Quality Partner Newsletter

January 2020

Issue date: January 2020

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Welcome to the seventeenth 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:

- Effective use of error proofing
- Sanctioned interpretations
- Customer requirements verses customer specific requirements
- What is accreditation
- Questions and answers

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

I am sure 2020 will be challenging for many of us, but let's not focus on the happenings 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 2019 there were more than 74,000 IATF 16949 certified sites globally.

Of this, 72% of these certificates were issued to organizations in the Asia Pacific region, 15% in Europe, 8% 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 major nonconformities raised in 2019, over 2500 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)

For minor nonconformities, clause 8.5.1.1, control plan, was the number one, with over 9000 nonconformities raised, with 8.3.5.2, manufacturing process design output, as number two, with over 8000 nonconformities.

Error proofing

In the 2016 publication of IATF 16949, there was an increased emphasis on the use of error proofing as part of defect prevention, with error proofing being mentioned 12 times in the standard.

The IATF definition of error proofing is:

- “product and manufacturing process design and development to prevent manufacture of nonconforming products”

Additional guidance on error proofing can be found in CQI-18, where error proofing is defined as:

- Use of product characteristics, techniques, methods and/or devices during:
- Design phases or a product or process
- As part of an improvement or corrective action process

To ensure that:

- The product will function as desired and/or:
- The product design will allow the part to be assembled or manufactured only according to the design intent and/or
- Process errors will be detected at the source and defects will be prevented or, if discovered, will not be passed to the next process step. Therefore, a potential defect will not be sent to the customer.

This definition seems to intimate that mistake-proofing can be part of error proofing, where the manufacture of a defect may not be able to be prevented, but a system is in place to detect the defect in station, preventing further processing.

In IATF 16949, requirement 8.3.1.1, it 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”

This requirement focuses on ensuring an organization implements error proofing when introducing a new design (which could include a new product or new manufacturing process).

Integral to this should be identifying the potential use of error proofing when developing the DFMEA or PFMEA. Using the concepts in the AIAG-VDA FMEA handbook, this could be where high action priority (AP) rankings are identified. By implementing error proofing this could impact occurrence or detection.

IATF requirement 10.2.3 states:

“The organization shall have a documented process to determine the use of appropriate error-proofing methodologies. Details of the method used shall be documented in the process risk analysis (such as PFMEA) and test frequencies shall be documented in the control plan.”

In DFMEA, occurrence can be scored as 1 when “Failure eliminated through prevention control and failure cause is not possible by design” and detection as 1 when “Prior testing confirmed that failure mode or cause cannot occur, or detection methods proven to always detect the failure mode or failure cause.”

An example is the design of a SIM card for a mobile phone, which, due to the product design, cannot be assembled the wrong way in the device.

And in PFMEA, occurrence can be scored as 1 when “Prevention controls are extremely effective in preventing failure cause from occurring due to design (e.g. part geometry) or process (e.g. fixture or tooling design). Intent of prevention controls – Failure Mode cannot be physically produced due to the Failure Cause”, and detection as 1 when “Failure mode cannot be physically produced as designed or processed, or detection methods proven to always detect the failure mode or failure cause.”

Obviously there may be technical or economic constraints when deciding on the use of error-proofing, but decisions should be made using risk-based thinking. Step 7of the AIAG-VDA handbook approach to developing FMEA gives the FMEA team the opportunity to summarise the results of the FMEA activity to Management, including a list of the high action priority risks identified and recommended improvement actions.

Now let’s look at error proofing devices:

The definition in CQI-18 is:

- “Use of mechanical, electronic or software devices used to prevent or detect some critical requirement for the product or process. Solutions can be technical (closed loop) or behavioural (human reaction)”

The term Poke-Yoke is often used in the automotive industry; the definition in CQI-18 is:

- “Generally low cost, devices used in the Jidoka (prevention) system that will stop process in order to prevent the production of potentially defective product. This term is sometimes used in industry to signify all types of error proofing devices.”

