



IATF - International Automotive Task Force

IATF 16949:2016 – Frequently Asked Question (FAQ)

IATF 16949:2016 1st Edition was published in October 2016. In response to questions from the IATF recognized certification bodies and stakeholders, the following questions and answers were reviewed by the IATF. Unless otherwise indicated, Frequently Asked Questions are applicable upon publication.

An FAQ is an explanation of an existing requirement within IATF 16949:2016.

FAQ 1 - 11 issued in month of **October 2017**.

FAQ 12-20 issued in month of **April 2018**.



NUMBER	IATF 16949 REFERENCE	QUESTIONS AND ANSWERS
1	<p style="text-align: center;">Foreword – Automotive QMS Standard</p>	<p><u>QUESTION:</u> Why are there two manuals (IATF 16949:2016 and ISO 9001:2015)? Two manuals instead of one manual makes it much more difficult to read and understand the requirements.</p> <p><u>ANSWER:</u> The IATF and ISO were not able to reach a licensing agreement to publish IATF 16949 in an integrated document. In order to not further delay the launch of the new IATF 16949 standard, the IATF decided to publish in a two-manual format.</p> <p>Prior to release, the IATF did confirm with international accreditation organizations that other industry sectors use a two-manual format model to define their sector specific requirements, and auditing with the two-manual model, while not optimal, is effective.</p> <p>The IATF maintains strong cooperation with ISO by continuing the liaison committee status ensuring continued alignment with ISO 9001.</p>
2	<p style="text-align: center;">Foreword – Automotive QMS Standard</p>	<p><u>QUESTION:</u> Why are the two manuals (IATF 16949:2016 and ISO 9001:2015) so much more expensive than the ISO/TS 16949 version?</p> <p><u>ANSWER:</u> Without the co-licensing agreement between ISO and the IATF for the integrated format of IATF 16949, the IATF was not able to negotiate a discount for the ISO 9001:2015 standard.</p> <p>The IATF kept the price of the automotive specific content consistent with prior pricing. Essentially, the difference is the full list price to ISO for their publication of ISO 9001.</p>



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3	Foreword – Automotive QMS Standard	<p><u>QUESTION:</u> What should be done if translation errors are discovered in the IATF 16949 standard?</p> <p><u>ANSWER:</u> The IATF uses a defined process for managing translations of the standard, including “cross-checking” the translation to ensure accuracy. If an organization, or a certification body, identifies what is believed to be a translation error, they should contact either the IATF member industry association or the Oversight Office supporting their certification body.</p>
4	4.4.1.2 Product safety	<p><u>QUESTION:</u> What is the scope of this clause? Many organizations focus on regulatory/statutory requirements of the product and do not believe they have product safety related manufacturing product or processes.</p> <p><u>ANSWER:</u> This clause focuses on product and manufacturing process characteristics that affect the safety performance of the final assembly. These characteristics may not be directly addressed in regulatory/statutory requirements, but may be defined by the customer.</p>



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5	<p style="text-align: center;">5.3.1 Organizational roles, responsibilities, and authorities — supplemental</p>	<p><u>QUESTION:</u> Is the intent that responsibilities be assigned to the function (e.g. Quality), a specific title (e.g. Quality Director) or a named individual (e.g. Bob Smith)?</p> <p><u>ANSWER:</u> Responsibilities are assigned to the role/position (i.e. specific title, Quality Director) within the organization. Although individuals may have those responsibilities in their roles, the responsibilities remain with the role (e.g. Quality Director). Therefore, top management will assign the responsibility and authority to the role, not to the individuals by name.</p>
6	<p style="text-align: center;">7.1.5.1.1 Measurement system analysis</p>	<p><u>QUESTION:</u> Are MSA studies required for each instrument or device?</p> <p><u>ANSWER:</u> 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.</p>

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7	7.1.5.3.2 External laboratory	<p><u>QUESTION 1:</u> When can the equipment manufacturer be used to calibrate inspection and test equipment? 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)?</p> <p><u>ANSWER 1:</u> The inspection or test equipment manufacturer developed the methodology to maintain and adjust the equipment to meet calibration requirements as part of the design and manufacture of the inspection or test equipment. Therefore, the original equipment manufacturer of the inspection and test equipment is qualified to calibrate the equipment they designed and manufactured.</p> <p>The organization shall obtain customer approval before using any original equipment manufacturer for calibration services.</p> <p><u>QUESTION 2:</u> If the organization has inspection, measuring and test equipment in the final assembly and test area, is it considered an internal laboratory?</p> <p><u>ANSWER 2:</u> No. In-line measurement and test equipment used in any part of the manufacturing process or assembly process is not considered to be an internal laboratory.</p>



