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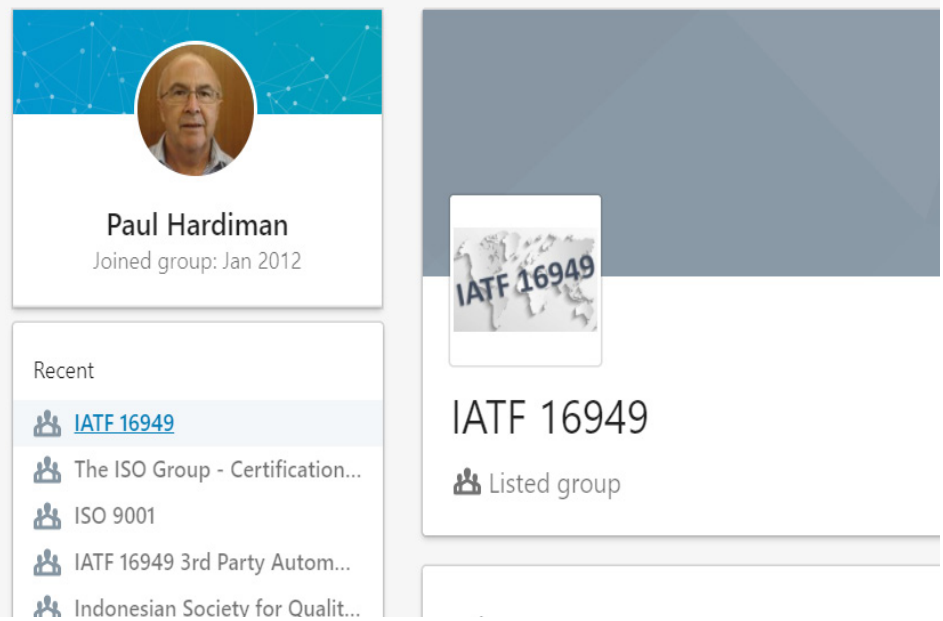


Welcome to the twentieth edition of the Quality Partner newsletter. The newsletter is designed to keep readers up to date with developments in Quality Management Systems.

For this edition I sought ideas and inspiration from the IATF 16949 LinkedIn group. The group is a great forum to share and discuss issues with IATF 16949 and the associated scheme, with over 36,000 members.

Considering ideas from the group, this issue focuses on:

- The IATF Common audit report application (CARA)
- VDA 6.5 Product audit
- Auditing the interactions between the automotive core tools
- 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 newsletter August 2020 IATF have made the momentous decision to allow remote auditing, where, due to the Covid 19 pandemic, onsite auditing is not safe, or legally possible to undertake.

Full details of this will be confirmed in the 5th edition of the IATF Covid response, expected for publication at the end of October 2020. This follows a lot of lobbying from myself and the IATF 16949 certification bodies that safety of auditors must come first.

This follows the decision by IATF to allow organizations to undertake remote internal audits if it can demonstrate the risks and opportunities have been effectively considered.

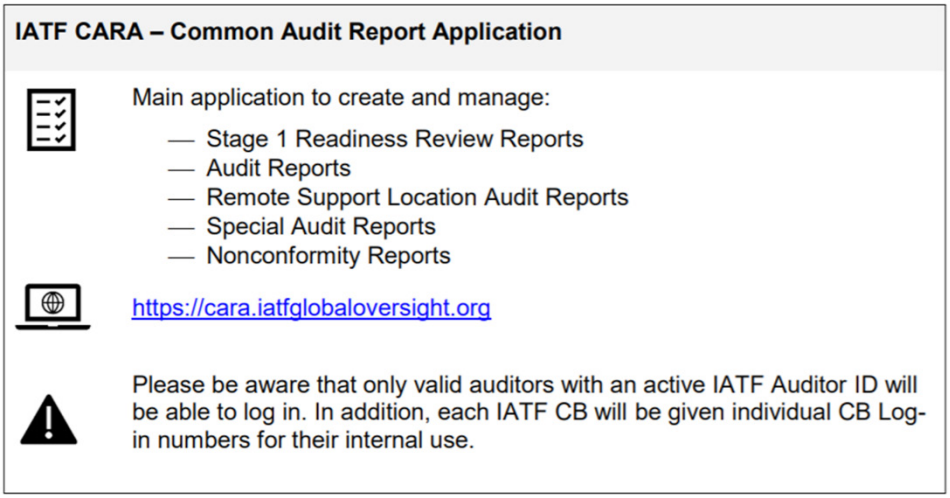
I have developed an online remote training programme focused on effective remote auditing techniques. This course is aimed at experienced internal or second party auditors who want to learn best practice techniques for undertaking remote audits For more information on the course and dates contact: paul.hardiman@qualitypartner.co.uk

If you have any training needs related to IATF 16949 or the related core tools do not hesitate to contact me. Courses can be delivered face to face (if safe to do so) or by remote technology.