Once error proofing is implemented IATF 16949 10.2.4 requires:

“The process shall include the testing of error-proofing devices for failure or simulated failure. Records shall be maintained. Challenge parts, when used, shall be identified, controlled, verified, and calibrated where feasible. Error-proofing device failures shall have a reaction plan.”

The IATF definition of challenge part is:

- “part(s) of known specification, calibrated and traceable to standards, with expected results (pass or fail) that are used to validate the functionality of an error-proofing device or check fixtures (e.g., go / no-go gauging)”

The frequency of testing will depend on risk, but the key thing is this should be documented in the control plan, and records maintained to demonstrate the frequency has been complied with. In the event of an issue being identified with the error proofing device, operators need to be trained in how to react (as defined in the reaction plan in the control plan).

So, in summary, error proofing methodology should be built into the documented product and process design process.

For existing processes, error proofing may be implemented as part of ongoing continual improvement or based on internal or external issues with the product or process (reactive use).

The key thing is, while it is great to have error proofing, it is only effective if the functioning of the relevant device/instrument is verified as being effective, by competent operators, on an ongoing basis.

What is an IATF 16949 Sanctioned Interpretation and where to find them

So, what is a sanctioned interpretation?

The IATF definition is:

“A Sanctioned Interpretation (SI) changes the interpretation of an IATF 16949 requirement which itself then becomes the basis for a nonconformity”
Since the publication of IATF 16949 in September 2016, interested parties to the scheme, including auditors, clients and consultants, have sometimes fed back to IATF Oversights that certain requirements in the IATF standard for achieving IATF recognition are not clear.

Typically, IATF review and reissue the standard when there is a re-publication of ISO9001, normally every 5-10 years. That would be a long time to wait to introduce a change!

Once a change through a SI has been approved by IATF, the change is published on the IATF Global oversight website, in the IATF approved global languages:

https://www.iatfglobaloversight.org/iatf-169492016/iatf-169492016-sis/

Each issued SI is issued in a standard format:

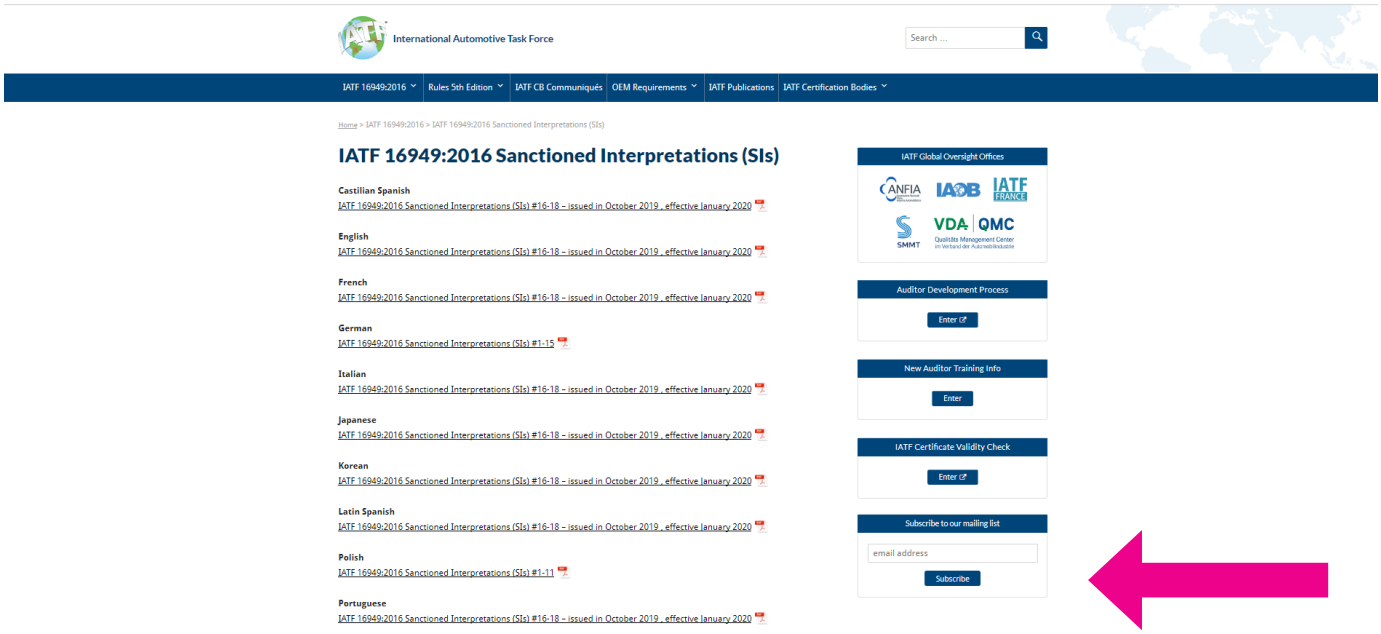
NUMBER	IATF 16949 REFERENCE	SANCTIONED INTERPRETATION
3	**6.1.2.3 Contingency plans**	The organization shall: a) – b) (…) c) prepare contingency plans for continuity of supply in the event of any of the following: key equipment failures (also see Section 8.5.6.1.1); interruption from externally provided products, processes, and services; recurring natural disasters; fire; utility interruptions; **cyber-attacks on information technology systems;** labour shortages; or infrastructure disruptions; ***Rationale for change:*** *Organizations need to address the possibility of a cyber-attack that could disable the organization's manufacturing and logistics operations, including ransom-ware. Organizations need to ensure they are prepared in case of a cyber-attack.*

