process, prior to full production

- As part of a problem-solving process (customer or internal problems)
- As part of the continual improvement process

Data should be used to help prioritize, especially for an existing process, which could include internal and external quality data (e.g., PPM, rework, repair etc.), and field/warranty issues.

A decision must be made whether to do the reverse FMEA on a part specific FMEA, a family FMEA or foundation FMEA. Foundation FMEA's are typically created for a generic manufacturing process, for example stamping, riveting etc. that are used to manufacture multiple part numbers. A family FMEA is a specialized version of the foundation FMEA, specific to a family of products manufactured on a common manufacturing process. In the latest Ford CSR's, foundation FMEA's, from which part specific FMEA should be derived from, are mandated.

How should the reverse FMEA be undertaken and documented?

There is no specific reference manual, defining how to undertake and document a reverse FMEA, defined in IATF 16949, Annex B or customer specific requirements.

Therefore, an organization can define how Reverse FMEA's are undertaken and recorded.

In the AIAG-VDA handbook, a lot of emphasis is placed on the FMEA team having a detailed understanding of the manufacturing process being evaluated, and the 4M influences on the process that can affect the process outputs.
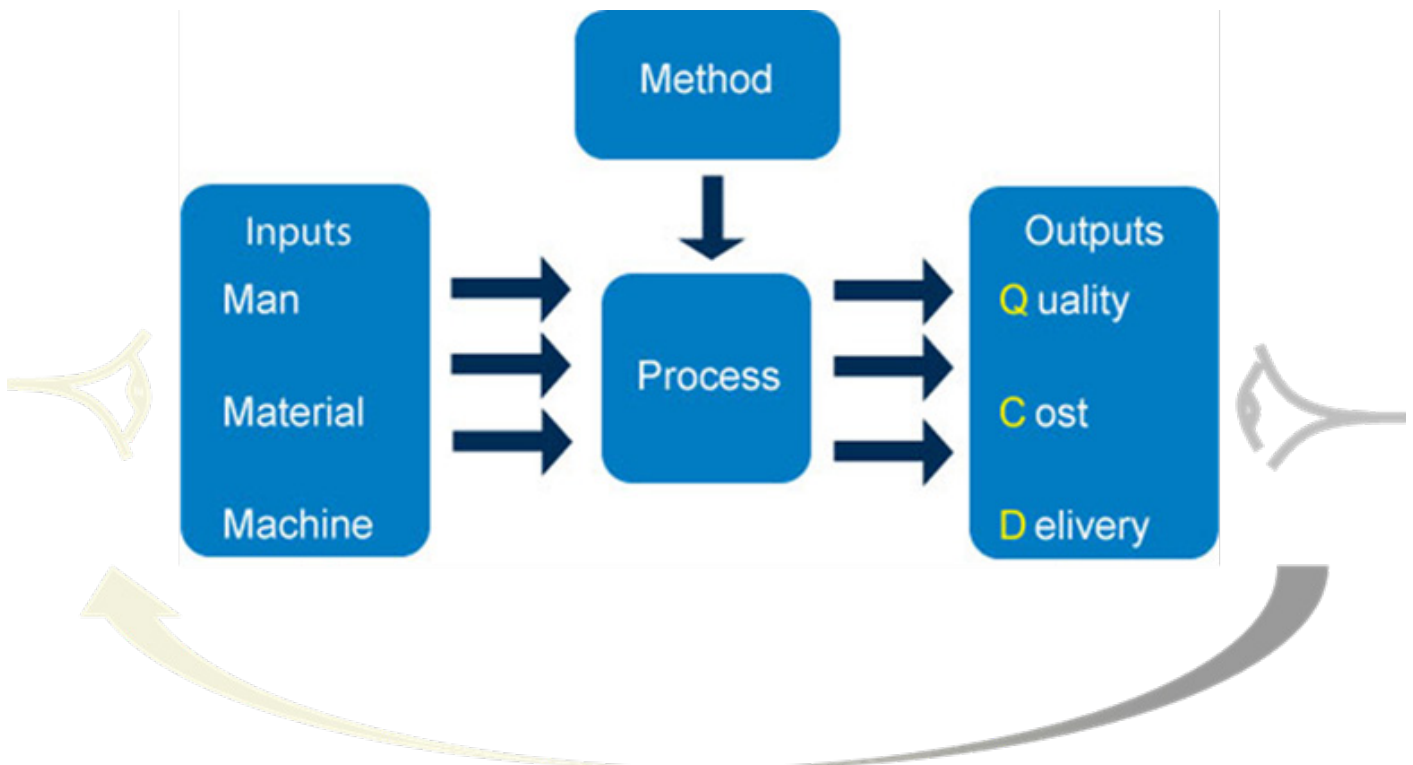
The aim of the reverse FMEA is to evaluate if all the relevant 4M risks have been captured, documented and the relevant controls have been put in place to mitigate or manage the risks.