IATF Common audit report application (CARA)

Since the beginning of the IATF scheme in 1999, the report formats used by the IATF recognised certification bodies varied. Although reports should have contained the minimum information as specified in the IATF rules, the structure and content of reports was often vastly different.

For the last couple of years IATF has been developing a browser-based application called CARA. The formal launch of this was communicated through a certification body communique, and the issue of sanctioned interpretations to align CARA to the IATF rules. Although CB's are currently trialling the use of CARA now, the formal launch date is January 2021. CARA will be used for all IATF audits, including initial, surveillance, recertification, transfer and special.



So, what does this mean to IATF third party auditors and IATF certified organizations?

For 3rd party IATF auditors there will be pros and cons.

The pros include, especially if auditors work for multiple certification bodies, that the same report format will be used by all. Also, IATF are allowing more audit time to complete the audit reporting (maximum 15% of the total audit time verses 10% before)

The cons include getting used to the reporting tool!

For IATF certified organizations, as well as receiving IATF audit reports in a standard CARA format, they will have to respond to any nonconformities raised in IATF 3rd party audits through the CARA browser.

In the next couple of months, the certification bodies will be providing their clients more details, including videos produced by IATF to help understanding the reporting tool and its application, and how to respond to nonconformities through the browser.

Let us see how successful the launch is, more to follow in the next edition!

VDA 6.5 Product audit

This year has seen the publication of a revision to VDA 6.5 Product Audit: Guidelines. The 3rd revision was issued in March 2020. Compliance with the principles in the manual is mandated by some customer specific requirements.

As well as defining the product audit process in detail, the manual attempts to clarify the relationship between product audit, and layout inspection and functional testing. We will further explore this in this article.

Firstly, let us have a look at the related requirements in IATF 16949: 2016:

9.2.2.4 Product audit

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

8.6.2 Layout inspection and functional testing

A layout inspection and a functional verification to applicable customer engineering material and performance standards shall be performed for each product as specified in the control plans. Results shall be available for customer review.

NOTE 1 Layout inspection is the complete measurement of all product dimensions shown on the design record(s).

NOTE 2 The frequency of layout inspection is determined by the customer.

So firstly, let us look at the definition of “product”:

Product can be divided into the following categories:

- Hardware (e.g. Components (mechanical, electronic, electrical) and assemblies)
- Software (e.g. For control units, navigation systems etc.)
- Bulk materials (e.g. Lubricants)

And the definition of an audit:

- “a systematic, **independent** and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled”

VDA 6.5 makes it clear that product audits are NOT a repeat of the normal in-process or final inspections/ tests done in the production process, as specified in the control plan.

Product audits are additional, independent verifications that evaluate products from the customers perspective to verify conformance to the defined specifications, and to identify potential for continuous improvement.

Audit programme

As product audits are part of IATF 16949 requirement 9.2.2.1, product audits must be scheduled according to an internal audit programme. IATF 16949 does not specify the frequency of product audits or how they should be programmed but requires customer specific requirements must be considered.

If an organization manufactures many products, consideration can be given to grouping products into families.

In developing the audit programme for product audits, input data must be collected which may include:

- Customer and any legal/regulatory requirements related to product audit
- Risk analysis from DFMEA or PFMEA
- Customer complaint data (including any field failures or warranty data)
- Internal performance data (scrap, rework, OEE etc.)
- Results of previous product audits
- Strategic importance of the product (s), considering risks and opportunities (% of output, growth potential etc.)
- Maturity level of the product (new product or with long proven history)

Based on the review of this data an audit programme for product audits can be developed. In VDA 6.5 an example of a risk matrix is shown, showing the product groups (and sub-groups if applicable), and then risks levels of 1 (low risk), 3 (medium risk) and 9 (high risk) for each evaluation criteria (evaluation criteria could include the points shown above).

While this matrix is not mandated, it is a good way to demonstrate compliance with the requirement in 9.2.2.1 which states *"The audit programme shall be prioritized based upon risk, internal and external performance trends, and criticality of the process(es)."*

There is no requirement in IATF 16949 for all products to be audited in any specific time-period (for example every three years), the frequency can be a risk-based decision by the organization. However, to be able to demonstrate ongoing compliance with the IATF requirements, and least one or more product audits must be undertaken in each 12-month period (otherwise in the 3rd party IATF audits there would be no evidence of compliance with this requirement).

In developing the audit programme it must be assured that there are sufficient qualified product auditors, and sufficient availability of physical resources (test and measuring equipment etc.) to be able to implement the programme effectively.