The SI is given a number, the relevant IATF 16949 clause is cited, and the change to the requirement is indicated in blue. So, in the example shown, the requirement for a contingency plan to cover cyber-attacks on information technology requirements is added.

Each SI includes a rationale for why the change was made.

Typically, sanctioned interpretations are issued by IATF 1 to 3 times per year.

By adding your e-mail address in the subscribe box shown, you will automatically be updated with any new sanctioned interpretations.



The subscription screen can be seen at:

https://www.iatfglobaloversight.org/iatf-169492016/iatf-169492016-sis/

So, let's summarise:

Any IATF certified organization needs to review any new sanctioned interpretations and make the necessary changes to their quality management system, in accordance with the defined timing specified when the relevant SIs are released.

Auditors (Internal, second and third party) also need to be aware of the SIs and the changes will affect the audit criteria.

Customer requirement verses Customer specific requirement

A question I often get asked is the difference between customer requirement and customer specific requirement.

The IATF definition of customer requirement is:

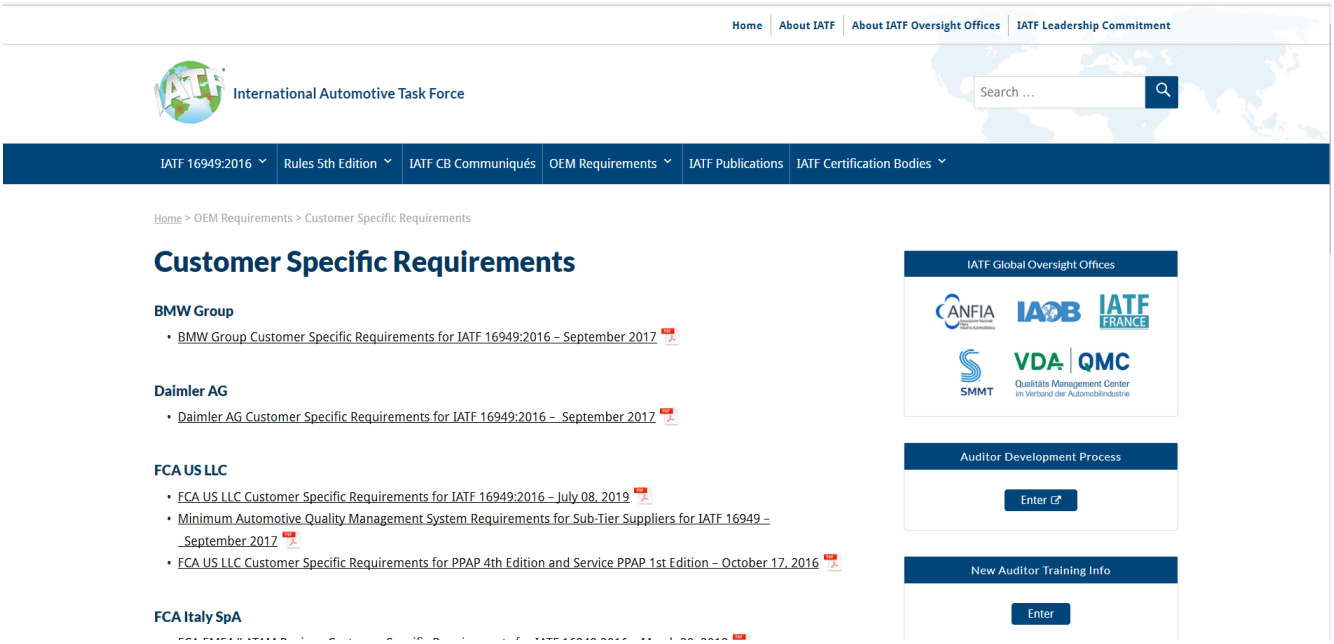
- "All requirements specified by the customer, for example technical, commercial, product and manufacturing process-related requirements, general terms and conditions, and customer-specific requirements."

