Quality Partner Newsletter

January 2019

Welcome to the fourteenth 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:

- Revision of MMOG-LE
- Manufacturing process design input
- Questions and answers

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

I am sure 2019 will be challenging for many of us, but let's not focus on the things we cannot influence, but the things that we can which will include maintaining IATF 16949 certification and continual improvement.

IATF I6949 certification status

At the end of November there were 64,531 IATF 16949 certified sites globally.

Of these, 69% of these were issued to organizations in the Asia Pacific region, 17% in Europe, 9% in North America and 5% in the rest of the world.

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

Regarding analysis of the 4500 major nonconformities raised globally in the first 11 months of 2018, over 55% of these were raised against nonconformity and corrective action (10.2.1) or problem solving (10.2.3). This is not surprising, as some of these major nonconformities would have been raised because the corrective action from minor nonconformities from previous visits had not been effectively implemented (where the rules mandate that the minor gets escalated to a major and a new major raised against corrective action).

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Materials Management Operations Guidelines: Logistics Evaluation

I think one of the most under used assessment tools is MMOG-LE (Materials Management Operations Guidelines, Logistic Evaluation).

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 in order to facilitate efficient and effective physical and information flows between internal and external partners.

Using MMOG-LE is mandated by several vehicle manufacturers through customer specific requirements for IATF 16949, with some customers requiring suppliers to undertake an annual assessment and report the results through customer portals.

For example, Ford customer specific requirements state:

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

Key requirements for MMOG/LE (Material Management Operation Guideline/Logistics Evaluation) compliance include:

- *Annual MMOG/LE assessment completed and reported 1 May to 31 July each year*
- *Adherence to Ford production and service delivery rating requirements for all regions as stated in Q1*
- *Part identification and tracking*
- *Lot traceability throughout the value chain (lot traceability shall include subcontracted components of an assembly/module that are associated with compliance to any inverted delta requirement)*
- *Electronic communication with Ford and sub-tier suppliers*
- *Management and maintenance of the Ford DDL CMMS3 system*
- *Prevention of damage or deterioration of supplied products*
- *Use of the appropriate packaging forms and maintenance of the Ford DDL CMMS3 DAIA Packaging screen, as applicable. Packaging requirements and forms can be found in the packaging GTC Web Guides at https://web.fsp.ford.com/gtc/production/index.jsp?category=guides*
- *Management and maintenance of returnable dunnage. Returnable container requirements are available through the GTC Web Guides at https://web.fsp.ford.com/gtc/production/index.jsp?category=guides*
- *Adequately trained personnel, as defined in MMOG/LE."*

From experience, I believe many of the evaluations are done as a tick box exercise sat in front of the TV, rather than using MMOG-LE as a great assessment tool to identify weaknesses in an organizations supply chain processes and drive continual improvement.

In early 2019 a 5th edition of MMOG-LE will be issued, with changes focused on:

- Risk management
- Cybersecurity
- Digitalisation
- Industry 4.0
- Alignment with IATF 16949

In the current 4th version of MMOG-LE, there are 197 criteria in the “full” version broken down into 6 chapters, each criteria is identified with a risk ranking weighting, with red F3 criteria the highest risk (3 points for compliance), yellow F2 medium risk (2 points for compliance) and FI the lowest risk (1 point for compliance). An excel scoresheet is used to calculate the overall assessment score, which is reported as an A, B or C ranking.

A “Basic” version of MMOG-LE contains 106 of the 197 criteria used in the full version and has been developed specifically for use within the lower tiers of the supply chain while retaining the core fundamental principles of the full version. Vehicle manufacturers typically require their first tier suppliers to use the full version and then the lower tier suppliers use the Basic version, but again this will be defined by customer specific requirements.

In the pending 5th edition, the likelihood is the same overall structure (Basic and full version and F3, F2, F1 risk ranking) will be maintained, but it will have more emphasis on risk-based thinking, with more F3 criteria.

Although the Excel based MMOG/LE assessment tool has served the industry well over the past decade, the MMOG-LE workgroup has developed a modern browser-based application called MMOG.np (New Platform) to take its place worldwide. The application has been exhaustively tested by key users in Europe and North America. The MMOG.np will replace the Excel version, which will not be updated to the 5th edition.

