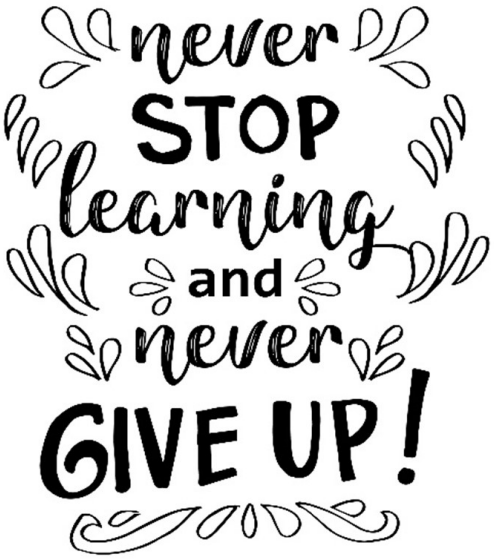
Quality Partner Newsletter May 2021

Issue date: May 2021



Firstly, I hope you are all safe and well.

Welcome to the twenty second 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.

For this edition I again 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 45,000 members.

Considering ideas from the group, this issue focuses on:

- Calibration, Verification and Measurement System Analysis (MSA)
- IAOB-SMMT You Tube channel update
- Risk and opportunity
- Questions from LinkedIn colleagues and answers

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

Despite the terrible situation with Covid 19, the number organizations certified to IATF 16949 continues to grow with 80,977 IATF 16949 certified sites at the 31 March 2021.

This number does not include the thousands of remote support functions that support many of the certified sites.

The top 3 countries continue to be China (40720 sites), India (6368 sites) and Republic of Korea (5170 sites).

I hope you enjoy this edition of the newsletter. Let us continue to network and learn together!

For more information on Quality Partner onsite and remote courses related to IATF 16949, best practice auditing, and effective implementation of the automotive core tools contact: paul.hardiman@qualitypartner.co.uk

For More Information Visit www.qualitypartner.co.uk

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Calibration, Verification and Measurement System Analysis (MSA)

This article focuses on an effective understanding and application of the following requirements in IATF 16949: 2016:

- 7.1.5.2 Measurement traceability
- 7.1.5.2.1 Calibration/verification records
- 7.1.5.3.1 Internal laboratory
- 7.1.5.3.2 External laboratory
- 7.1.5.1.1 Measurement system analysis

These are requirements that are critical in helping ensure that capable measurement systems are used to verify that an organizations product or manufacturing process meets the specified requirements. However, if wrongly applied, this can cost an organization a significant amount of wasted resources (time and money).

7.1.5.2.1 Calibration/verification records

This requirement must be read in association with the ISO9001 requirement 7.1.5.2 Measurement traceability, which includes:

"When measurement traceability is a requirement, or is considered by the organization to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be:
a) calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards……..."

A commonly accepted definition of calibration is:

"A set of operations that establish, under specified operating conditions, the relationship between a measuring device and a traceable standard of a known reference and uncertainty."

According to IATF 16949 calibration can either be done in an organization's internal laboratory or an external laboratory (see below).

So, what is verification?

Firstly, if we look in the ISO9000 definitions, verification is defined as:

“confirmation, through the provision of objective evidence that specified requirements have been fulfilled”.

Obviously, this is a general definition, not specific to measuring equipment.

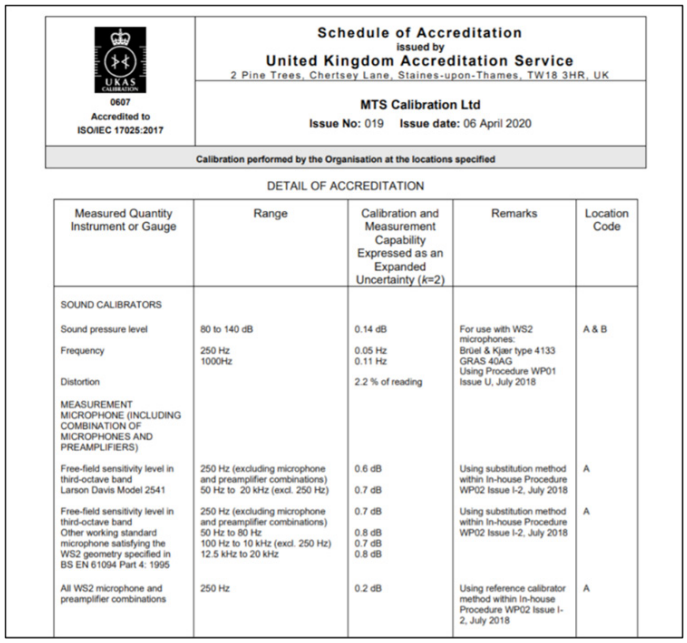
Let us explore the requirements in more detail:

In determining what needs to be calibrated, we must consider customer requirements, legal and regulatory requirements, and the organizations own requirements, considering associated risks.