So, using this definition, customer specific requirements are part of customer requirements.
The IATF definition of customer specific requirements is:

- "interpretations of or supplemental requirements linked to a specific clause(s) of this Automotive QMS Standard"

Whereas all IATF members, and many other vehicle manufacturers mandate IATF 16949 certification of their suppliers, they also add additional quality management system requirements through customer specific requirements.

IATF members publish their customer specific requirements on the IATF global oversight website.



https://www.iatfglobaloversight.org/oem-requirements/customer-specific-requirements/

It is important that, as part of feasibility review, organizations review any customer specific requirements, especially for any new customer.

Complying with customer specific requirements can have significant cost implications.

Some examples:

- Ford customer specific requirements for layout inspection (8.6.2) states:

“The organization shall perform annually a layout inspection (to all dimensional requirements) on at least 5 parts.”

This can take a significant amount of time to collect and record this data, especially for complex parts.

- GM customer specific requirements for manufacturing process audit (9.2.2.3) states:

“The organization shall incorporate an internal layered process audit process to assess compliance to standardized processes, to identify opportunities for continuous improvement, and to provide coaching opportunities. The layered process audit is led by Management who are competent to conduct the audits.”

Again, to set up and maintain a layered process audit system can take significant time and effort, as well as investment in the relevant training for management and other supervisory personnel who will be involved in the audit process.

- VW Group customer specific requirements for second party audits (7.2.4 and 8.4.2.4.1) states:

“The process-audits in the supply chain must be conducted in accordance to Formel-Q-Capability by certified VDA 6.3 auditors (see auditor qualification in Section 3.2 of FQF 8.0).”