In evaluating who is competent to undertake product audits, the criteria in 7.2.3 (including SI 4) must be considered, namely: *"At a minimum product auditors shall demonstrate competence in understanding product requirements and use of relevant measuring and test equipment to verify product conformity."*

A list of competent product auditors must be maintained. To achieve competency, there is no specific need for training, competency can be achieved by education of experience.

Once the audit programme is finalized, the audits must be allocated to competent product auditors to plan, undertake, and report the audits in accordance with the organizations documented internal audit process. In the planning phase, the auditor needs to decide where in the process to take the sample (s) from to audit (in-process or final product), review the relevant product specifications/standards, review internal and external performance data and ensures availability of the relevant measuring and test equipment to make any product measurements.

Undertaking the audit will include notifying the relevant departments/personnel, removing the parts from the production process, labelling the parts, undertaking the relevant inspections/measurements/tests, and then recording the results.

Any nonconformities identified need to be documented and categorized in accordance with the organization defined process/criteria. This could be major/minor nonconformity, or in VDA 6.5 it gives an example of major defect A, major defect B or minor defect C.

Obviously if issues are found in product audit, this means that the normal process to ensure product compliance has not worked effectively, so immediate action must be taken in terms of correction/ containment, and then detailed root cause analysis, using a defined methodology, to identify the causes to enable systemic corrective action to be undertaken.

Now let us explore the link between product audit (IATF 16949 9.2.2.4) and Layout inspection and functional testing (IATF 16949 8.6.2).

Typically, by the nature of the word “audit”, a product audit will not normally check every product dimension, and hence cannot be used to replace the need for layout inspection.

However, if product audits are done on a finished product, and check all dimensions in the design record, then there is no reason why the record of the audit cannot be used as both evidence of product audit and layout inspection. Any additional functional verification would also have to be completed as specified in any customer requirements.

Finally, do not forget to include the frequency of layout inspection in the relevant control plan, taking into account customer specific requirements.

In conclusion VDA 6.5 gives useful guidance on developing an audit programme, and planning and

undertaking product audits. Compliance to VDA 6.5 is only mandated if specified in customer specific requirements.

VDA 6.5 Online training

In association with Quality Partner Thailand, I have developed an online training course for the updated VDA 6.5. The online workshop will help delegates understand:

- The IATF 16949 requirements related to product audit and product auditor qualification
- Customer specific requirements related to VDA6.5
- The product audit process defined in VDA 6.5 including:
  - Developing a product audit programme, incorporating risk-based thinking
  - Planning, undertaking, and reporting the results from product audits
  - Closing out findings from product audits
- The differences between product audit and layout inspection

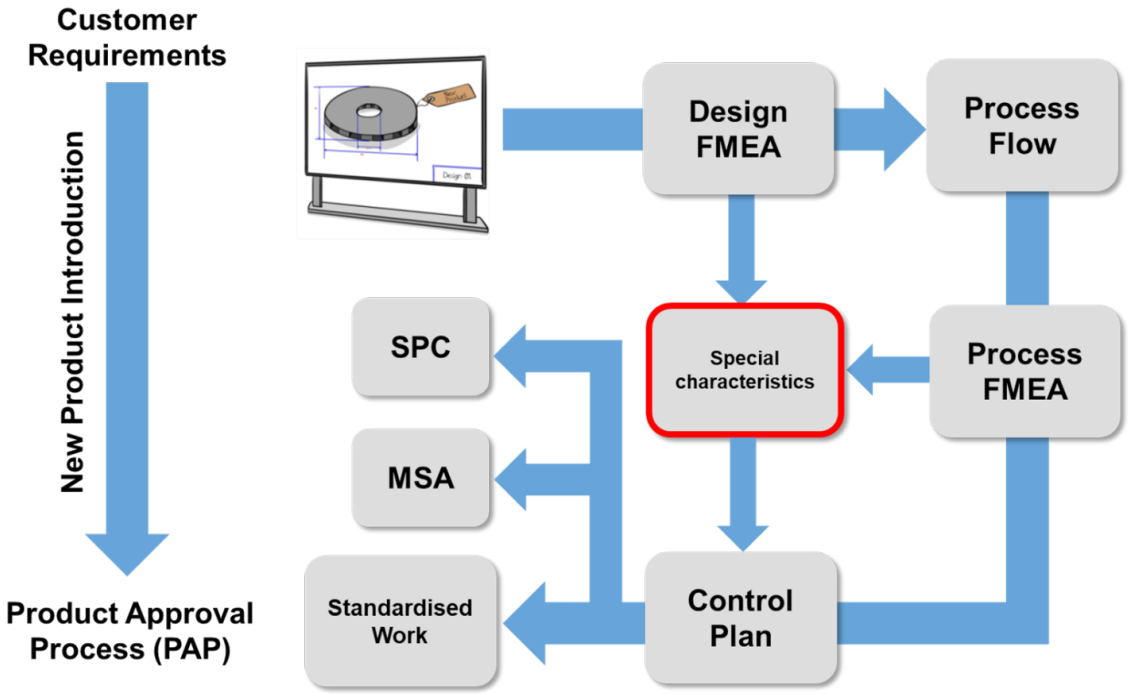
The workshop, planned for the 2nd December 2020 is priced at an amazing $50 per delegate, fully inclusive of all course materials and certificate. For more information or to book places visit https://www.qualitypartner.org/en/online-course/vda-6-5-product-audit-2020-edition/