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8	7.5.1.1 Quality management system documentation	<p><u>QUESTION:</u></p> <p>Does the document (which could be a table, list or a matrix) have to include non-IATF OEMs and Tier 1s? Do all customer requirements beyond CSR's need to be included in the document?</p> <p><u>ANSWER:</u></p> <p>The organization is responsible for evaluating customer requirements, including customer-specific requirements, and including them in the scope of the organization's quality management system, per IATF 16949, Section 4.3.2.</p> <p>A document (which could be a table, a list or a matrix) is required as part of the quality manual, per IATF 16949, Section 7.5.1.1 d). The document shall include <u>all</u> direct customers of the certified organization, which may include IATF OEMs, non-IATF OEMs, and other automotive customers (i.e. tier-1, tier-2, etc.).</p> <p style="padding-left: 40px;">For example, a tier-2 organization must consider the customer requirements, including customer-specific requirements, of all its customers. The Tier-2 organization does not need to consider the customer requirements of the automotive OEM if the OEM is not its direct customer.</p> <p>It is important to note that the non-IATF OEM customers and other automotive customers may have customer requirements in an internal document that is shared with their suppliers (e.g. such as a supplier quality manual) or in a specific document available to the public (e.g. internet).</p> <p>Identifying customer-specific requirements may be difficult if the non-IATF OEM or other</p>

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<p style="text-align: center;">8 (cont.)</p>		<p>automotive customers do not clearly link to IATF 16949 clauses in their customer requirement documents. A way to identify if any customer-specific requirements exist is to compare sections of the IATF 16949 standard where the term « if required by the customer » exists and verify if the existing customer requirement document lists any specific requirements that are related to a requirement in the IATF 16949 standard. If yes, that customer and their requirements should be added to the document (which could be a table, a list or a matrix) in the quality manual.</p> <p>Organizations are <u>not</u> expected to take the customer’s requirements, including customer-specific requirements, and convert them into a CSR format that aligns with the IATF 16949 clauses similar to what has been published by the IATF OEMs.</p>
<p style="text-align: center;">9</p>	<p style="text-align: center;">8.4.2.2 Statutory and regulatory requirements</p> <p style="text-align: center;">and</p> <p style="text-align: center;">8.6.5 Statutory and regulatory conformity</p>	<p><u>QUESTION 1:</u> What is the perspective (on statutory and regulatory conformity)? What is considered sufficient evidence of conformity to applicable statutory and regulatory requirements (8.6.5)?</p> <p><u>ANSWER 1:</u> As defined in 8.3.3.1 g) and 8.3.4.2, the organization is required to have an approach to research, identify, obtain copies of, review, understand, and assure compliance with the statutory and regulatory requirements for the product they are manufacturing in the country where they are manufacturing products and the destination country where they are shipping the products to.</p> <p>The intent of 8.4.2.2 is that the organization designs into their product development methodology/business process(es) and their supplier management methodologies/business process(es), one or more approaches for obtaining confirmation and evidence from their suppliers that the products and services being provided by the supplier comply with the statutory and</p>



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<p style="text-align: center;">9 (cont.)</p>	<p style="text-align: center;">8.4.2.2 Statutory and regulatory requirements (cont.)</p> <p style="text-align: center;">and</p> <p style="text-align: center;">8.6.5 Statutory and regulatory conformity (cont.)</p>	<p>regulatory requirements of the country where the supplier is manufacturing them, the country where the organization is using them, and the country where the organization ships their product to, if provided by the customer.</p> <p>The intent of 8.6.5 is to require the organization to check the records of conformance/compliance received from the supplier to assure that the lot code, batch number, or comparable traceability information for the product are covered by the evidence provided by the supplier. This could be done upon receipt from the supplier, or while the product is in inventory, but must be done prior to release of the product into the organization’s production flow.</p> <p><u>QUESTION 2:</u> Did the intent of clause 8.4.2.2 change from ISO/TS 16949 to IATF 16949?</p> <p><u>ANSWER 2:</u> The intent of the clause did not change. The ISO/TS 16949 requirement was “All purchased product shall conform to applicable statutory and regulatory requirements”. In this “passive voice” wording, the IATF decided their expectations were not clear. The new requirement is more explicit about what is to be done, when it is to be done, and what evidence is required to support compliance.</p>