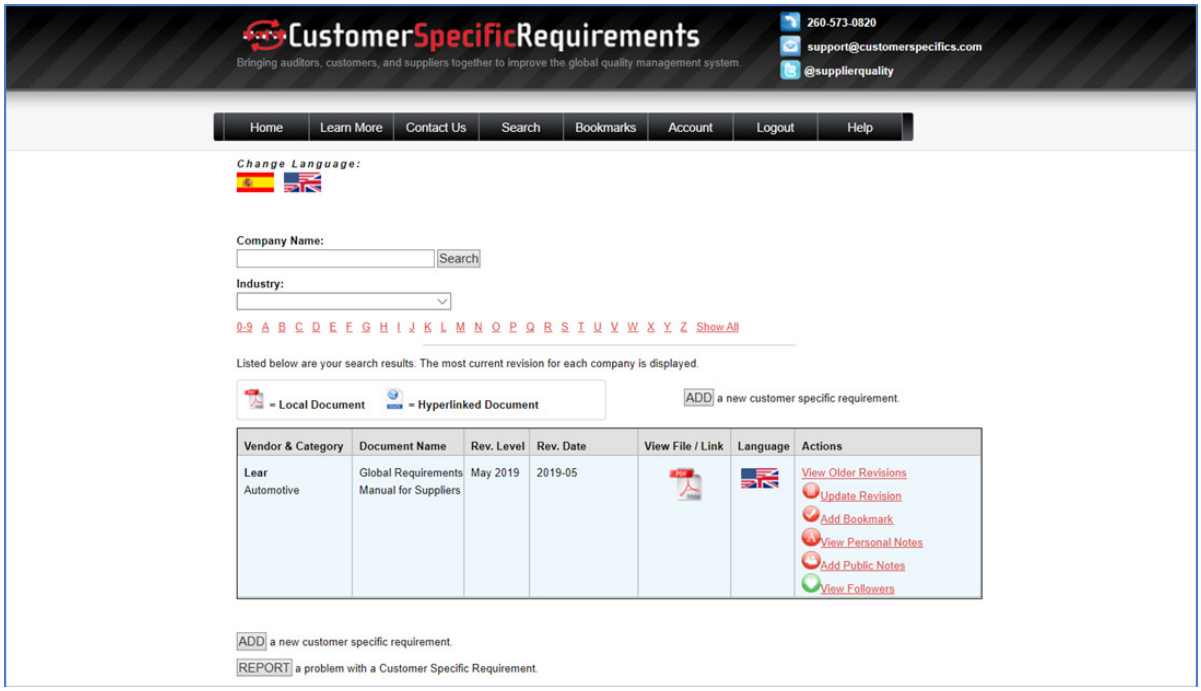
To become a VDA 6.3 certified auditor, candidates must meet very strict entry requirements, attend four days of sanctioned training followed by one day of exams (written and interview). Again, this can have significant cost implications.

Customer specific requirements do not just apply to IATF OEM members.

Any organization in the automotive supply chain can add customer specific requirements for suppliers.

The issue is these can sometimes be difficult to find!

One potential source is **www.customerspecifics.com**



The site, which is free to access (once you have set up a username and password), has a search facility by industry (including automotive) and by a specific company name.

The example in the screen shot is for Lear Automotive, who according to the site, were last updated in May 2019. While there is no guarantee that this is the latest version, at least it is a starting point, especially if undertaking a feasibility review for a new customer.

In reviewing the Lear requirements this raises an interesting question. The requirements in the document are not written to match the clauses of IATF 16949.

An example:

16.8 Production Part Approval

“16.8.1 Suppliers are not authorized to begin production or ship material to Lear prior to obtaining approval from the Lear receiving facility per the requirements of the AIAG Production Part Approval Process (PPAP) Manual, according to the latest revision level. Any deviation to this requirement must be approved in advance and agreed by Lear in writing.”

In Lear requirements this is 16.8, but in IATF 16949 the relevant clause is 8.3.4.4 Product approval process.

So, is this a customer specific requirement?

In my view it is, but some would argue it is not as it is not specifically “linked”, as specified in the definition:

- “interpretations of or supplemental requirements linked to a specific clause(s) of this Automotive QMS Standard”

Whether or not this is a customer specific requirement, the requirement of the customer (in this case Lear) still must be met, within the framework of the Quality Management System.

In summary, many organizations do not pay enough attention to customer specific requirements in their contract review process, which can end up causing customer dissatisfaction, and possible significant unbudgeted internal costs.

What is accreditation and what to look for in ISO9001 supplier certificates?

One of the much-discussed requirements in IATF 16949 is the certification requirements for suppliers to an IATF 16949 certified organization.

Let’s start with basics: what is the meaning of accreditation?