Typically, at minimum, any measuring or test equipment specified on the control plan needs to be either calibrated and/or verified.

If the decision is made to calibrate the equipment externally, the requirements of 7.1.5.3.2 External laboratory must be met, considering the recently amended sanctioned interpretation SI 10.

Firstly, the organization should investigate if there is an ISO/IEC17025 accredited laboratory, who has the type of equipment in their accreditation scope, available to undertake the calibration.



Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

0607
Accredited to
ISO/IEC 17025:2017

MTS Calibration Ltd
Issue No: 019 **Issue date:** 06 April 2020

Calibration performed by the Organisation at the locations specified

DETAIL OF ACCREDITATION

Measured Quantity Instrument or Gauge	Range	Calibration and Measurement Capability Expressed as an Expanded Uncertainty (*k*=2)	Remarks	Location Code
SOUND CALIBRATORS				
Sound pressure level	80 to 140 dB	0.14 dB	For use with WS2 microphones: Brüel & Kjær type 4133 GRAS 40AG Using Procedure WP01 Issue U, July 2018	A & B
Frequency	250 Hz 1000Hz	0.05 Hz 0.11 Hz		
Distortion		2.2 % of reading		
MEASUREMENT MICROPHONE (INCLUDING COMBINATION OF MICROPHONES AND PREAMPLIFIERS)				
Free-field sensitivity level in third-octave band Larson Davis Model 2541	250 Hz (excluding microphone and preamplifier combinations) 50 Hz to 20 kHz (excl. 250 Hz)	0.6 dB 0.7 dB	Using substitution method within In-house Procedure WP02 Issue I-2, July 2018	A
Free-field sensitivity level in third-octave band Other working standard microphone satisfying the WS2 geometry specified in BS EN 61094 Part 4: 1995	250 Hz (excluding microphone and preamplifier combinations) 50 Hz to 80 Hz 100 Hz to 10 kHz (excl. 250 Hz) 12.5 kHz to 20 kHz	0.7 dB 0.8 dB 0.7 dB 0.8 dB	Using substitution method within In-house Procedure WP02 Issue I-2, July 2018	A
All WS2 microphone and preamplifier combinations	250 Hz	0.2 dB	Using reference calibrator method within In-house Procedure WP02 Issue I-2, July 2018	A

Example of an accredited laboratory scope

IATF 16949 FAQ 7 asked the question: “If an accredited laboratory exists but is very remote and/or expensive and the inspection or test equipment manufacturer is nearby and available can they be used (even if they are not accredited to ISO/IEC 17025)?”

Unfortunately, the answer to this question was removed and now refers to SI 10, which does not clearly answer the question!

In my view, if the organization can demonstrate they have investigated if an accredited laboratory for the type of equipment, and concluded that one is not available in the country they reside, then there is a good justification to use the original equipment manufacturer, or a non-accredited laboratory. In this case the organization must provide evidence they have evaluated the calibration provider against the requirements of 7.1.5.3.1.

This could be by a questionnaire, supporting information provided by the laboratory/original equipment manufacturer or if it is seen as high risk, an onsite audit of the provider by the organization.

At least now the SI10 now makes it clear that customer approval is not required in this situation.

In either of the situations (accredited lab, OEM, or non-accredited lab) above the calibration certificate shall include:

- The mark of accreditation if an ISO/IEC 17025 laboratory is used.
- Evidence what standard/specification was used to undertake the calibration.
- The as received and after any adjustment readings.
- Evidence showing the equipment used to provide the traceability to national or international standards.
- The measurement uncertainty.
- A statement of conformity to specification after calibration.

Upon receipt of any certificate, the organization must demonstrate an effective process of review to verify the acceptability of the results and suitability for ongoing use for the measuring and test equipment.

If the decision is made to calibrate the equipment internally, the requirements of 7.1.5.3.1 Internal laboratory must be met.