In my view one of the reasons that FMEA is not always fully effective is that people working close to the process (e.g., Operators, Team Leaders etc.) are not involved in the initial risk analysis. However, to involve operators in the process of completing a full FMEA in many cases would not be practical.

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One technique I have seen work effectively is to use a simplified version of a risk analysis, considering the 4M influences, to get shop floor input to the FMEA, and reverse FMEA.

Machines and materials (what machines/materials needed?)	Risks related to machines and materials	Man (who is involved in operating the process?	Risks related to Man

Inputs: Use the input as an indicatore where to start the risk analysis

List process work elements to transition input to output

Outputs: Use the output as an indicator where to stop the rik analysis

Define work sequence within process step

Method: List the in place or needed to operate process	Risks related to methods	Requirements/results: List what the process step is trying to achieve to meet customer or internal requirements

This information collecting can be done on the shop floor, with a facilitator gathering input from the shop floor personnel on what is in place to control the 4M, and importantly what they see as some of the actual or potential risks that could affect the process achieving the desired results.

This information can then be used by the reverse FMEA team as an input to the review and update of the PFMEA.

Let's look at an example, for an injection moulding process, and a failure mode of short shot.

1. Failure Effects (FE)	Severity (S) of FE	2. Failure Mode (FM) of the Process Step	3. Failure Cause (FC) of the Work Element	Current Prevention Control (PC) of FC	Occurrence (O) of FC	Current Detection Controls (DC) of FC or FM	Detection (D) of FC/FM	PFMEA AP
Your plant: The plastic clip can not be assembled to garnish Ship to plant: The garnish ASM can not be assembled to the A pillar	7	Short shot	The technician setting up parameter not as the defined Condition Table	1. WI 5641 Standard for seting injection molding machine 2. Job set up verification (1st piece inspection)	5	Operator perform visual inspection 100% (FM)	6	M

Questions that could be asked during the Reverse FMEA activity, on the shop floor, are:

*   What is the current internal and external performance data related to short shots?
*   What are the trends in the data? (Improving or getting worse)
*   Is WI 5641 available to the technician and is there evidence of competency? (Talk to technician)
*   How have the setting parameters in WI 5641 been verified as being correct to produce conforming product?
*   Is there evidence of 1st piece inspection?
*   When is the 1st piece selected? (After machine is stabilised, set number of pieces etc.)
*   Is there evidence of 100% inspection by the operator?
*   What are the acceptance criteria of the visual inspection, how are the standards communicated?
*   Are the prevention/detection controls linked to the control plan and work instructions?
*   Are there any other potential causes of failure identified in the 4M analysis that have not been considered in the PFMEA?
*   Is there opportunity to implement error proofing/mistake proofing to the process?
*   What actions have/can be undertaken to reduce the risk?
*   Have any defined improvement actions been effectively implemented?

The team can record notes while on the shop floor, any potential improvements recorded, and then the facilitator can update the PFMEA, and if appropriate the control plan and other documentation, and circulate to the Reverse FMEA team for approval.

The change record for the PFMEA can be used to record the reverse FMEA details, and what changes were made as a result of the review.

