Quality Partner Newsletter

April 2020

Issue date: April 2020

Welcome to the eighteenth edition of the Quality Partner newsletter. The newsletter is designed to keep readers up to date with developments in Quality Management Systems.

This issue focuses on:

- MMOG-LE 5th edition
- National Manufacturing Competitiveness Levels (NMCL) programme
- Understanding 8.7.1.4 Control of reworked product
- Questions and answers

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

Since the last edition of the newsletter in January 2020 how things have changed in the world!

I do not think any of us would have predicted the impact the Covid-19 virus would have on the world economy, the automotive industry and our own personal lives.
I always try to stay positive. This is an ideal time, while many of us are working from home in various states of lockdown, to do the jobs we have put off because we were too busy, but also to take the time to understand more about Quality Management System standards and requirements.
I have adopted a way of thinking:

"Go to bed with one extra piece of learning/knowledge you did not have when you woke up!"

To help with this I have 500 free links to a series of 11 videos on the automotive core tools with associated exams, valid for 3 months.

Each video is 10-15 minutes long and is supported by an online exam. If you get 8 or more correct from 10 questions, you get an automatically generated PDF certificate, which you can maintain on record as evidence of learning.

The videos cover APQP, FMEA, Control plan, MSA, SPC and PPAP.

If you're interested email paul.hardiman@qualitypartner.co.uk and I will send you the links!

For More Information Visit www.qualitypartner.co.uk

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Materials Management Operations Guideline / Logistics Evaluation (MMOG-LE)

Many organizations have made significant progress with improvement in product quality, with big reductions in parts per million defects (PPM), but for logistics processes (supplier performance, internal logistics efficiency and customer delivery performance) there is often scope for significant improvement.

The goal of IATF 16949 is:

- continual improvement
- emphasizing defect prevention and the
- reduction of variation and waste in the supply chain

Many IATF 16949 certified organizations maybe focus more on improving Quality and Cost, rather than Delivery. If we think about people doing internal or external audits related to IATF 16949, many are from a quality background not logistics. So, what tool can we use to understand more about supply chain weaknesses?

First developed in 2005, Materials Management Operations Guideline / Logistics Evaluation (MMOG-LE) provides an excellent assessment framework to drive improvement in an organization's logistics processes. In 2019 the 5th edition was released by AIAG and Odette. Some automotive OEMs mandate internal assessments against the MMOG-LE criteria; for example Ford CSRs for IATF 16949 require:

"The organization is required to achieve level "A" on the Material Management Operation Guideline / Logistics Evaluation (MMOG/LE) to achieve and maintain Q1."

So, let's have a look at the structure of MMOG-LE.

- Two types of assessment are included, FULL and BASIC. The full version is designed to be used by OEMs or first tier suppliers. For suppliers lower down the supply chain, the recommendation is to start with the basic version, and over time migrate to the full version.

- The assessment criteria are broken down into 6 chapters, namely:

  - Chapter 1: Strategy and improvement
  - Chapter 2: Work organization
  - Chapter 3: Capacity and production planning
  - Chapter 4: Customer interface
  - Chapter 5: Production and product control
  - Chapter 6: Supplier interface

- There are 187 assessment criteria in the Full and 102 assessment criteria in the Basic

- Each criterion is designated a weighting and scoring as shown below

Weighting:	F1	= 1 pt	A Supply Chain Management (SCM) process that demonstrates an additional level of control of operational processes, contributing to the organization's overall competitiveness. Complying with F1 criteria contributes to the organization's long-term sustainability and/or competitiveness.
	F2	= 2 pts	A Supply Chain Management (SCM) process that demonstrates control of operational processes and has significant importance to the efficiency and effectiveness of the organization's operations. If an F2 criterion is not met, the organization's performance and/or customer satisfaction may be seriously affected.
	F3	= 3 pts	A key Supply Chain Management (SCM) process that is a fundamental requirement of the organization's operations. If an F3 criterion is not met, there is a high risk of interruption and/or incurring increased costs to the organization's and/or customer's operations.

Whereas with the 4th edition of MMOG-LE the assessment could be completed in an Excel spreadsheet, for the 5th edition it must be completed in an IT application called MMOG.np.