Effective auditing of the interactions between the automotive core tools

In recent months IATF has rolled out more online training and exams to third party IATF 16949 auditors, further stressing the need for auditors, when applying the automotive process approach, to effectively audit the interactions between the automotive core tools.

Based on this, and other requests from friends on LinkedIn, this article explores the best was to audit the core tools whilst undertaking internal or second party IATF 16949 audits.

In the past 12 months, over 1000 IATF certified organizations have had their certificates placed in a state of suspension, because of major nonconformities related to the effective application of the core tools. Many of these relate to lack of effective implementation and update of the PFMEA and control plan.



For internal audits, the requirement 9.2.2.3 Manufacturing process audit states:

"The manufacturing process audit shall include an audit of the effective implementation of the process risk analysis (such as PFMEA), control plan, and associated documents."

So, what should a manufacturing process audit focus on?

The key thing is for the auditor not only to verify the individual core tools are used effectively, but that the deployment of the tools has been done is a structured way, with clear linkages between them.

It is essential that customer requirements (including customer specific requirements) are understood. This could include understanding any customer specified special characteristics, either related to product or process.

Next, if the organization is product design responsible (Defined in IATF as "organization with authority to establish a new, or change an existing, product specification") it is mandatory that, as part of the product design a DFMEA is created, taking into account customer inputs, including special characteristics.

With simultaneous engineering, while the product design is being finalized, work could be started on designing the manufacturing process to make the product (including any prototypes), including creation of the process flow diagram, and understanding potential process risks in the PFMEA. This should consider the outputs from the product design team, including special characteristics from the DFMEA.

Either simultaneously, or after completion of the PFMEA, the PFMEA output should be the input into developing the control plan. Whilst some software will create a draft control plan, developed from the completion of the PFMEA, in many cases the control plan is developed separately, often by a different team to that of the PFMEA.

PFMEA

Process Step / Function	Requirements	Potential Failure Mode	Potential Effect (s) of Failure	Severity	Classification	Potential Cause(s) of Failure	Current Process Controls *Prevention*	Occurrence	Current Process Controls *Detection*	Detection
OP03 A pillar garnish injection *- Inject the melted compound resin by injection machine into the mold to form shape as drawin[1] ecified*	No appearance defects, e.g. flash [2]	Flash [2]	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 End User: Garnish ASM loose , open	7 [3]		Insufficient clamping force to close the gap [4]	Machine PM system as plan [5]	3	Operator perform visual inspection 100% [6]	6

Control Plan

PART/ PROCESS NUMBER	PROCESS NAME/ OPERATION DESCRIPTION	MACHINE, DEVICE, JIG,TOOLS, FOR MFG.	CHARACTERISTICS			SPECIAL CHAR. CLASS	METHODS					REACTION PLAN
			NO.	PRODUCT	PROCESS		PRODUCT/PROCESS SPECIFICATION/ TOLERANCE	EVALUATION/ MEASUREMENT TECHNIQUE	SAMPLE SIZE	SAMPLE FREQ.	CONTROL METHOD	
OP03 [1]	A pillar garnish injection [1]	Injection machine [1]	1	Appearance (Flash) [2]		[3]	No Flash	Visual	100%	100%		Rework
			2		mould clamping force [4]		200 kN	Control Pannel [6]	Initial setup [6]	_ [6]	Machine PM as plan [5]	

Given that issues with PFMEA and control plan are both in the top 10 major nonconformities found on IATF

audits, this should be a focus in internal manufacturing process audits, especially the linkages between the PFMEA and control plan. An example of linkages between the PFMEA and control plan is shown above.

Once the control plan is finalized, this should then give the relevant information to identify “each type of measurement system” to undertake the appropriate measurement system analysis, and then to undertake the relevant statistical studies (e.g. Cpk, Ppk), focused on any special characteristics.

Finally, it should be ensured that the standardized work instructions are written considering the control plan requirements.