In this case an organization must be able to answer the questions below:

- What standard/procedure will be calibration be undertaken against?
- If required by the standard/procedure, how is the work environment controlled where the calibration is performed?
- How are the personnel doing the calibration competent to perform the calibration (considering education, experience and/or training) and are records to demonstrate this?
- What calibration standards are used to demonstrate traceability to national or international standards?
- How are the calibration results evaluated and what criteria is used for acceptability?
- What records are maintained to demonstrate the above activities are performed effectively?

Answers to these questions should be included in the documented process for calibration/verification records or defined in the internal laboratory scope.

Whether the calibration is performed externally or internally it needs to be defined in a documented process what action is taken if a piece of inspection measurement and test equipment is found to be out of calibration or defective during its planned calibration (see 7.1.5.2.1 Calibration/verification records d))
Now let us evaluate “verification”.

In the ISO9001 7.1.5.2 it talks about “calibrated or verified, or both…”, whereas in IATF 16949 7.1.5.2.1 it mentions several times “calibration/verification records”.

In the IATF internal and external laboratory requirements it only mentions calibration, not verification.
Confused? I think many people are, leading to different interpretations of the requirements!

Let us go back to the ISO9000 definition of verification:

"confirmation, through the provision of objective evidence that specified requirements have been fulfilled".

Relating this to measuring and test equipment, verification can include:

- Confirming the performance of the instrument based on given specifications or requirements.
- Ensuring that the instrument is working correctly for its intended purpose.
- Checking the equipment covering it's normal working range, not the entire range.
- Deciding what to do based on the verification result. (which could include no action, or the need for recalibration, adjustment etc.)

In my view, it is the IATF expectation that where equipment is "considered by the organization to be an essential part of providing confidence in the validity of measurement results", then the equipment must be calibrated, not only verified.

Verification can be used to reduce risk, with an aim to detect, between the defined calibration period, if the equipment is still fit for use, by checking against a known reference standard (s). In my view this evidence of verification also provides evidence of Measurement System Analysis (bias, linearity, and stability).

An example. A micrometer is calibrated externally annually by an accredited laboratory, but to reduce risk, the organization made the decision to verify the micrometer monthly in the internal laboratory, against slip blocks, traceable to national standards. The verification is done against a documented work instruction, including defined acceptance criteria. Records of the verification are maintained.

Measurement system analysis (MSA)

I believe this is one of the most misunderstood requirements in IATF 16949, both by organizations and auditors.

The requirement states:

"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. The analytical methods and acceptance criteria used shall conform to those in reference manuals on measurement systems analysis. Other analytical methods and acceptance criteria may be used if approved by the customer……"

Note: "Prioritization of MSA studies should focus on critical or special product or process characteristics."

The key word is "**type**".

IATF 16949 FAQ 6 states:

"Question: Are MSA studies required for each instrument or device?"

"Answer: **No**. A complete statistical study on each single piece of equipment is not required. Instruments with the same characteristics (e.g., measurement range, resolution, repeatability, etc.) can be grouped and a sample instrument (representative of the gauge family) can be used for the statistical study."

When auditing MSA, one of my first questions would be to any organization:

“What criteria have you used to group measuring systems into types/families?”

I believe many IATF 16949 certified organizations would not be able to answer this question effectively. In the FAQ 6 it mentions the measurement range, resolution and repeatability can be factors in determining “types”. While I can understand how the measurement range and resolution can be factors, I am not sure how repeatability can be determined until MSA studies are undertaken?

I believe there are many more things that can be considered in determining “types”. Let us look at an example:

An organization has the following evaluation measurement techniques specified on the control plan:

0-25mm micrometers: There are 25 used in verifying the product, all measuring plastic moulded components, over a range of 5mm to 22mm, by operators all qualified in the use of the equipment. One product checked has a special characteristic, 21+/- 0.01 mm. All micrometers are the same type “Mitutoyo” with the same resolution, but 5 are manual and 20 digital (digital used to check product with special characteristic). All are used in the same work environment.

Visual inspection: Product (25 part numbers, of which 5 are defined as appearance items (see IATF 16949 8.6.3)) are visually checked during the manufacturing process for compliance to the defined visual standards, by operators, and then inspectors at final inspection. The lighting in the production area is minimum 250 lux whereas in the final inspection is 500 lux (a customer defined requirement). During the visual inspection, the following product features are checked:

- Short shots, surface inclusions, scratches, clarity of screen printing

After any visual inspection, a pass or fail decision is made by the operators or inspectors.