A general description is

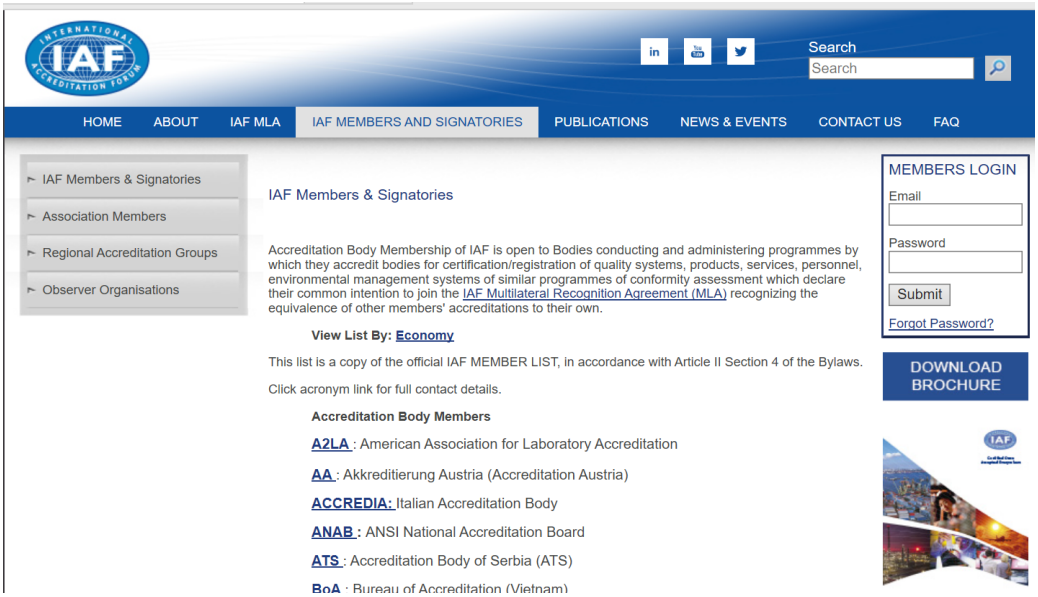
- “The action or process of officially recognizing someone as having a particular status or being qualified to perform a particular activity.”

So, what does this mean in the context of IATF 16949?

IATF requirement 8.4.2.3 Supplier quality management system development states:

a) certification to ISO 9001 through third-party audits; unless otherwise specified by the customer, suppliers to the organization shall demonstrate conformity to ISO 9001 by maintaining a third-party certification issued by a certification body bearing the accreditation mark of a recognized IAF MLA (International Accreditation Forum Multilateral Recognition Arrangement) member and where the accreditation body’s main scope includes management system certification to ISO/IEC 17021;

Details of IAF MLA members can be found at **https://www.iaf.nu/articles/Accreditation_Body_Members_by_Name/52**



When an organization reviews a supplier certificate, they should look for evidence that the certificate has details of which certification body issued the certificate, what is the scope of certification (this should match the product or service you are purchasing), what is the expiry date and what accreditation mark is on the certificate.

An example is shown below:

EAGLE Registrations Inc.
SERVICE • INTEGRITY • VALUE

ANAB ACCREDITED
MANAGEMENT SYSTEMS CERTIFICATION BODY

Certificate No. 5350 (Recertified April 13, 2018-5 Copies)
April 17, 2018 through April 16, 2021

Certificate of Registration

This is to certify that the Quality Management System of

The Gund Company, Inc.

2121 Walton Road St. Louis, Missouri 63114 USA
809 Philip Drive, Waukesha, Wisconsin 53186 USA
10501-3 West 133rd Avenue, Cedar Lake, Indiana 46303 USA
930 Gartshore Street, Fergus, Ontario N1M 2W7 CA
Carr. Est. 431 Km 2+200 Lote 55, Parque Tecnológico Inovación,
El Marques, Queretaro, MX 76246

Has been assessed by EAGLE Registrations Inc. and conforms to the following standard:

ISO 9001:2015

Scope of Registration

The Manufacture, Fabrication and Distribution of Engineered Material Solutions Including Industrial Plastics and Electrical Insulating Materials and Components

Director of Certification

40 N. Main Street, Suite 1880 | Dayton, OH 45423 | USA | 937.293.2000 or 800.795.3641
www.eaglecertificationgroup.com

In this certificate example, the certification body is accredited by ANAB, and ANAB can be found on the IAF website as an IAF MLA (International Accreditation Forum Multilateral Recognition Arrangement) member.

You will find some certificates where the IAF logo is also included on the certificate:
So, why did IATF introduce this requirement?