In summary, manufacturing process audits, if done effectively, can mitigate risk of major nonconformities in third party audits, and more importantly identify areas for process improvement.

For more information on the range of internal and second party auditor courses available from Quality Partner, contact Paul Hardiman at paul.hardiman@qualitypartner.co.uk

Courses can be delivered face to face (if safe to do so) or using remote technology.

Ask the expert

Quality Partner’s expert, Paul Hardiman

Question
In the IATF requirement for management review, an organization must cover actual and potential field failures. Can you explain an acceptable way of demonstrating this?

Answer
You are correct, the relevant requirements in 9.3.2.1 Management Review input are:

j) identification of potential field failures identified through risk analysis (such as FMEA);
k) actual field failures and their impact on safety or the environment.

Whereas k) is easier to understand, with the relevant personal preparing a summary of any field failures, the results of the causes and the relevant corrective actions as an input to management review, understanding how to address j) is more challenging!

Let us consider FMEA. DFMEA is mandatory for any design responsible organizations, and PFMEA for all IATF 16949 certified organizations. The personal responsible for managing the effective implementation of FMEA could prepare a periodic summary report, which could include:

- Summary of any DFMEA and/or PFMEA activities undertaken since the last Management Review
- Summary of the highest risks identified. For FMEA’s completed using the AIAG 4th edition reference manual this could be a summary of the highest RPN’s/ S x O. For FMEA’s completed using the AIAG/ VDA handbook, the action priority (AP) rankings (H. M, L) can be used to summarize the biggest risks.

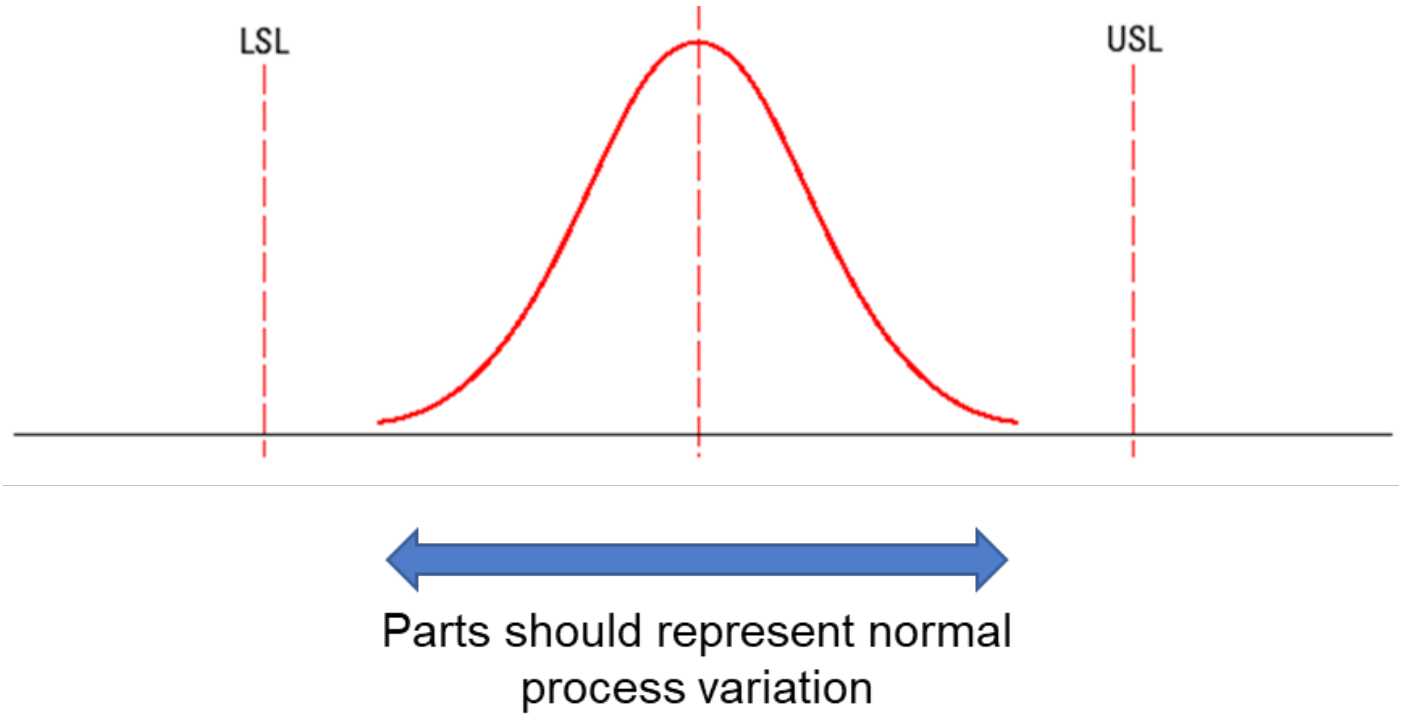
The key thing is not just to report the results, but Management need to commit the necessary resources to ensure risk reduction activities are implemented in accordance with defined timing requirements. A record of this needs to be documented as part of the Management Review output records.