Access to MMOG.np can be purchased at https://www.odette.org/mmog/information

Upon completing the full assessment, an overall A, B or C ranking is achieved based on:

A	1. Compliance to all F3 and, 2. Non-compliance to less than 9 F2-criteria and, 3. A total score of 95% or higher.	The organization is compliant in all key criteria and can demonstrate that the supply chain management processes in use at the facility are best practices. Annual assessments are carried out with the goal of ensuring sustainable and best practice processes. In support of continual improvement, the development of an action plan should be considered in order to eliminate any remaining unmet criteria.
B	1. Compliance to all F3 and, 2. Non-compliance to more than 15 F2-criteria and, 3. A total score of 85% or higher.	Although most of the fundamentals of supply chain management are demonstrated the organization is deficient in several areas that compromises the efficiency of internal performance and may impact its ability to support the needs of the customer. An action plan should be developed and implemented in a timeframe that meets the needs of the business and its customers.
C	1. Non-compliance to any F3 or, 2. Non-compliance to 16 or more F2-criteria or, 3. A total score of less than 85%.	The organization is deficient in one or more key areas of supply chain management. This situation creates a high risk of disruption to customers and demonstrates a lack of efficiency and control of internal processes within the existing supply chain strategy. Management commitment will be required to create, prioritize and implement action plans in a timely manner to avoid serious or prolonged issues with the customer.

For the basic version, the overall ranking is either ZA, ZB or ZC based on:

ZA	1. Compliance to all F3 and, 2. Non-compliance to less than 9 F2-criteria. 3. A total score is not considered.	The fundamentals of supply chain management are in place and the organization demonstrates evidence of process controls and continuous improvements efforts. However, the full version of the MMOG/LE Assessment would have to be completed in order to fully understand if industry best practices have been met.
ZB	1. Compliance to all F3 and, 2. Non-compliance to 9 to 15 F2-criteria. 3. A total score is not considered.	Although most of the fundamentals of supply chain management are demonstrated, the organization is deficient in several areas that compromises the efficiency of internal performance and may impact its ability to support the needs of the customer. An action plan should be developed and implemented in a timeframe that meets the needs of the business and its customer(s). To fully understand the level of risk and opportunities for improvement, it is recommended that the organization completes the full version of the assessment.
ZC	1. Non-compliance to any F3 or, 2. Non-compliance to 16 or more F2-criteria. 3. A total score is not considered.	The organization is deficient in one or more key areas of supply chain management. This situation creates a high risk of disruption to customers and demonstrates a lack of efficiency and control of internal processes within the existing supply chain strategy. Management commitment will be required to create, prioritize and implement action plans in a timely manner to avoid serious or prolonged issues with the customer.

MMOG-LE is aligned with IATF 16949, in promoting the process approach incorporating risk based thinking, and adds many more detailed requirements related to the management of the organization's logistics processes.

In the 5th edition of MMOG-LE there is additional focus on:

- The links between strategies, objectives and continuous improvement
- Risk management including contingency plans and cybersecurity policies and practices
- Improving skills in all aspects of the logistics processes
- Promoting the use of electronic data interchange (EDI) in the supply chain

So, in conclusion, MMOG-LE is a great tool for helping to identify improvement opportunities in all the logistics processes. An assessment can be used as evidence of a system audit of the logistics processes in the context of IATF 16949.

For more information, or details of available training, contact paul.hardiman@qualitypartner.co.uk

Quality Partner Limited is proud to announce it has been approved as an approved provider under the National Manufacturing Competitiveness Levels (NMCL) programme.

National Manufacturing Competitiveness Levels (NMCL) is a system developed by an ADS Group Limited (ADS) and Society of Motor Manufacturers & Traders (SMMT) led consortium, supported by industry primes and OEMs.

The Consortium has established a national, quality assured, best practice approach to improving the competitiveness of manufacturing supply chain companies to:

- Raise workforce capability
- Increase productivity
- Boost UK economic growth
- Increase export levels

NMCL Automotive is a programme that uses the NMCL system to support the automotive sector. The programme utilizes £16m of UK Government funding to engage with over 100 companies over three years. The funding is used to support improvement activities in the automotive supply chain through training, coaching and mentoring.