CERTIFICATE

This is to certify that

VLSI Standards, Inc.
5 Technology Drive
Mail Stop 7-2086
Milpitas, CA 95035
United States of America

has implemented and maintains a **Quality Management System**.

Scope:
The design and manufacture of calibration standards and references, related services, and particle deposition systems.

Through an audit, documented in a report, it was verified that the management system fulfills the requirements of the following standard:

ISO 9001 : 2015

Certificate registration no.	10000561 QM15
Date of original certification	2001-02-23
Date of certification	2017-10-09
Valid until	2020-10-08

ANAB ACCREDITED
MANAGEMENT SYSTEMS CERTIFICATION BODY
IAF

DQS Inc.

Brad McGuire
Managing Director

Accredited Body: DQS Inc., 1130 West Lake Cook Road, Suite 340, Buffalo Grove, IL 60089 USA

In a world of de-regulation, some certification bodies issue certificates without any nationally recognised accreditation, and as such, this can give doubt on the integrity of the certification. For example, if no accreditation (checking), who checks the certification body has an effective process to allocate competent auditors etc?

At this time there is no available listing of ISO9001 IAF compliant certificates, although I believe this is being worked on - watch this space!

Ask the expert

Question:

Quality Partner's expert, Paul Hardiman

In the context of IATF 16949, what is a manufacturing process?

Answer:

First we should look at the definition of manufacturing specified in IATF 16949:

Manufacturing

process of making or fabricating

- production materials;
- production parts or service parts;
- assemblies; or
- heat treating, welding, painting, plating, or other finishing service

Next let's look at the definition of a process:

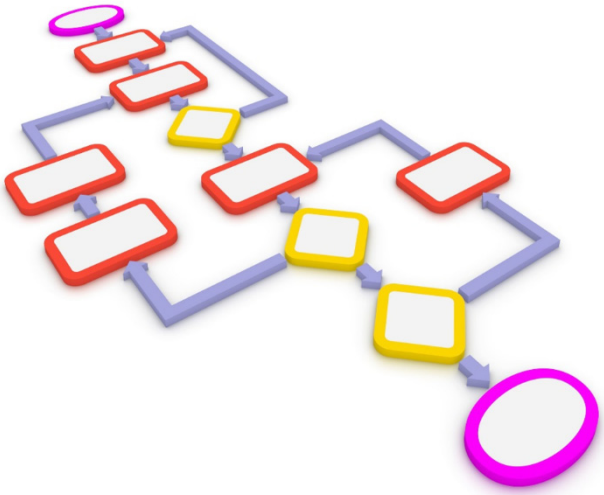
- "a set of interrelated or interacting activities that use inputs to deliver an intended result"

So, an overall manufacturing process is made up of a number of value-added activities to transition an input (which could be raw materials, components etc.) to an output (for example a product) that meets an automotive customer specified requirement.

In clause 8.3.5.2 of IATF 16949 it requires that an organization defines a

e) manufacturing process flow charts/layout

The format of the flowchart/layout is not specified in IATF 16949, but the customer could specify this in customer specific requirements. The flow chart should cover from materials receipt to product dispatch.



It is important for the person planning the internal audit programme to understand the manufacturing processes.

The IATF requirement 9.2.2.3 states:

“The organization shall audit all manufacturing processes over each three-year calendar period to determine their effectiveness and efficiency using customer-specific required approaches for process audits. Where not defined by the customer, the organization shall determine the approach to be used.” Also, for internal auditors 7.2.3 states

“At a minimum, manufacturing process auditors shall demonstrate technical understanding of the relevant manufacturing process(es) to be audited, including process risk analysis (such as PFMEA) and control plan.”

Question:

A company manufactures only one production part number for a vehicle manufacturer. The vehicle manufacturer is responsible for the product design. In this factory there is only one machine to produce this part. However, they also manufacture parts for 2nd and 3rd tier automotive customers where they design the parts and tools. They intend to be certified to IATF 16949.

What should the scope of certification cover?

Answer:

The key is all AUTOMOTIVE products must be included in the scope, at whatever level in the supply chain. So, in this case if the parts they design are going to an automotive customer, the scope must include design, so the scope must be the design and manufacture of.....