More details on this can be found at https://www.odette.org/mmog/information

In conclusion, whether MMOG-LE is a customer specific requirement or not, I recommend you consider using the assessment tool as a way of identifying opportunities for improvement in all supply chain related processes. MMOG-LE is compatible with IATF 16949, but the requirements are more specific and go deeper in all aspects of managing the internal and external supply chain.

8.3.3.2: Manufacturing process design input

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.

You may wonder why we picked this clause for discussion as it does not feature in the top 10 list of major or minor nonconformities raised in 2018. However, 8.3.5.2 Manufacturing process design output does, with over 650 major nonconformities and over 10000 minor nonconformities being raised in 2018. Some of these are caused by an organization not understanding all the required input requirements in 8.3.3.2.

IATF 16949 added some new inputs to manufacturing process design such as:

- targets for timing;
- manufacturing technology alternatives;
- new materials; product handling and ergonomic requirements, and;
- design for manufacturing and design for assembly.

In addition, the former NOTE regarding error-proofing methods has become a requirement in the new standard.

Product design outputs are defined in clause 8.3.5.1. These outputs typically include:

- product drawings
- DFMEA
- Product special characteristics that may be identified either on product drawings or in a separated list
- Labeling requirements, etc.

All the product design outputs can have an effect on manufacturing process design.

If the organization is design responsible, these inputs can be obtained from product design process. For organization's who are not product design responsible, product design data should be sought from the customer.

Now let's look at the some of the requirements in 8.3.3.2: Manufacturing process design input:
The organization shall identify, document, and review manufacturing process design input requirements including but not limited to the following:

a) product design output data including special characteristics

In the first paragraph, IATF 16949 requires the organization to identify, document and review manufacturing process design inputs. A simple method for meeting this requirement could be to develop a table, an example is shown below:

b) targets for productivity, process capability, timing, and cost;

	Manufacturing process design inputs table		Review date:
Project name: **Review Team:**		**Customer:**	
Input requirement	**Requirement reference document (IATF 16949, CSRs, Organization)**	**Requirement information**	**Result of review**
product design output data including special characteristics	IATF 16949 clause 8.3.3.2	-Product drawing: PD 123- A01 -List of product special characteristics: CTF012-00	Documents have been reviewed and include all necessary information
Customer requirement (if any)	IATF 16949 clause 8.3.3.2	Customer assembly manual STD 9271612378:2016	The tolerance for press force has not been identified. Only 500 daN mentioned in the assembly manual

One of the most important inputs for manufacturing process designers are targets (or expectations) which the organization expects that the designed manufacturing process will acheive.

A definition of productivity is shown on the next page.

Productivity

-Quality, state or fact of being able to generate, create, enhance or bring forth goods, services and knowledge.
ISO 30400:2016.Human resource management — Vocabulary

-A measurement of output for a given amount of input.
https://asq.org/quality-resources/quality-glossary/p

-The word "productivity" relates to the "output" (of goods and services produced) in relation to the quantity of resources or inputs used to produce them. Some examples of input are labor, materials,

A productivity target can be stated as the volume of product produced per machine or people per unit of time. For example, 10 products per person per hour or 100 parts/per machine/ per hour.

Targets for process capability can be expressed by Cpk or Ppk indices or nonconformity rate, considering customer specific requirements.

Targets for timing will often be influenced by customer requirements, but for internally led developments timings also need to be defined and monitored.

Again, cost target are an important factor for manufacturing process designer. Designers should know how much money they can spend for developing a manufacturing process. This target can be used as a trade-off factor for evaluation and selection between alternatives.

c) manufacturing technology alternatives;

Manufacturing process alternatives are derived through innovation, benchmarking or technology monitoring processes in the organization. Usually, there are several possible technologies which can be used for a specific process.

During manufacturing process design, the designer will select the best method by comparison with some criteria. An example table is show below, which could provide objective evidence that alternatives have been considered:

	Manufacturing technology alternatives table					Date:	
Technology alternatives	Criteria/Weight						Final Score
	Cost	Capability	Environmental aspect	Maintenance	Capacity	Complexity	
	W=30	W=10	W=20	W=20	W=20	W=10	
Result:							
Scoring method: 1(the worst), 2, 3, 4, 5 (the best)							

Any risk ranking criteria and weightings would be up to the process design team.