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<p style="text-align: center;">9 (cont.)</p>	<p style="text-align: center;">8.4.2.2 Statutory and regulatory requirements (cont.)</p> <p style="text-align: center;">and</p> <p style="text-align: center;">8.6.5 Statutory and regulatory conformity (cont.)</p>	<p><u>QUESTION 3:</u> How do you manage and maintain current knowledge of statutory and regulatory requirements for international suppliers?</p> <p><u>ANSWER 3:</u> IATF 16949, section 8.6.5, does not require the organization to be aware of or keep a list of all the international statutory and regulatory requirements for the externally provided processes, products or services they purchase. The organization is required to review the results of, audit, or otherwise periodically verify, that the supplier’s process is robust and assures compliance with the latest applicable statutory, regulatory and other requirements in the countries where they are manufactured and in the customer-identified countries of designation.</p> <p><u>QUESTION 4:</u> How can our system comprehend the statutory and regulatory requirements if they are not communicated to the organization by the customer?</p> <p><u>ANSWER 4:</u> The clause as worded expects the customer to provide information to the organization of where the products are going to be shipped. Changes to the applicable statutory and regulatory requirements due to changes in these destinations are only a requirement to the organization “if provided” by the customer.</p>



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<p>10</p>	<p>8.4.2.3.1 Automotive product-related software or automotive products with embedded software</p>	<p><u>QUESTION 1:</u> What is the definition of “embedded software”? When is it applied?</p> <p><u>ANSWER 1:</u> The formal definition of embedded software will be released as a future IATF 16949 sanctioned interpretation (SI).</p> <p>Embedded software is specialized for the particular hardware that it runs on and typically has time and memory constraints.</p> <p>The software development capability self-assessment is conducted where the organization has the responsibility to design and develop software to meet a customer’s specification or requirements.</p> <p>If the organization subcontracts the software development process for use in a part(s) that it manufactures, then the organization needs to ensure that the supplier who is responsible for designing and developing the software has implemented an automotive software development capability self-assessment.</p> <p><u>QUESTION 2:</u> If the organization does not develop the embedded software, how does the organization have expertise to evaluate the software provided by a supplier?</p> <p><u>ANSWER 2:</u> If the organization is not responsible for the design and development of embedded software, then the organization needs to ensure the supplier who is responsible has validated the functionality of the software and that it meets the customer’s requirements.</p>



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11	8.7.1.7 Nonconforming product disposition	<p><u>QUESTION 1:</u> What is the intent and requirements for “rendering unusable” prior to disposal? When and where does the “rendering unusable” of product need to occur?</p> <p><u>ANSWER 1:</u> The intent is to ensure that the product cannot find its way into the unofficial aftermarket, onto a road vehicle, or accidentally shipped to the customer. The process of rendering nonconforming product unusable, does not have to occur in the manufacturing area as long as the product is rendered unusable prior to final disposal.</p> <p><u>QUESTION 2:</u> How does the organization control this?</p> <p><u>ANSWER 2:</u> The organization is responsible to develop and implement a nonconforming product disposition process and verify its effectiveness.</p>

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<p>11 (cont.)</p>	<p>8.7.1.7 Nonconforming product disposition</p>	<p><u>QUESTION 3:</u> Can the organization use a service provider to render the product unusable?</p> <p><u>ANSWER 3:</u> Yes, it is acceptable to contract the process of rendering the product unusable to a service provider. If a service provider is used, the organization needs to approve, and periodically verify, how the supplier is rendering the product unusable.</p> <p><u>QUESTION 4:</u> Does nonconforming product disposition apply only to final product or does it also apply to component/interim sub-assembly?</p> <p><u>ANSWER 4:</u> This requirement applies to the product that has gone through the part approval process and that the organization is shipping to the customer.</p> <p><u>QUESTION 5:</u> For rendering unusable, how much damage needs to be done to the nonconforming product?</p> <p><u>ANSWER 5:</u> The nonconforming product needs to be rendered unusable and unrepairable. There is no requirement for crushing or pulverizing the product into many pieces.</p>

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12	Throughout the IATF 16949 Standard	<p><u>QUESTION:</u> Is it acceptable to document multiple processes in one “documented process”? Or do they each have to be individual documented processes?</p> <p><u>ANSWER:</u> Yes, it is acceptable for an organization to group multiple documented processes into one (or more) processes. Each documented process does not have to be a standalone process. Organizations should document their processes as it makes sense to their individual business and organizational needs.</p>
13	4.4.1.2 Product safety	<p><u>QUESTION:</u> What are the requirements regarding the levels of training and the particular criteria required to be identified in relation to product safety (4.4.1.2)?</p> <p><u>ANSWER:</u> As with all personnel competency requirements, the people assigned to specific tasks need to be competent for that task. That competence needs to include the rules and regulations associated with the task.</p> <p>The safety requirements in 4.4.1.2 are very specific as to what is required. The sections include, referring to IATF 16949 section 4.4.1.2:</p> <p>a) suppliers are expected to be aware of all statutory and regulatory requirements associated with the markets for use of the parts, as identified by the customer. The supplier needs to know where to research the regulations for all affected countries or regions.</p>