Question
When undertaking a Gauge R&R MSA study, can you explain how samples should be selected for the study?

Answer
Good question! In the AIAG 4th edition reference manual, it states “Selection of parts is critical for proper analysis and depends entirely on the design of the MSA study, purpose of the measurement system and availability of part samples that represent the production process”

The AIAG reference manual states that the variation in the sample parts (Part Variation (PV)) is used to calculate the Total Variation (TV) of the study. This is important in the calculation of Gauge R&R (i.e. %GR&R verses TV).

Selecting sample parts for the study may mean taking samples over several days production, covering potentially several batches of the same product. This should ensure samples represent the normal (6 sigma) variation from the process.



The variation in the parts selected could be confirmed prior to undertaking the study by a process expert measuring the 10 parts selected and comparing with historic data from the process variation/process capability data for the same or similar products manufactured.

I know historically some organizations have deliberately selected samples from outside the specification limits with the aim to get a better GR&R result, but in my view this is wrong. Why undertake a study that does not represent the measurement system ability to effectively measure the normal process variation from a process? Is it the intent of the manufacturing process to produce out of specification parts?

Question
We have several measurement systems in our organization which destruct the samples in gaining the measurement. How can we undertake measurement system analysis (MSA) for this type of equipment?

Answer

Attribute equipment

Variable equipment

Attribute agreement analysis

Repeatably and Reproducibility studies (Gauge R&R)
- Non-destructive
- Destructive

Stability

Linearity

Bias

As stated in IATF requirement 7.1.5.1.1 Measurement system analysis “Statistical studies shall be conducted to analyse the variation present in the results of each type of inspection, measurement, and test equipment system identified in the control plan.”

So, to meet this requirement, MSA must cover attribute and variable measurement systems, including non-destructive and destructive systems specified on the control plan.

However, this does not have to be GR&R!

The first thing is to understand the way the equipment is calibrated, the frequency of calibration, the results of previous calibrations (if available) and the associated risks if the equipment drifts out of calibration in between the calibration intervals.

The next is to understand the measurement process, for example if there is the potential for appraiser variation in the measurement process (or maybe the measurement process is automated with no potential for appraiser variation).

Once this is understood the appropriate type of MSA study can be determined.

If the measurement process is primarily automated the conclusion maybe, that in between the calibration intervals, that a check will be done against a known reference sample (s), of known values, to monitor any drift in the equipment. In MSA speak, this would be bias, linearity and stability.

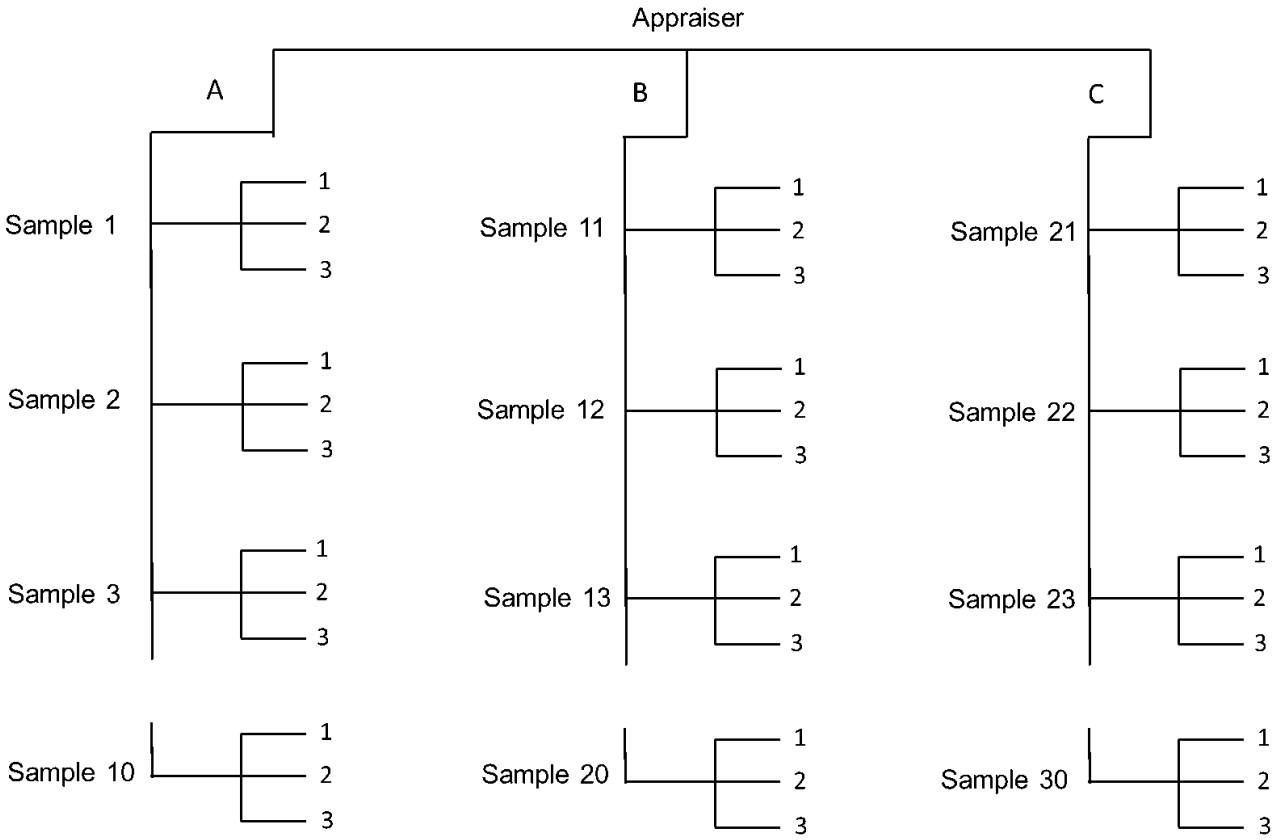
For example, for a hardness testing machine, the reference standard could be a certified test block (s). For a tensile test, the reference standard maybe a certified material with a known tensile strength.