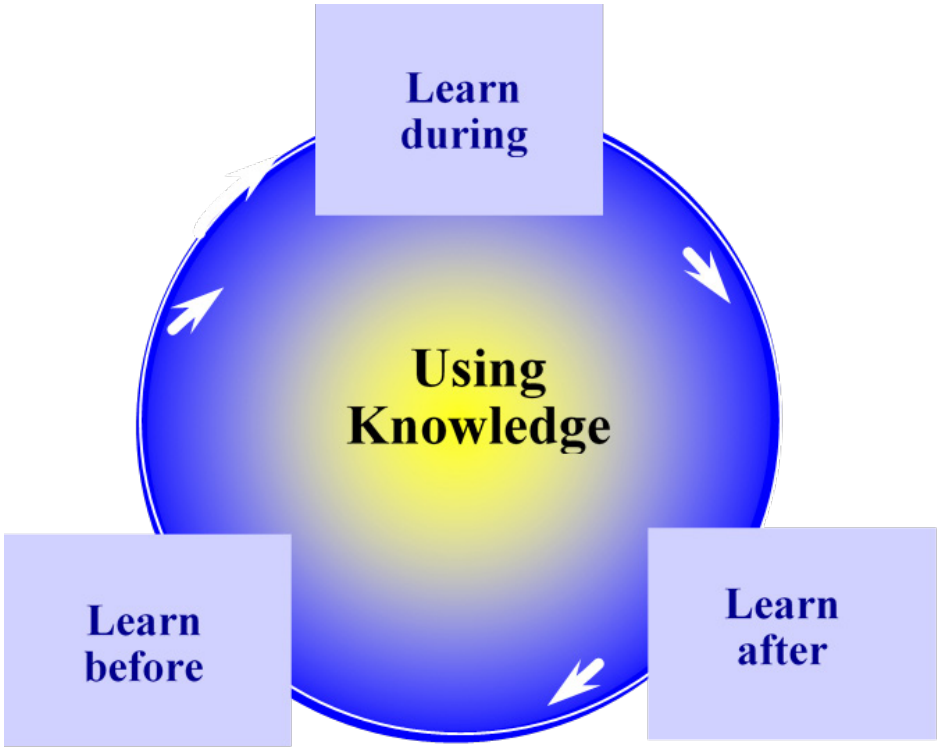
d) customer requirements, if any;

Customers can define requirements to their supplier's that will influence the design of the manufacturing process and the types of manufacturing process to be used. For example, the customer drawing may define MIG welding, vacuum carburizing etc., specific mistake proofing requirements, or specific labelling requirements etc.

Organizations shall consider these inputs and part of feasibility review and then incorporate the requirements when designing the manufacturing process.

e) experience from previous developments;

During development of a manufacturing process, people gain valuable knowledge (combination of information and experience) which can act be used as a guide for developing new processes. This clause is also linked to the ISO9001: 2015 requirement Organization knowledge. Many knowledge management (KM) models emphasize on learning before, during and after a project. The diagram below shows British Petroleum (BP) KM model.



After finishing a project, tproject team should review the project and try to capture lessons learned by asking following questions:

- What was expected to happen?
- What actually happened?
- What went well, and why?
- What can be improved, and how?
- What are the lessons that can be used in the future?

The organization needs to define a method of storing such lessons learnt information to ensure the information can be retrieved when instigating a new project.

f) new materials;

New materials are usually outputs of product design which act as an input for manufacturing process design. New materials may require new equipment or tooling, so it is important to consider new materials in manufacturing process design.

Also, materials not specified in the product design, but the process design team decide are needed as part of the process also need to be defined, procured and validated as part of any new or modified process introduction. For example, to release a molding from a tool, the team may identify a new release agent, with improved properties to the type previously used.

g) product handling and ergonomic requirements;

The method which the product shall be handled through the process is an important factor for manufacture process design. This could include the handling in process, to transfer a product between processes (roller conveyor) or the handling of the final product, etc. Environmental aspects should be considered when addressing handling.