Spectrophotometer: This is used to verify colour. Samples are placed into a set position into a machine, and the machine gives a defined reading, which is compared to the relevant product specification. There are two machines, both the same specification, both calibrated. All product checked are in a similar range.

Example of a Spectrophotometer

Let us try to determine the types of measuring and test equipment systems from the above information, for which we need to perform MSA studies for.

These are some possible prompt questions:

- What types of materials is the measurement system being used to measure?
- What types of characteristics are being checked (e.g., Thickness, height etc.)?
- What is the measurement range that the measuring or testing equipment is being used?
- Are all the measuring systems the same type (for example same discrimination etc.)

- Are any special characteristics being measured, if so with what?
- What are the tolerances of the range of products being measured?
- What work environments (temperature/humidity/cleanliness) is the equipment being used in?
- What are the competency levels defined for those using the equipment?

Answers to these questions may help us determine the “types” of measuring systems, and the types of studies that may be relevant.

Firstly, let us consider the 0-25mm micrometers.

In my view there is a minimum of two studies that need to be performed, one on the manual and one on the digital type. As there is the opportunity for appraiser variation, GR&R studies would be a suitable type of study.

In selecting the parts to measure, the focus should be on the part with a special characteristic for the study using the digital micrometer. For the manual type, maybe the parts and characteristic selected to measure for the study would be the most difficult to measure (maybe parts at the top end of the range, 22mm). The appraisers for both studies would be the normal users of the equipment, undertaking the study in the normal work environment.

For the visual inspection, considering the information provided, I think there needs to be a minimum of two attribute agreement studies undertaken, one in the production area and one in final inspection. The parts selected for the study should focus on a part that is an appearance item, with maybe the strictest internal/ customer requirements related to visual attributes.

For the Spectrophotometer, from the information provided, the appraiser has little influence on the measurement process, so in this case a GR&R would not be the most appropriate study.

A better approach would be to have a defined “reference standard” (sample for comparison, measured on a more accurate instrument), and then, at a frequency based on risk, the reference standard would be checked in the machines, and the observed average of several readings (maybe 3-5) recorded. Any deviation from the reference standard would be recorded, and if deviation beyond the defined limits, a reaction plan would be triggered (for example adjust or recalibrate). In MSA speak, this would be checking for bias and stability.

In summary, a MSA plan defining the types of equipment could be:

Measurement system type	**Type of study**	**Parts selected for study**	**Appraisers selected for study**	**Work environment for study**
0-25mm micrometer: Digital	GR&R	Part with special characteristic*	Operators	Production area
0-25mm micrometer: Manual	GR&R	Parts at top end of measurement range (22mm)	Operators	Production area
Visual inspection	Attribute agreement analysis	Appearance item**	Operators	Production area 250 lux
Visual inspection	Attribute agreement analysis	Appearance item**	Inspectors	Inspection area 500 lux
Spectrophotometer	Bias and stability	Known reference standard	Operator	Where machine is located

*Parts for a GR&R study (typically 10) should be selected from the normal production process, representing the normal process variation (not sequential parts, may be over several hours/days of production). Outliers should not be included.

**Parts selected for an attribute agreement analysis (typically 30-50) should include good and bad parts, ideally with some close to the boundary between pass and fail.

Finally, when should any MSA study be repeated?

Unless defined by the customer (in their documented CSR's), there is NO frequency defined in IATF 16949 or any reference manual I know of. A study may need to be repeated in the event of:

- Improvement for a measuring system with unacceptable results
- Customer or internal measurement issues with the relevant measurement system
- Changes in skill level of appraisers
- Changes in product tolerance or acceptance criteria
- Changes in the work environment
- Improvement in process capability

Changes in people (for example the people involved in the original study) is not a mandatory reason to repeat studies, as the initial appraisers were probably only a sample of people involved in using the measurement system, all who should have be trained against the same criteria.