Full details of the scope of Quality Partner approval can be found at:

https://www.sc21.org.uk/providers/quality-partner/

If you already have secured funding and are looking for an approved competent provider contact paul.hardiman@qualitypartner.co.uk

If your organization is in the UK and is interested in gaining funding support under the programme full details can be found at:

https://www.nmcl.co.uk/nmclprocess/#Automotive

IATF 16949 Clause 8.7.1.4: control of reworked product

I would like to thank Morteza Kheirkhah for his contribution in preparing this article on the control of rework product. If you would like to receive the full version of the article contact morteza kheirkhah mo.kheirkhah@gmail.com

Let's start by looking at the ISO9000: 2015 related definitions:

Nonconformities are caused by factors that should not be present in a process (e.g. Special causes). There will always be variation in a process (e.g. Common cause), but variation does not always result in a nonconformity. Nonconformities arise when the variation exceeds the defined specifications. The factors that cause nonconformity on one occasion will (unless removed) cause nonconformity again and again. Before describing the requirement, the title of this subclause needs to be explained. In ISO 9001:2008 the title of the related clause (8.3) was "control of nonconforming product", but in the latest version (ISO 9001:2015) it changed to "control of nonconforming outputs" in the title of subclause 8.7.

The Reason behind this change is:

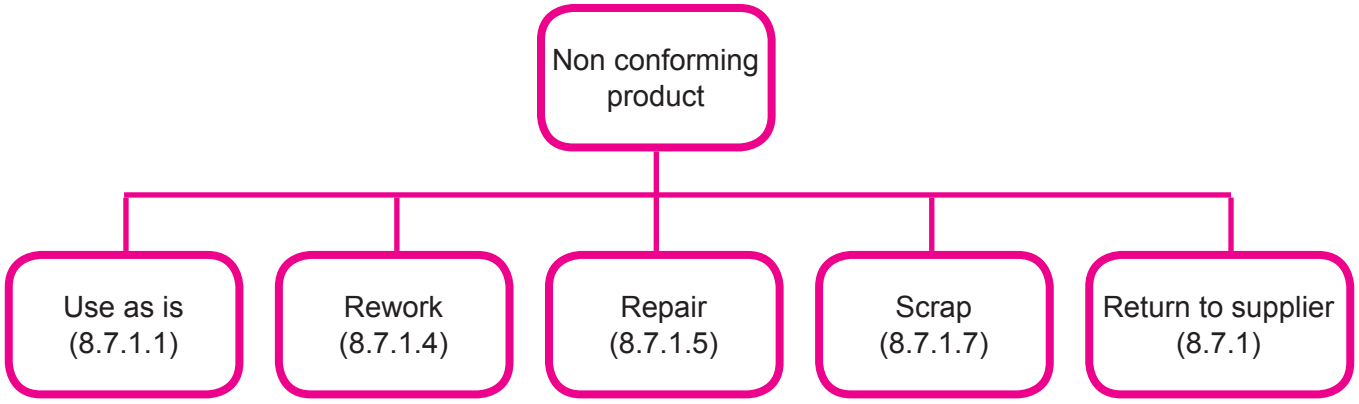
- "Output" refers to both product and service
- It refers to all nonconforming outputs at all stages of products and services provision (at any stage in the manufacturing process)

So, based on the above explanation, the scope of subclause 8.7.1.4 is any nonconforming product from the first stage of the manufacturing process to the final operation, any nonconformities on final product characteristics specified by customer specifications or any interim product characteristics specified by the organization which will be finalized in the next operation. In other words, any rework done on any characteristics (interim or final) of nonconforming products produced in any manufacturing operation would be included in the scope of this requirement.

Products that do not conform to the defined requirements are those that have been examined against pre-defined requirements (e.g. in a control plan) and judged to be at variance with those requirements. The requirements are not limited to customer requirements, and therefore a nonconforming product is one that fails to meet one or more of the following:

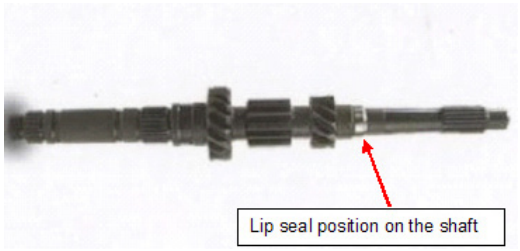
- the specified customer requirements
- the applicable regulatory requirements
- the organization's own requirements

Usually, a nonconforming product is treated by the methods illustrated below:



Suppose that your company is a manufacturer of an automotive gearbox component. After grinding, you find that the diameter of the lip seal position is greater than the specified dimension. So, you decide to rework the shaft to correct the diameter. IATF 16949 8.7.1.4 states:

"The organization shall utilize risk analysis (such as FMEA) methodology to assess risks in the rework process prior to a decision to rework the product. If required by the customer, the organization shall obtain approval from the customer prior to commencing rework of the product."