Remember product design is the designing of the product, not the tool; the tool design is covered by manufacturing process design.

Question:

It was identified during an internal audit on Records Management that QA were not complying with IATF 16949:2016 7.5.3.2.1 'Record retention' requirement as our calibration records are only retained for 3 years. The process owner has challenged the validity of the finding. Can you clarify what the retention time should be?

Answer:

When considering retention of records, you must take into account customer specific requirements (if any), legal and your own organization requirements in defining retention times.

IATF 16949 clause 7.5.3.2.1 states:

"Production part approvals, tooling records (including maintenance and ownership), product and process design records, purchase orders (if applicable), or contracts and amendments shall be retained for the length of time that the product is active for production and service requirements, plus one calendar year, unless otherwise specified by the customer or regulatory agency."

This does not specifically mention calibration records.

So, if there are no customer, legal or organization requirements 3 years is enough to meet the standard. However, if there was a measurement issue and it resulted in a liability claim, you may want to consider keeping the records of calibration longer.

Question:

I am wondering if you could help me in clarifying the conditions for a special status and the initiation of the decertification process.

Example 1:
The customer receives a notification from GM informing them they have been placed on New Business Hold)

Should the organization inform the certification body in 10 days in this case?

Example 2:

The customer receives a Level 0 escalation letter from VW (Level 0 = The supplier has problems, the lowest official escalation level at VW group).

Should the customer inform the certification body in 10 days in this case?

Are all escalation levels considered a special status, or only the highest ones (e.g.: new business on hold).

What exactly is your understanding for a special status?

Answer:

A very interesting question, that, if I am honest, is not clear in the IATF scheme.

Firstly, the definition of special status is

- “Notification of a customer-identified classification assigned to an organization where one or more customer requirements are not being satisfied due to a **significant** quality or delivery issue.”

In the IATF rules, 5th edition, it states:

8.1 Initiation of the decertification process

b) the client advises the certification body of a special status condition from an IATF OEM. Notification from the client to the certification body shall occur within ten (10) calendar days from receipt of the special status condition or otherwise specified by the customer;

In addition to this requirement, you should consult customer specific requirements.

In the Example 1 GM customer specific requirements state:

“The organization shall notify their Certification Body within **5** business days of receiving notice of special status condition of GM New Business Hold – Quality. The Certification Body shall take the decision to place the organization on immediate suspension* upon receiving notice of GM New Business Hold – Quality (NBH).”
In this case, the customer specific requirements add an interpretation to the IATF rules and the organization must inform the certification body within 5 business days and not 10 calendar days as defined in the rules. In example 2 this is less clear, as there is no specific requirement related to this in the VW IATF 16949 customer specific requirements.

In Formel Q, which is referenced in the CSRs, it states:

“Should these measures and improvement programmes, required by the VW group, not be adequately implemented in time and this defect occur repeatably, the existing VW group escalation principle will apply.”

So, although in the example VW have notified the supplier of issues, in my view this would not be deemed as a customer notification of **significant** quality or delivery issues.

However, in any audit, the auditor should follow up on how the issues with VW had been identified and escalated to Management review. If not, the auditor can raise a major nonconformity, which would trigger the decertification and suspension process.

Question:

Recently, we internally have been confused with the definition about Product and Process characteristics within our internal audit team.

Product characteristics only means finished product; the product characteristics of process within the process flow chart are Process characteristics. Is it correct?

Do you have official definition or explanation about product and process characteristics?

Answer:

The IATF definition related to special characteristics is:

- “classification of a product characteristic or manufacturing process parameter that can affect safety or compliance with regulations, fit, function, performance, requirements, or subsequent processing of product”

I have always interpreted this that a product characteristic is something related to a feature of the product (this could be of the final product specified by the customer, or a characteristic of the product defined internally as critical to producing the specifications of the customer).

A process characteristic is not directly related to the product but is a characteristic related to the manufacturing process (for example temperature, pressure, speed etc.) that is critical to control to meet the product characteristics.