Summary

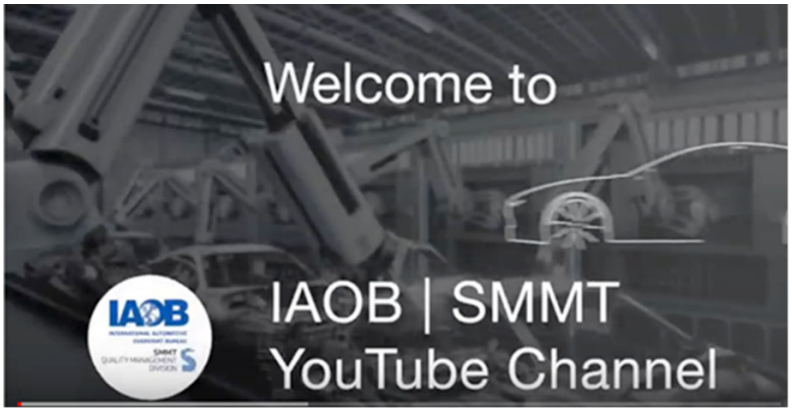
This is a complex topic and difficult to fully explain in a few pages. I encourage those of you who are involved in implementing or auditing these requirements to do more study/training. If you do not agree with any of my points, please feel free to e-mail me at paul.hardiman@qualitypartner.co.uk or start a conversation on LinkedIn!

Quality Partner have a one-day online or classroom workshop on calibration and/or MSA that can be tailored to meet an organizations specific needs. For more information contact paul.hardiman@qualitypartner.co.uk

IAOB-SMMT You Tube channel

The IAOB-SMMT You Tube channel, which is free to access at https://www.youtube.com/channelUCocqSC84cx_Bs-xEbhQr9pQ goes from strength to strength, with over 4200 active subscribers. Each week a new video is published, related to some aspect of best practice auditing or changes in the IATF scheme.

Recently we filmed a series related to best practice in undertaking remote audits, which will be released in the coming weeks.



If you have not done so already, make sure you subscribe!

Also, we are always keen to get your feedback on the videos posted, and any ideas you have for future series. Either post the information on the You Tube site, or e-mail me at paul.hardiman@qualitypartner.co.uk

This article has been provided by one of my friends Morteza Kheirkhah, mo.kheirkhah@gmail.com who is a regular reader of my newsletter, and one who always asks me great challenging questions!

Actions to address risks and opportunities.

ISO9001 2015 requirement 6.1 defines requirements related to actions to address risk and opportunity.

However, to address this requirement effectively we also need to understand the interaction with other ISO9001: 2015 requirements, including:

- Internal and external issues (clause 4.1)
- Needs and expectations of interested parties (clause 4.2)
- Conformity of products and services and the ability to enhance customer satisfaction (clause 5.1.2)

A question that often arises whether risk and opportunities must be identified for each QMS process?

There are some documents published by ISO which send misleading signals on whether risk and opportunity identification is a requirement for all processes. Following statement which has been reproduced from ISO/TS 9002, a guideline for application of ISO 9001:2015, states:

f) the organization should ensure that any actions needed to address risks and opportunities associated with the processes are implemented (see ISO 9001:2015 6.1)

This seems to imply that risk and opportunities need to be identified for all QMS processes.