Ergonomics is a matter which is directly related to people health. Manufacturing process designer should be aware about ergonomic requirements/principles and try to meet/incorporate them in their design.
For example, the height of assembly roller conveyor if operators are to be expected lift/unload after an operation is complete.

h) design for manufacturing and design for assembly.

Design for manufacturing and assembly (DFMA) is another subject which is considered in product design. By this requirement the standard wants the people who do the process design to know the assumptions the product design team used for design for manufacture and assembly. For example, if the product design team considered unidirectional (Z-axis) assembly for the product, the manufacturing process design team should design the process and fixtures in a way that all the parts can be assembled on the product in Z-axis direction with no need for additional rotation of the product or its fixtures.

In the last paragraph of the clause 8.3.3.2 the standard states:

The manufacturing process design shall include the use of error-proofing methods to a degree appropriate to the magnitude of the problem(s) and commensurate with the risks encountered.

This requirement was a NOTE in the former ISO/TS 16949 standard which has become a requirement in IATF 16949.

The requirement asks the organization to use error-proofing methods such as contact sensors or image processors to prevent manufacturing of nonconforming products or detect nonconforming products. Although, the error-proofing definition only refers to methods to prevent manufacture of nonconforming product, but it seems that the scope of this requirement also covers methods to detect nonconforming products if prevention is not possible (e.g. Cost limitations imposed by the customer in payment for tooling etc.)

To do this, the organization should have criteria for identifying the opportunity for error-proofing based on the magnitude of the problem and the risks encountered. The following can be used for identifying the opportunity for error-proofing:

- Results from FMEA. High risk failures can be identified based on severity or severity-occurrence from FMEA document
- Historical warranty and quality information of similar parts

- Operator dominant processes

Organization can use a table such as the following one for identifying error-proofing opportunities and the result of evaluation:

		Identification of potential error proofing opportunities									
				Reason for error proofing			Error proofing evaluation			Action plan	
Row	Part name	OP#	position	High severity	External (customer) quality problem	internal quality problem	Practical	Feasible (cost/benefit)	result	Resp.	Due date
1	Input shaft	120	Dia. 20 +0.013		✓ (3 quality alerts within 6 months)		Ok (physical contact sensor)	Ok (estimated cost: 2000$)	To be made	Russ	2018-11

In conclusion, the requirements of process design have been significantly enhanced, but if applied correctly can help in improvement of customer satisfaction and defect prevention.

Questions & Answers

Quality Partner's expert, Paul Hardiman

Question:
One of the inputs to management review IATF 16949 9.3.2.1 is:

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

I am looking for an effective way to address this requirement, can you give me some ideas?

Answer:
Yes, whereas the requirement k) "actual field failures and their impact on safety or the environment" is easier to address if any field failures have occurred since the previous management review (as failures in this case have happened), requirement 9.3.2.1 j) is more difficult to address as the failure has not occurred.

Obviously, it is not practical for the management team to review each FMEA as part of a management review process My suggestion is for the process owner (s) responsible for DFMEA (if applicable) and PFMEA to produce a summary of the highest risks identified (which could be RPN, high severity or high severity x occurrence, considering any customer specific requirements) along with the actions planned to reduce the risks.

This summary could be presented as part of the management review input. This would serve two purposes, one to make management aware of the purpose and benefits of using FMEA effectively and secondly to get their input on risk reduction efforts, including provision of the necessary resources (human and physical) where needed.

Question:
My organization does not have product design responsibility for any of our current automotive customers, what requirements in IATF 16949 8.3 are we allowed to exclude from our quality management system?

Answer
Let's first look at the IATF rules, section 6.1 which states:

"When determining product design responsibility, the certification body shall allow two options:

1. Client responsibility, including outsourced design; or
2. Customer responsibility.

If the client provides evidence that it is not design responsible, the certification body shall exclude IATF 16949, 8.3 Product Design from the client's audit scope."

In IATF 16949 8.3.1.1 Design and development of products and services — supplemental states:
"The requirements of ISO 9001, Section 8.3.1, shall apply to product and manufacturing process design and development and shall focus on error prevention rather than detection.

The organization shall document the design and development process."
In IATF 16949 8.3 the requirements specific to product design are 8.3.2.2 Product design skills, 8.3.3.1 Product design input and 8.3.5.1 Design and development outputs.