Can we video the process, and then use this to conduct the reverse FMEA in the office?

If there are potential issues with safety, especially in the time of the Covid 19 pandemic, that restricts groups of people gathering on the shop floor, one possible option is to video the actual manufacturing process (which could include talking to operators), and then evaluate the videos away from the process. I would conclude this is not the preferred approach, but is an option to be able to start the Reverse FMEA process.

Could manufacturing process audits be used as evidence of Reverse FMEA?

Although there is a linkage between Reverse FMEA and manufacturing process audits, in the fact that both activities need to review the PFMEA and control plan, the purpose is different.

The Reverse FMEA must be undertaken by a multidisciplinary team who have responsibility for ensuring the manufacturing process effectiveness and efficiency.

The manufacturing process audits must be undertaken by competent auditors, who are independent from the process, who's task is to verify that the manufacturing process is being effectively controlled to produce the desired results, in accordance with the PFMEA and control plan.

Conclusion

Whether we like it or not, IATF members are mandating the use of Reverse FMEA to their suppliers through CSR's.

Whether mandated or not, does it make sense that FMEA teams should get out of the conference rooms and down to the shop floor and observe what really happens?

If the answer is yes, then why not try Reverse FMEA as part of a problem solving or continual improvement activity.

MMOG-LE

Global Materials Management Operations Guidelines/Logistics Evaluation (MMOG/LE) is a self-assessment and continuous improvement tool that provides the means to enhance materials management efficiency and accuracy while reducing costs from errors and waste. MMOG/LE is a global standard of industry best practice for supply chain management processes.

Its purpose is to establish a common definition of supply chain management best practice to facilitate efficient and effective physical and information flows between internal and external partners.

Compliance to MMOG-LE is a requirement of several vehicle manufacturers and suppliers in the automotive supply chain.

In 2020 MMOG-LE 5th edition was issued.

Quality Partner have produced a series of 10 videos to help viewers understand:

*   The history and background of MMOG-LE
*   The alignment to IATF 16949
*   The structure of MMOG-LE
*   The assessment process
*   Details of the contents of the 6 chapters

For more information on how to purchase individual videos, or the full series visit:
https://qualitypartner.co.uk/mmog-le-5th-edition/

Quality Partner can also provide training, delivered either onsite or remote for MMOG-LE.

The available training includes:

*   A half day Management awareness course
*   A one-day awareness of the MMOG-LE structure, contents, and requirements
*   A two-day course on how to undertake an effective MMOG-LE assessment

For more details contact Paul Hardiman at paul.hardiman@qualitypartner.co.uk

Ask the expert

Question
Just a quick question about customer claims. If we got customer claim that we send them faulty part, we record on our claim tracker and we replace the part or issue a credit, if we are not clear about the issue, we get the faulty part back for investigation. Most of the claims relate to individual mistakes by the assembly operators.

My question: if the customer is not asking, is it mandatory to do an 8D report for every claim?

And is it essential to update the relevant PFMEA?

Answer
The relevant requirements in IATF 16949 are:

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10.2.3 Problem solving

"The organization shall have a documented process(es) for problem solving SI20 which prevent(s) recurrence, including:

a) defined approaches for various types and scale of problems (e.g., new product development, current manufacturing issues, field failures, audit findings);……."

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."

There is nothing in either requirement that you must use an 8D approach for every single part returned, unless specified by the customer.

However, you are required to carry out problem solving in accordance with your documented process to try to take all actions possible to prevent reoccurrence. Just stating "human error" is not acceptable.

In the problem-solving process reference needs to be made to the relevant PFMEA, but this does not mean a team has to be convened for each individual return, this information can be collected, analysed as an input to the FMEA review process.

Question
Our company is certified to IATF 16949. To meet the management review requirement in ISO9001 and IATF 16949 we currently have an annual management review. Due to the large numbers of inputs defined in the standards, it takes many days for me to prepare the relevant information, and then the last review we had was nearly 2 days in duration. We really want to restructure the process; do we have to have an annual review that covers all the input requirements?