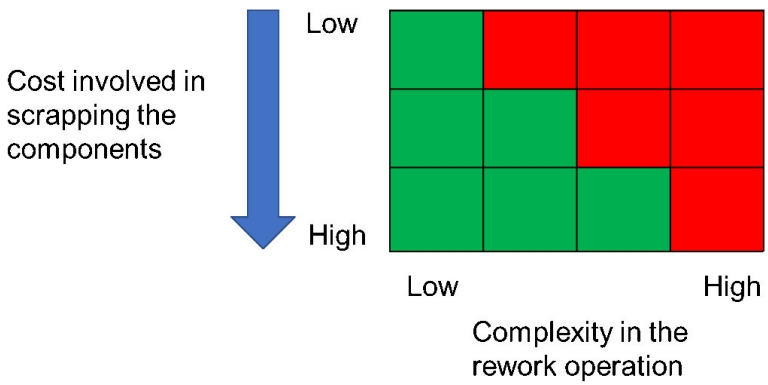


Experience shows that the possibility of failure occurring in the rework operation is greater than the original operation. During rework, other characteristics of the product produced in earlier operations may be damaged. Hence, in the first paragraph of this clause the standard requires that the organization does a risk analysis to decide whether undertaking rework is feasible.

There is no specific requirement about the risk analysis method, however, IATF 16949 refers to FMEA as one way of undertaking a risk analysis.

If using the FMEA approach, risks need to be considered not just related to the product characteristic in question, but the risk of damaging/changing other characteristics of the product.

IATF allows other risk analysis methods to be used, for example a cost verses criticality matrix, which evaluates the complexity of the rework operation versus the value of the component, as shown below.



Next, the requirement states:

"If required by the customer, the organization shall obtain approval from the customer prior to commencing rework of the product."

Some customers like PSA (an IATF OEM) require their suppliers to have a list of authorized rework operations and the authorized rework operations must be included as part of part/process approval. For rework operations that have not been included in the original authorized rework list, the organization should follow the customer concession process and gain approval before undertaking the rework.

The next paragraph in 8.7.1.4 states:

"The organization shall have a documented process for rework confirmation in accordance with the control plan or other relevant documented information to verify compliance to original specifications."

As mentioned in "Note 1" of the rework definition in ISO 9000:2015, any action taken to correct the nonconformity will change the product and therefore it should be re-verified prior to it being released, to ensure that the work has been carried out as planned and has not affected features that were previously found to be conforming.

The requirement mandates the organization to have a documented process for rework confirmation. It is not necessary to have a separate process in the quality management system. Rework controls could be included in the nonconforming product/process disposition process.

The next paragraph in IATF 16949 states:

"Instructions for disassembly or rework, including re-inspection and traceability requirements, shall be accessible to and utilized by the appropriate personnel."

Rework is done within a manufacturing process, so it should have a standard work instruction consistent with clause 8.5.1.2 (standardized work), which should be legible and accessible for relevant personnel, and relevant personnel must be competent in the rework operation.

Re-inspection requirements can be defined in a work instruction, the control plan or any other related documents.

One important thing is that for reworked products appropriate levels of traceability shall be maintained. Traceability mechanisms for reworked parts should be defined by the organization. Some OEMs, like PSA, require their suppliers to mark rework parts (e.g. colour marking), but the traceability requirement can be met by other means, such as recording the serial number of reworked parts or batch numbers.

Finally, in the last paragraph of the requirement it states:

"The organization shall retain documented information on the disposition of reworked product including quantity, disposition, disposition date, and applicable traceability information."