All the other requirements in 8.3 are applicable to process design (which cannot be excluded by any organization seeking or maintaining certification to IATF 16949.).

From a practical point of view, what this means when introducing a new product or developing a new manufacturing process is:

- The input requirements must be clearly defined (which could come from the customer requirements, legal or regulatory requirements, or the organizations own requirements)
- The activities must be effectively planned, considering any customer timing requirements (which may include producing prototype samples), including resources to develop all the relevant process documentation (e.g. Process flow, PFMEA, control plan, standardized work etc.) and validation activities. Regular reviews must be undertaken to ensure timing requirements are met, with a summary provided for input into management review
- When developing the PFMEA/Control plan and considering risk, any customer defined special characteristics must be considered and based on the organization knowledge additional special characteristics may be identified
- All procurement activities related to the new product or process need to be effectively managed (including selection of any new suppliers, any new materials needed, any new outsourced processes etc.)
- Any changes made during the new product or process introduction need to be effectively managed
- Upon completion of the new product or process introduction customer part approval requirements must be met (e.g. PPAP)

As defined in the IATF requirement, this process must be documented (but how it is documented is at the discretion of the organization)

Question
I am looking for ways of further promoting the importance of all employees (including Top Management, process owners and shop floor workers etc.) working to the defined processes in the Quality Management System and providing input on process improvement. Would welcome any input.

Answer
I think in most cases employees do not deliberately not work to the defined processes, it is often because a lack of awareness of the purpose of a Quality Management System, a lack of awareness of what the defined processes/instructions are, and a failure to understand the potential consequences of not following processes. In most organizations induction training normally includes showing the employee the quality policy, the structure of the quality system and then maybe some on the job training in the specific process/ tasks. Then it is "get on with the job"!

This discussion is also linked to the requirement in IATF 16949 7.3.1 Awareness — supplemental "The organization shall maintain documented information that demonstrates that all employees are aware of their impact on product quality and the importance of their activities in achieving, maintaining, and improving quality, including customer requirements and the risks involved for the customer with non-conforming product."

And ISO9001: 2015 5.1.1 Leadership and commitment General

"Top management shall demonstrate leadership and commitment with respect to the quality management system by:

h) "engaging, directing and supporting persons to contribute to the effectiveness of the quality management system

The first thing is Top Management and the defined process owners must be engaged and themselves understand the purpose of, and the benefits that can be obtained, by having an effectively implemented Quality Management System.

Then, by demonstrating their understanding and commitment, they can then promote the importance to all employees. This can be supported by Gemba walks, communication meetings, participation in layered audits etc.

Quality Partner has developed a series of videos on understanding the purpose of quality, environmental and health and safety management systems and understanding the requirements in a practical common-sense way. For more information visit https://qualitypartner.co.uk/iso9001/introduction-to-management-system-standards-and-requirements/

These can be used as part of an employee induction, or for ongoing awareness training.

Question
If a Customer audits our site using the VDA6.3 methodology:

1. Is it acceptable for the customer to leave the site without providing a VDA6.3 score or a spreadsheet?
2. Is it acceptable for the customer to wait to send the score, grade and the spreadsheet back to the supplier days or weeks after the audit?
3. Is it acceptable to use the same evidence to subtract points on two different questions? For example, and 5.4 and 5.7.

Answer
The problem is with VDA 6.3, as it is not a third-party certification scheme, there are no clear rules to address your questions. It is a second party process audit standard, and as such there is no requirements (unlike IATF!) for when to leave the report or communicate the assessment score.

However, in section 4.6 of VDA 6.3 its states:

"In the final discussion the audited organisation and its representatives are presented with a report. This report focuses on:

- Notification of the audit results and the audit findings, when necessary with explanations.
- Specifying the next steps, such as dates for defining the corrective actions (action plan) or arranging a repeat audit if necessary.
- The audit report must not contain other findings to what were given at the final discussion."

So, in conclusion against your point 1 and 2 in the question, VDA seem to indicate that the report should be left before the team leave the site, especially to avoid "no surprizes", but if they do not, there is no mediating body you can go to. You just have to communicate with the customer and press them to provide the report and any findings.