Answer
The short answer is no!

You should look at management review as being a process, rather than an event.

Key things to consider are:

ISO9001: 2015 5.1 Leadership and commitment

"c) ensuring the integration of the quality management system requirements into the organization business processes"

and

IATF 16949 5.1.1.3 Process owners.

"Top management shall identify process owners who are responsible for managing the organization's processes and related outputs. Process owners shall understand their roles and be competent to perform those roles (see ISO 9001, Section 7.2)."

To manage an organization, do Top Management teams only meet annually?

Of course not, Management teams may meet daily, weekly, monthly, bi-annually etc. to discuss performance, risks, changes etc., all of these are requirements related to IATF 16949 and the Quality Management System.

Why not consider these meetings as part of the management review process?

Many organizations develop a matrix to show which inputs are covered in each meeting, at what frequency. The input requirements that are not covered can either be incorporated into an existing meeting, or can be covered in a smaller annual review (that might be aligned with the review of the strategic direction/business plan for the next period).

Evidence of the meetings/reviews need to be documented, but not necessarily in formal minutes. The key thing is there is a process to track any actions from the meetings/reviews to ensure they are effectively addressed and closed.

Question
We currently have over 140 control plans. It is becoming increasing difficult to manage these, and we are always finding issues in our own internal audits, and in external 3rd party audits. The control plans are not used on the shop floor, and are normally only referred to in internal, customer, or 3rd party audits. We have detailed operator instructions in place to control the assembly of the different type of products we manufacture.

We want to move towards family control plans. My question is would it be acceptable to have a very generic control plan to cover all products, that simply refers to the work instructions?

I have drafted the example below:

Proc. No	Process Name Operation Description	Machine,Device Jig,Tools,For,Mfg	Characteristics			Special Char. Class	Product ,Process, Specification, Tolerance	Evaluation Measurement Technique	Sample		Control Method	Reaction plan
			No	Product	Process				Size	Freq		
3	Incoming Inspection	n/a	n/a	Arrival control checklist	n/a	n/a	n/a	n/a	n/a	n/a	n/a	IATF 8.7.1.4
4a	OP10	Control Instruction	n/a	Control Instruction	Control Instruction	Control Instruction	Control Instruction	Control Instruction	Control Instruction	Control Instruction	Control Instruction	IATF 8.7.1.4
4b	OP20	Control Instruction	n/a	Control Instruction	Control Instruction	Control Instruction	Control Instruction	Control Instruction	Control Instruction	Control Instruction	Control Instruction	IATF 8.7.1.4
4c*	OP30*	Control Instruction	n/a	Control Instruction	Control Instruction	Control Instruction	Control Instruction	Control Instruction	Control Instruction	Control Instruction	Control Instruction	IATF 8.7.1.4
4d*	OP40*	Control Instruction	n/a	Control Instruction	Control Instruction	Control Instruction	Control Instruction	Control Instruction	Control Instruction	Control Instruction	Control Instruction	IATF 8.7.1.4
4e*	OP50*	Control Instruction	n/a	Control Instruction	Control Instruction	Control Instruction	Control Instruction	Control Instruction	Control Instruction	Control Instruction	Control Instruction	IATF 8.7.1.4
4f*	OP60*	Control Instruction	n/a	Control Instruction	Control Instruction	Control Instruction	Control Instruction	Control Instruction	Control Instruction	Control Instruction	Control Instruction	IATF 8.7.1.4
4g*	OP70*	Control Instruction	n/a	Control Instruction	Control Instruction	Control Instruction	Control Instruction	Control Instruction	Control Instruction	Control Instruction	Control Instruction	IATF 8.7.1.4
4h*	OP80*	Control Instruction	n/a	Control Instruction	Control Instruction	Control Instruction	Control Instruction	Control Instruction	Control Instruction	Control Instruction	Control Instruction	IATF 8.7.1.4
4i*	OP90*	Control Instruction	n/a	Control Instruction	Control Instruction	Control Instruction	Control Instruction	Control Instruction	Control Instruction	Control Instruction	Control Instruction	IATF 8.7.1.4
4j*	OP100*	Control Instruction	n/a	Control Instruction	Control Instruction	Control Instruction	Control Instruction	Control Instruction	Control Instruction	Control Instruction	Control Instruction	IATF 8.7.1.4
4k*	OP110*	Control Instruction	n/a	Control Instruction	Control Instruction	Control Instruction	Control Instruction	Control Instruction	Control Instruction	Control Instruction	Control Instruction	IATF 8.7.1.4