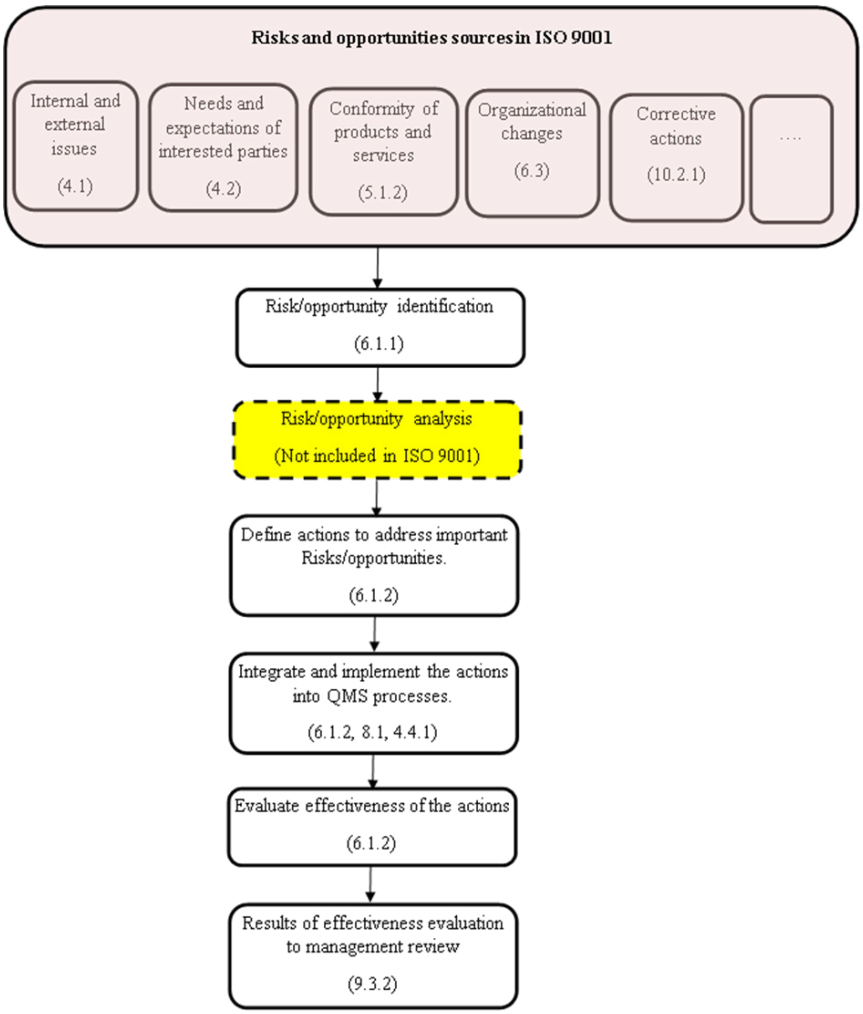
The application of the ISO 9001: 2015 requirements related to risks and opportunities can be as outlined below:

Based on clause 6.1.1, ISO 9001: 2015 requires an organization to determine its risks and opportunities after understanding its context (clause 4.1), its interested parties and their needs and expectations (clauses 4.2 and 5.1.2).

Then, as it has been mentioned in clause 6.1.2, the organization must plan actions to address the determined risks (e.g., reduction of product price as an action in response to the risk of emersion of new competitors). These actions shall be implemented through QMS processes based on clauses 6.1.2 b), 8.1 and 4.4.1 f),

Finally, the organization shall evaluate the effectiveness of actions taken (clause 6.1.2 b)) and take a summary of effectiveness evaluation to management review (clause 9.3.2 e)).

The diagram below shows the ISO 9001: 2015 requirements related to risks and opportunities and their sequence.



Summary

The effective understanding of the ISO9001: 2015 requirements related to risk and opportunity is always subject to debate and discussion. I think it is fair to say that many organizations pay lip service to the requirements, seeing it as a paperwork exercise, rather than integrating the concept of risk-based thinking into their business processes. Do you agree?

We will discuss “Opportunity” more in the next newsletter.

Ask the expert

Quality Partner's expert, Paul Hardiman

Question
When we undertake a GR&R study and the result is between 10% and 30% "may be acceptable", can you suggest the best was to document whether this is acceptable? Do we have to inform the customer?

Answer
Unless there is a customer specific requirement, there is no need to inform the customer of a GR&R value between 10% and 30%.

Also remember the acceptance criteria of GR&R is not defined by IATF 16949, it will either be specified in the customer specified reference manual, or against the criteria specified by the organization.

% EV	=	100 (EV/TV)
	=	100(0.002/0.048)
	=	4.05
% AV	=	100 (AV/TV)
	=	100(0.005/0.048)
	=	9.53
% GRR	=	100 (GRR/TV)
	=	100(0.005/0.048)
	=	10.35
Gage system may be acceptable		
% PV	=	100 (PV/TV)
	=	100(0.047/0.048)
	=	99.46
ndc	=	1.41(PV/GRR)
	=	1.41(0.047/0.005)
	=	13
Gage discrimination acceptable		

10-30% may be ok depending on application

In the case you quote, you need to document a risk analysis on how you have analysed the results (for example, where is most of the variation coming from, AV Appraiser variation or EV equipment variation), and is there any action that can be taken to reduce the % variation (for example re-training of the users, adding a fixture to the measuring system etc.). In the example above the biggest proportion of the variation is coming from the appraiser.

Also, in making the decision, you could consider the criticality of the characteristics to be measured (e.g., it may not be acceptable for a special characteristic measurement but could be used for non-critical characteristic). You could also consider reviewing the R&R% against to the characteristic tolerance, if the measurement system used only for accepting/reject parts rather than monitoring processes (e.g., stability, capability) as the GR&R% may be reduced to below 10% due to a large tolerance of the part.