Retention of information on reworked product helps the organization and its customer to investigate any subsequent problems, either in the customer plant, or when fitted to a vehicle in the field.

The record shall include at least the following information, in addition to that mentioned in ISO 9001 clause 8.7.2:

- quantity of reworked parts

- disposition type (rework)
- disposition date
- traceability information (e.g. serial numbers, batch code, etc.)

The traceability mechanism for reworked product shall comply with the requirements of clause 8.5.2.1.
In summary, many organizations have incurred excessive external or internal costs due to a lack of effective management of rework. While organizations must develop effective rework controls, in the spirit of the goal of IATF 16949, by applying defect prevention, elimination of the need for rework is the best solution!

Ask the expert

Quality Partner's expert, Paul Hardiman

Question:

Will you please give me some practical examples regarding IATF clause 8.4.2.1?

Also, is there any specific purpose in using the words Validation or Controls instead of verification, testing, inspection, measurement?

Answer:

Firstly, let's look at the requirement. This was added through sanctioned interpretation 7 against the requirement:

8.4.2.1 Type and extent of control — supplemental

"SI 7. Where characteristics or components "pass through" the organization's quality management system without validation or controls, the organization shall ensure that the appropriate controls are in place at the point of manufacture."

There is no definition in IATF of the meaning of "pass through" characteristics or components.

However, the generally accepted understanding is:

"Pass through characteristics (of a product or material) or components are purchased by an organization from a supplier, neither value added work is done to change the product characteristic or component within the organization nor further verification/validation applied on them, and then this is passed on to the customer (which could be as a separate supplied component or as part of an assembly)"

Obviously, this poses a potential risk to the customer that the organization must manage.

Now let's look at the terms "validation" and "control":

In ISO9000, the term validation is defined as:

"Validation confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled."

Note 1: The objective evidence needed for a validation is the result of a test or other form of determination such as performing alternative calculations or reviewing documents.

Note 2: The word "validated" is used to designate the corresponding status.

Note 3: The use conditions for validation can be real or simulated.

There is no definition for control, but there is for “quality control”

“Quality Control: part of quality management focused on fulfilling quality requirements.”

The reason this requirement has been added to 8.4 (Control of externally provided processes, products and services) is that the organization needs to demonstrate, if they do not do any validation or control, that the control is in place at the supplier (manufacturer).

This could be demonstrated in several different ways including:

- Supplier certification to IATF 16949
- Second party audits at the supplier (system, process or product)
- Organization personnel resident at the supplier site to do patrols, firewall checks etc.
- The supplier providing the relevant evidence that the characteristic/component meets the defined performance specification (statistical data, evaluation by a designated laboratory etc.) with each shipment

The type and extent of control will depend on the relevant supplier performance and risks identified.

Let’s look at an example. An engine manufacturer buys in filters. At the last assembly point in the production process the filter is fitted to the engine, a check is done to verify it is correctly attached, but no checks in the organization are undertaken of the filter itself.

In this case this is a pass-through component. If the filter does not work effectively this could affect the customer or end user, so the organization (engine manufacturer) must demonstrate how they select and control the supplier of the filters, as outlined above.

The same requirements would apply, even if the filter was not fitted to the engine, but was supplied with the engine, under the supply contract from the customer.

Question:

We have identified several measurement systems we need to undertake MSA for, both attribute and variable. How do we determine how many samples and how many appraisers we need to use in the studies?

Answer:

This is not specified in IATF 16949. In requirement 7.1.5.1.1 Measurement system analysis.

It states: *"The analytical methods and acceptance criteria used shall conform to those in reference manuals on measurement systems analysis."*

So, if there are CSRs related to MSA these must be complied with. For example, in the Ford CSRs it states:

"Variable gauge studies (GR&R) should utilize a minimum of 10 parts, 3 operators and 3 trials.

Attribute gauge studies (Attribute agreement analysis) should utilize a minimum of 50 parts, 3 operators and 3 trials."

If there are no CSRs, the organization can choose what reference manual to use, including the analytical methods (sample size etc.) and the acceptance criteria.