On point 3 of your question, I was taught by VDA that you cannot "double hit" for the same nonconformity, you pick the one most suitable requirement. If they are using the same objective evidence in marking down several question it would be pointless, as the corrective action would be the same!

Question
On their last audit our external third-party auditor for IATF 16949 consistently used the terms COP, MOP and SOP, but I cannot find any reference to these, or any definitions in IATF 16949. Can you help?

Answer
These terms were introduced by IATF as part of the process approach training for third party auditors for ISO/TS16949: 2002 and has continued through the updates of the standard and the transition to IATF 16949.

The definitions given in the training are:

- COP: **C**ustomer **O**riented **P**rocesses focus on meeting external customer needs
- MOP: **M**anagement **O**riented **P**rocesses are processes owned by Top Management focused on ensuring that customer, interested party and organization requirements are met, by providing adequate resources, reviewing performance, and taking action when specified objectives are not met
- SOP: **S**upport **O**riented **P**rocesses are processes to ensure adequate support to the Customer Oriented Processes to ensure customer and interested party requirements are fulfilled.

Examples could be:

COP: Marketing and sales process
MOP: Business planning and review process
SOP: Maintenance process

In the IATF requirements there is no mandate to use these terms when identifying the QMS processes.

The requirement in 4.4. of ISO9001: 2015 states:

"The organization shall determine the processes needed for the quality management system and their application throughout the organization……"

If in your quality management system, you have clearly defined the processes needed, assigned owners for each process, defined the process sequence and interaction and are monitoring and measuring performance against specified objectives this is acceptable.
What you call the processes is your organization decision, for example you could call, Main processes,

Core Processes etc.

Question:
As far as I know, in the PFMEA the only chance to reduce the Severity rating is to act on the design (e.g. from naked tube to tube with protection sleeve to reduce the severity of melting under high temperature). Is it possible to reduce the severity ranking by process change? How?

Answer:
The text book answer is severity can only be changes by product design change, not process. The only exception is the situation where severity has been scored high due to risk of harm to the operator (internal risk), in this case by re-designing the manufacturing process severity can be reduced.
In the AIAG reference manual, the severity ranking table is shown below:

Effect	PFMEA - Suggested Severity Criteria. Severity of Effect on Product (Customer Effect)	Rank	Effect	PFMEA - Suggested Severity Criteria. Severity of Effect on Process (Manufacturing/Assembly Effect)
Failure to Meet Safety and/or Regulatory Requirements	Potential Failure mode affects safe vehicle operation and/or involves noncompliance with government regulation without warning	10	Failure to Meet Safety and/or Regulatory Requirements	May endanger operator (machine or assembly) without warning.
	Potential Failure mode affects safe vehicle operation and/or involves noncompliance with government regulation with warning	9		May endanger operator (machine or assembly) with warning.
Loss or Degradation of Primary function	Loss of primary function (vehicle inoperable, does not affect safe vehicle operation).	8	Major Disruption	100% of product may have to be scrapped. Line shutdown or stopped shipments
	Degradation of primary function (vehicle operable, but at reduced level of performance).	7	Significant Disruption	A portion of the production run may have to be scrapped. Deviation from the primary process including decreased line speed or added manpower
Loss or Degradation of Secondary Function Degradation of Secondary function	Loss of secondary function (vehicle operable, but comfort/convenience functions inoperable).	6	Moderate Disruption	100% of the production run may have to be reworked off line and accepted
	Loss of secondary function (vehicle operable, but comfort/convenience functions at reduced level of performance).	5		A portion of the production run may have to be reworked off line and accepted
Annoyance	Appearance or Audible Noise, vehicle operable item does not conform and noticed by most customers (>75%)	4	Moderate Disruption	100% of the production run may have to be reworked in station before it is processed.
	Appearance or Audible Noise, vehicle operable item does not conform and noticed by many customers (50%)	3		A portion of the production run may have to be reworked in station before it is processed.
	Appearance or Audible Noise, vehicle operable item does not conform and noticed by discriminating customers (<25%)	2	Minor Disruption	Slight inconvenience to process, operation or operator.
No effect	No discernable effect	1	No Effect	No discernable effect

You can see a severity of 9 or 10 for a manufacturing/assembly effect is where there is a danger to the operator. In this case the severity could be reduced by making design changes to the manufacturing process.