In both cases, in between the calibration intervals, a check could be done against the reference standard (s), in the normal work environment, and the results recorded. Over time (stability), data could be analysed (maybe using the principles of SPC) to identify any changes in the measurement system.

If changes are detected, this could trigger an investigation and maybe a recalibration.

Where there is the potential for appraiser variation in the destructive measurement system, GR&R can be considered as an appropriate MSA study.

To undertake this, the difficulty is that, in the measurement process, the part is destroyed, and as such the measurement cannot be repeated on the same part. So, the key to a successful study is the sample selection for the study, and the way that the samples are randomly allocated to appraisers.



The diagram above shows how 30 samples are taken from the normal production process. For each sample, either the sample is cut into 3 for test, or if this is not possible, 3 sequential parts are taken for each sample. The samples are then randomized, numbered, and then allocated to the three appraisers (people normally involved in the measurement process).

Measurements are then made for each sample parts, and recorded (so there should be a total of 30 measurements per appraiser, 90 in total).

To analyse the results, rather than a non-destructive “crossed” method of analysis, a nested method must be used. To do this statistical software is needed (ensuring in doing the GR&R analysis that the NESTED option is selected).

The results of the study are then analysed in the same way as a non-destructive GR&R study, with typical acceptance criteria of less than 10% GR&R being used to determine the acceptability of the measurement system.