The key thing is you need to demonstrate the statistical validity of any studies undertaken and acceptance criteria used.
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Question:

I have a question related to clause 8.5.1 (f)

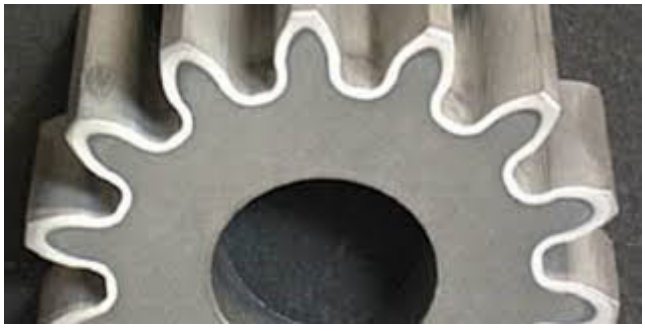
"the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement."

Can you explain the meaning of this, especially "where the resulting output cannot be verified by subsequent monitoring or measurement"?

Answer:

Firstly, this clause is part of ISO9001: 2015 and can apply to any type of organization. The meaning and application will be different in different industry sectors. But let's look at it within the context of IATF 16949, applicable to the automotive supply chain.

In some processes, for example heat treatment, (these were called "special processes" in previous editions of ISO/ Automotive standards) it is impossible to check all product characteristics by subsequent monitoring and measurement. (For example, dimensions can be checked by subsequent monitoring as they are non-destructive, but hardness and case depth cannot be, as to do this would destroy or damage the part).



So, in the IATF 16949 additional requirements, it adds requirements to develop a process FMEA to identify potential process risks and then define the relevant process or product controls to ensure the process output meets the defined specifications.

So, for example, in the case of heat treatment where a requirement is to achieve a specific hardness, a potential failure mode could be “surface hardness too low”

Prevention control should then focus on the optimization of the process parameters to achieve the correct hardness and then define the detection controls. They could be the validation and periodic revalidation of hardness by taking a sample of product, and, for example, measuring hardness and sectioning the product to measure case depth (both would destroy the part).

These controls (process and product) based on risk would then be transferred to the control plan and relevant work/inspection instructions and implemented on an ongoing basis.
By effective use of the PFMEA and control plan, this would help provide evidence of compliance with the ISO9001 requirement 8.5.1f. No additional documentation would be needed.

Question:

In our internal laboratory we have a Coordinate Measuring Machine (CMM). Do we need to undertake measurement system analysis?

Answer:

The first question to ask is if the CMM is referenced on a control plan (prototype, pre-production or production)?

If the answer is yes, then, according to requirement 7.1.5.1.1 this states “*Statistical studies shall be conducted to analyze the variation present in the results of each type of inspection, measurement, and test equipment system* ***identified in the control plan.****”*

Before we consider MSA, firstly we should check the calibration records, including the frequency of calibration. While many CMM manufacturers offer service and calibration contracts, you need to verify they are ISO/IEC 17025 accredited for this activity.

If not, you must inform and get approval from your customer (s) to use this OEM provider.

The next thing to consider is what is the most appropriate type of statistical study to check the measurement system variation. While GR&R could be considered, often there are not three trained operators of the CMM, and secondly, to do a full study with 10 parts, 3 appraisers and 3 trials (which is required by some CSRs) would take a significant amount of time and effort to complete the study.
Maybe a more appropriate statistical method would be measuring bias, linearity and stability. For most CMMs the equipment manufacturer will provide a “reference” sample (e.g. a sphere) for the operator to do periodic verifications against.

If this check was formalized, including the frequency of checking and the method of recording and the data analyzed (this could be a control chart(s)), this could be used as evidence of measurement system analysis.

Also, whereas calibration may be done every 12-24 months, by doing this structured verification (Bias, Linearity and Stability), it would reduce risk by identifying any “drift” in the equipment and enable action to be taken before causing any measurement errors.

So, in conclusion, if the CMM is on the control plan, MSA is not optional, it is mandatory!

Question

We are currently going through a process to restructure our IATF 16949 quality management system. We are going to identify three families of processes, namely Customer Orientated, Support and Management.