Answer

Firstly, Annex A in IATF 16949 allow for family control plans, stating:

"Control plans are established at a part number level; but in many cases, family control plans may cover a number of similar parts produced using a common process. Control plans are an output of the quality plan."

However, control plans must cover all the requirements defined in Annex A. The one you have drafted does not fulfil the Annex A requirements.

You need to look at the process flow charts for the 140 products you manufacture, and ask the question:

• What are the common process steps in manufacturing the products?
• Can the products be grouped into families?

This would then give the structure for developing foundation or family FMEA's to consider the risks at each stage of the process, and this would provide the input into the family control plans.

The family control plans would be the signpost to the relevant work instruction that would give the detail of the controls needed to ensure that products are manufactured to meet customer and internal requirements.

Question

We need to integrate this requirement 8.4.2.2 in our new product introduction process. Do you think if in our gate 1 (first review of design concept) of our NPI process we add a line mentioning that item, that would meet the requirement? Or shall we add a specific sentence somewhere?

Answer

You question raises a very important point related to the requirement. Although the requirement must be complied with for all existing products, an organization also needs to make sure that any new products also comply with the requirement.

8.4.2.2 Statutory and regulatory requirements

"The organization shall document their process to ensure that purchased products, processes, and services conform to the current applicable statutory and regulatory requirements in the country of receipt, the country of shipment, and the customer-identified country of destination, if provided.

If the customer defines special controls for certain products with statutory and regulatory requirements, the organization shall ensure they are implemented and maintained as defined, including at suppliers."

It is essential as much information as possible is requested from the customer in the enquiry phase, not just on the technical requirements of the product, but where the product will be shipped to and used. This information, if provided by the customer, will give information to discuss in the feasibility review related to any statutory or regulatory requirements that may be applicable before any quotation is issued to the customer.

If you quotation is accepted by the customer, in the new product introduction process, the organization needs to ensure that any statutory or regulatory requirements are met, whether related to the product design, or the design of the manufacturing process.

There must be an effective process for communicating any statutory requirements to suppliers, including identifying and communicating any changes.

I am not aware of the specific details of your NPI process, and what is covered at each gate, but I think this would need to be addressed at all stages of the process, not just in the early stages.

Question
I have a question which I could do with some help on. For manufacturing process audits standard of IATF states to cover all shifts which we got a nonconformity for during our last IATF audit. We corrected it by conducting a manufacturing process audit on the night shift, however we have since changed the shift pattern.

We used to have two shifts working 4 days and 3 nights.

We now have four shifts to cover from Monday to Saturday morning.

- 4 days starting from Monday
- 3 nights starting from Monday night
- 4 days starting from Tuesday
- 3 nights starting from Wednesday night

Is it enough to say we have audited a night and day shift hence covering the requirement or would we be expected to audit the four different shifts?

Answer
The relevant requirement in IATF 16949 is 9.2.2.3 Manufacturing process audit

"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 thing is the timings of the shifts, not the crews of people.

So, for example if the timing of the shifts is 6am to 6pm and 6.00pm to 6.00am, this would count as 2 shifts, even though it might be manned by 4 crews.

In this case if you audited from 4pm to 8pm, you would cover both shifts in one audit, and could cover the shift handover at 6pm.

In developing the audit programme, reference must be made to performance data. So, for example, if there were more issues (internal or external) on a specific shift/crew of people then the audit frequency should reflect this.