If no improvement possible or viable, you need to justify how the risk of accepting nonconforming parts is controlled.

This could include process capability data to demonstrate that, although there is measurement system variation, it would have little impact on the ability of the measurement system to detect nonconforming product.

Question
We are in the process of implementing IATF 16949 and we have a question on what products to include in the scope of certification. We produce automotive components for over 40 customers, but only 5 customers are mandating we must be IATF certified. In addition, we have 20 non-automotive customers. Can we only include those products supplied to the 5 automotive customer requiring certification in the scope, and exclude the others?

Answer
In accordance with the Rules for achieving IATF recognition 5th edition, you must include all automotive products in the scope of IATF 16949 certification. The rules section 1 states:

"If a site supplies to a customer requiring third party certification to IATF 16949, then all automotive customers of the site shall be included in the scope of audit."

This is also mentioned in the definitions in section 10: Certificate scope.

"The scope statement displayed on the IATF 16949 certificate or the letter of conformance. This scope statement shall include only all design and manufacturing activities for automotive-related products and services. Manufacturing not meeting the applicability of IATF 16949 shall not be included in the scope of the IATF 16949 certificate."

So, in conclusion, the scope of the QMS related to IATF 16949 must cover all automotive customers and related products, none can be excluded. For the non-automotive product, while you can include them in your QMS, they cannot be included in the scope of your IATF certification.

Question:
We supply all the IATF OEM's. From the IATF member Customer Specific Requirements what are the top 5 requirements that most of them add additional requirements?

Answer:
I have produced a matrix showing the relationship between the IATF member CSR's and the IATF 16949 requirements. If anybody would like a copy, please e-mail me at paul.hardiman@qualitypartner.co.uk

Customer	4.1 Understanding the organization an	4.2 Understanding the needs and expec	4.3 Determining the scope of the qualit	4.3.1 Determining the scope of the QM	4.3.2 Customer specific requirements	4.4 Quality management system and its	4.4.1.1 Conformance of products and p	4.4.1.2 Product safety	5.1.1 Leadership and commitment gene	5.1.1.1 Corporate responsibility	5.1.1.2 Process effectiveness and effici	5.1.1.3 Process owners	5.1.2 Customer focus	5.2.1 Establishing the quality policy	5.2.2 Communicating the quality policy	5.3 Organizational roles, responsibiliti	5.3.1 Organizational roles, responsibili	5.3.2 Responsibility and authority for p	6.1 Actions to address risks and oppor	6.1.2.1 Risk analysis	6.1.2.2 Preventive action	6.1.2.3 Contingency plans	6.2 Quality objectives and planning to	6.2.2.1 Quality objectives and planning	6.3 Planning of changes	7.1.1 Resources-General	7.1.2 People	7.1.3 Infrastructure	7.1.3.1 Plant, facility and equipment pl	7.1.4 Environment for the operation of	7.1.4.1 Environment for operation of pl	7.1.5..1 Monitoring and measuring resc	7.1.5.1.1 Measurement system analysis	7.1.5.2 Measurement traceability	7.1.5.2.1 Calibration/verification record	7.1.5..3.1 Laboratory requirements-Inte	7.1.5.3.2 Laboratory requirements-Exte	7.1.6 Organizational knowledge
BMW								X																														
Daimler					X																																	
FCA USA								X									X																					
FCA EMEA/LATAM								X										X		X			X							X								
FORD										X			X				X						X							X			X				X	
GM																																						
PSA: Opel and Vauxhall									X																													
PSA: Peugeot and Citreon									X															X													X	
Renault		X						X																		X											
VW								X																														

The top 5 IATF requirements where the IATF OEM's identify additional requirements are:

- 8.6.2 Layout inspection and functional testing
- 9.1.2.1 Customer Satisfaction-Supplemental
- 9.2.2.4 Product audit
- 7.5.3.2.1 Record retention
- 4.4.1.2 Product safety

Surely IATF members should work to harmonise their CSR's, starting with these requirements, and integrate common requirements into the IATF standard?

On the IATF global oversight website it states:

"ISO/TS 16949 (1st edition) was originally created in 1999 by the International Automotive Task Force (IATF) with the aim of **harmonizing** *the different assessment and certification systems worldwide in the supply chain for the automotive sector."*

IATF 16949:2016 (1st edition) represents an innovative document, given the strong orientation to the customer, with inclusion of a number of consolidated previous customer specific requirements.