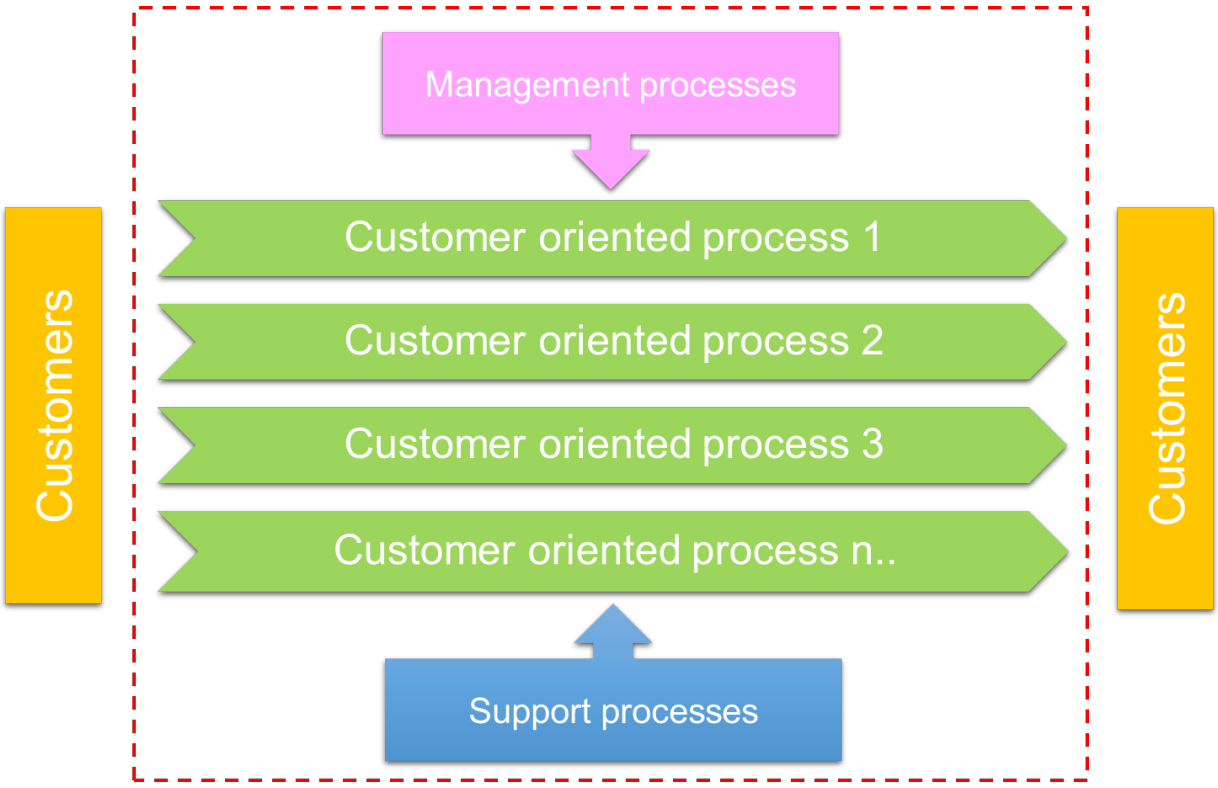
What is confusing us is where the mandatory “documented processes” referenced in IATF 16949 will fit within this structure?

Answer

I agree that IATF have confused things by introducing the term “documented process” in 21 places in the standard, without providing any definition.

My approach would be:

- Forget the term documented processes when you determine the high-level processes you need to run your business (customer orientated, support and management). Calling the by these definitions is not mandated by IATF but is a logical, accepted approach.



- For each business process assign an owner, define the relevant KPIs and create a risk-based turtle diagram (this is not mandated by IATF but is a good way of showing a high-level overview of the process)
- Then review the requirements in IATF 16949 where “documented processes” are required and see which process they fit best to. For example, the documented process related to 8.3.3.3 Special characteristics may fit under the New Product Introduction process. (A customer orientated process)
- Then document the mandatory “documented processes” in whatever form/media you want, it does not have to be a turtle (could be a flow chart, a procedure (but the procedure should show the way the process happens, from input to output) etc.
- Multiple requirements could be covered in one documented process, there does not need to be a separate process for each one.
  These “lower level” processes do not have to have specific KPIs.

- When documented, link to the relevant turtle diagrams under the “how box”

In conclusion do not document your system structure led by IATF 16949 requirements; rather, determine how your business operates and what you need to measure to determine the system is effective in meeting all interested party needs.