Question

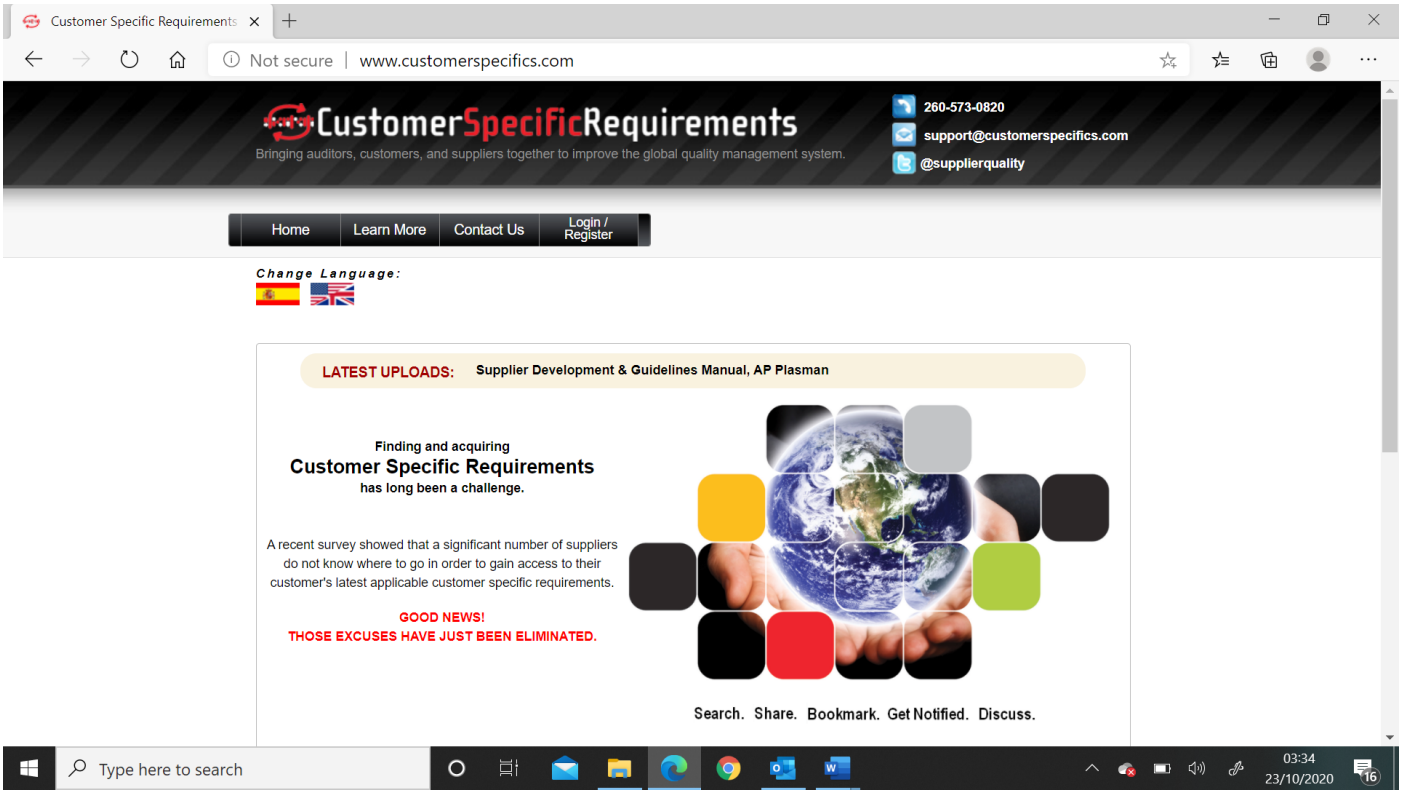
I am a third party IATF 16949 auditor. When auditing customer specific requirements I can access the latest version of the IATF member customer specific requirements through the www.iatfglobaloversight.org website. However, I must rely on the clients I audit to be able to access their non IATF OEM and supplier customer specific requirements. Are you aware of any source where we can access these customer specific requirements?

Answer
This is not just an issue for third party auditors, but also for organizations certified to IATF 16949, where they have enquiries from potential new customers and want to investigate if there are any applicable CSR's.

Firstly, as a third-party auditor your task is to audit the effectiveness of an organizations process for gathering, communicating, and implementing customer-specific requirements, with prioritization on any IATF member CSR's.

In auditing you will take a sample of the organization's customers, and then challenge the organization on how customer specific requirements are identified. Customer specific requirements could be provided by the customer through customer portals, by mail, by e-mail etc.

One source that can be used to investigate if an organization has customer specific requirements is www.customerspecifics.com. At this site, it is free for anybody to register. The site offers a search facility, not just for customer specific requirements for automotive, but for many other industries. There is no guarantee that the CSR's on the site are the latest version, as the site relies on users uploading the latest editions. But it at least identifies whether an organization has customer specific requirements.



Question
We have the task to update our contingency plan considering the Covid 19 pandemic. Can you give us any advice?

Answer
This will be a task, not only for you, but for most of the 80,000 certified IATF 16949 organizations!
Let us think first on the purpose of the contingency plan. The purpose is to ensure customer requirements are met by maintaining production output to meet production schedule requirements.

Obviously, a major risk to achieving this is goal is the potential disruption caused by the Covid 19 pandemic.

IATF requirement 6.1.2.3 Contingency Plan, mandates that at a minimum, an organization undertakes an annual contingency plan review by a multidisciplinary team, including Top Management.

In undertaking the review, the organization should firstly look at performance data, focusing on delivery performance, including premium freight. This is a way of challenging the effectiveness of the current contingency plan. Where customer delivery requirements have not been met, the reasons should be investigated, for example supplier shortages, transportation issues or labour shortages.

Taking this into account, each aspect of the contingency plan needs to be reviewed, considering any Covid 19 disruption, and updated accordingly.

At minimum this must include:

- key equipment failures
- interruption from externally provided products, processes, and services
- recurring natural disasters
- fire
- utility interruptions
- cyber-attacks on information technology systems
- labour shortages
- infrastructure disruptions

Obviously not all these items may have been affected by Covid 19, but where a risk has changed due to the pandemic, the contingency plan must be updated with a revised control, talking into account the lessons learnt.