While I agree some progress was made in the publication of IATF 16949 in 2016, there is a long way to go, and it seems the last 5 years things have got worse, not better, with more and more CSR's being issued. This introduces waste into the supply chain and does not match the IATF 16949 goal which states the aim is "continual improvement, defect prevention and **reduction of variation and waste**".

Question
We just had our IATF 16949 recertification. One minor nonconformity was that we had a different part revision number in work instruction compared to other process control documents (e.g., work instruction revision AA and route card, PFMEA and Control plan revision AB.)

My question. Does the work instruction, located in the work area, have to have part revision number written on it or it would be enough if we have it printed on route card, control plan and PFMEA?

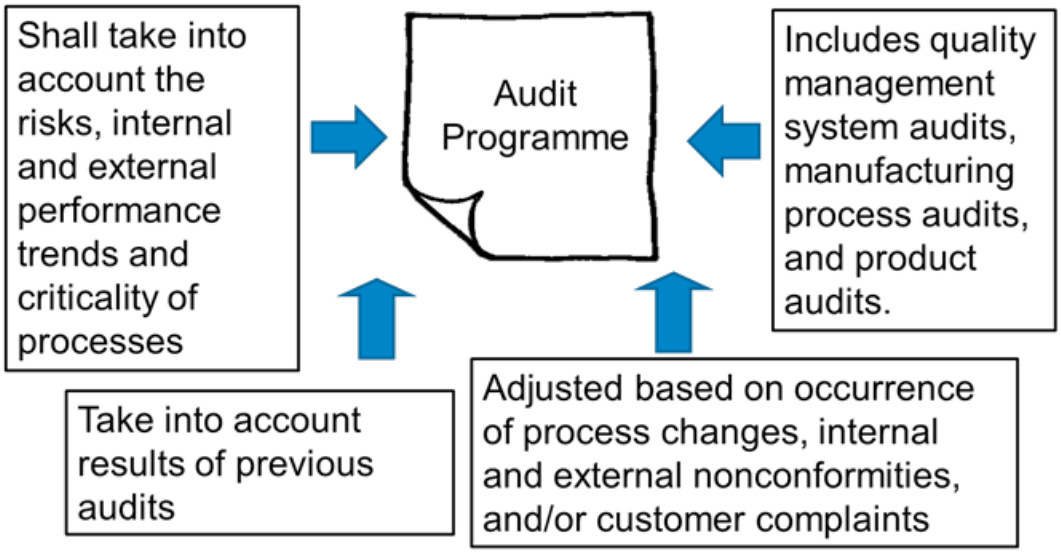
Answer
In my view if there is a robust process to review the implication of any drawing changes on the PFMEA, control plan and work instructions, the drawing revision level does not need to be on the WI. The work instruction would still need to be a controlled, authorised document. If this were questioned in an audit, you would explain the update process, and explain the operator does not need the drawing revision to undertake the job, they just need to follow the instructions that are defined. The route card would be a key document to ensure any part labels etc. are to the current revision level.

Question:
I kindly ask you to take into consideration the description of good practices for planning the internal system audit related to the below topic. During my audits, I found two general approaches related to the planning the internal system audit:

1. One single audit covering all QMS processes, conducted, for example, during a week, once a year. It is reported within a single audit report with details about each audited process.
2. Individual audits for each QMS process conducted one per month, for example.

It is reported within a single report for each process.

In this case I consider that it is hard to evaluate the interaction between processes and their functioning as an overall system.



Answer:
You raise a good question. I think the best could be a “hybrid” approach. I agree that by spreading audits over a three-year programme, the interactions between all the processes in the QMS may not be effectively audited.

However, whilst doing a full audit of all QMS processes in one big audit has the advantage that all the interactions between the processes can be audited, it does not demonstrate compliance with the IATF requirement 9.2.2.1 internal audit programme which states:

“The audit programme shall be prioritized based upon risk, internal and external performance trends, and criticality of the process(es).”

It would be difficult to justify all QMS processes having the same level of risk, criticality, and performance. By a “hybrid” approach, I mean that while you could do a high-level annual audit to verify the overall effectiveness of the QMS and its processes.

Additional audits of specific processes could be scheduled based on risk, criticality, and performance.
In addition to this, you would need to show effective planning of manufacturing process and product audits.