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		<p>b) Customer specifics will identify any customer notification requirements; therefore, knowledge in customer specifics (which may be taught by an internal designated subject matter expert).</p> <p>c) The special approvals for design FMEAs would be identified in customer specifics, see item b) above.</p> <p>d) and e) The identification of product safety related characteristics and their controls would be defined by the customer in its definition of special characteristics and required controls. The personnel developing PFMEAs and Control Plans would need to be knowledgeable in those areas of their customer(s) documents.</p> <p>Each line item f) through m) can also be similarly analyzed to determine the level of training and source of that training for each requirement within the safety requirements.</p> <p>Since many of the requirements depend upon customer specific requirements, there is no single complete industry training on this topic. The organization needs to review the customer and regulatory requirements associated with each of its parts appropriate for the intended country of use and safety-related part characteristics.</p> <p>Some customers may have specific requirements regarding product safety, training, knowledge, and personnel. It is the organization's responsibility to understand their customer's specific requirements related to product safety.</p>

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14	7.1.5.3.2 External laboratory	<p><u>QUESTION:</u> Is it required that the calibration certificate or (test) report of an external laboratory bears the mark (or logo or symbol) of the relevant national accreditation body that accredited the laboratory to ISO/IEC 17025?</p> <p><u>ANSWER:</u> Yes, only certificates of calibration or test reports including the mark of a national accreditation body are acceptable.</p> <p>The accreditation mark (often also called “accreditation logo” or “accreditation symbol”) of a national accreditation body provides documented evidence that the provided inspection, test, or calibration services were performed according to the accreditation scope and that they comply with the requirements of ISO/IEC 17025, and are subject to supervision of a national accreditation body.</p>
15	8.3.2.3 Development of products with embedded software	<p><u>QUESTION:</u> What is the acceptable method to assess a supplier’s software development capability?</p> <p><u>ANSWER:</u> The intent of IATF 16949, Section 8.3.2.3 is to apply the same level of rigor to the development of software as is expected in the development of hardware parts. Just like parts, software has defined performance, operating conditions, known inputs, specified outputs, parameters of environment (e.g. size of the file), regulatory requirements (if any), known failure modes, usage profiles, variability of conditions of operation, etc.</p>



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		<p>The planning, designing, writing, testing, confirming and production validation phases in the development of software are not very different in concept from the development of hardware parts. IATF 16949 provides a robust framework to validate that all necessary steps have been taken to design, verify, and produce hardware parts that continue to meet specification in mass production. While similar in concept, those steps are not the same for the development of software. Therefore, a different set of criteria are used to evaluate the methods used to develop software.</p> <p>Those criteria are not included in IATF 16949; therefore, other methods are referred to, such as Automotive SPICE and CMMI. There may be other acceptable methods available identified by some customers. Each customer may have a preferred tool to assess supplier software development capability. The organization should ask their customer(s) to confirm the acceptable assessment tool. Each customer may also specify a different approach used (e.g., customer on-site assessment, supplier self-assessment, or a combination of both).</p> <p>The role of the IATF 16949 internal or external auditor is not to have the knowledge to conduct the Automotive SPICE or CMMI assessments. However, the internal or external auditor should be familiar enough with the assessments to be able to recognize when a software assessment requirement has not been met and that there are corrective action plans in place, with the appropriate resources assigned. The IATF 16949 internal and external auditor should also know if the customer participates in that software development assessment and how that is documented.</p>

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16	<p style="text-align: center;">8.4.2.4.1 Second-party audits</p>	<p><u>QUESTION:</u> If there is low risk with an organization’s supplier(s), are 2nd party audits required? What is the intent?</p> <p><u>ANSWER:</u> The risk-based thinking approach, driven by ISO 9001:2015, needs to be incorporated for supplier management. The risk analysis needs to be completed and depending on the results of the risk assessment (see below), then a 2nd party audit may not be required.</p> <p>To support the risk analysis, the organization needs to consider criteria such as: supplier certification status, commodity complexity, new product launch(es), significant employee turn-over, product quality issues, delivery issues, customer specific requirements, and other risks to the organization or to their customer(s).</p>
17	<p style="text-align: center;">8.5.6.1.1 Temporary change of process controls</p>	<p><u>QUESTION:</u> Does there have to be an alternative process control for each primary control specified in the control plan?</p> <p><u>ANSWER:</u> No, it is not a requirement to have an alternative process control for every primary control.</p> <p>When introducing new products, an organization should consider the risk of the primary control potentially failing and, based on risk and severity of failure mode, decide where alternative process controls are needed. When back-up or alternate process controls are needed, then both the primary and alternative process controls should be defined in the process flow, PFMEA, control plan, and the standardized work available.</p>



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		<p>For existing processes, where there is a failure in the primary process control, and no alternative process control is defined, the organization should consider risk, (e.g. FMEA) and if approved, develop standardized work for an alternative process control, implement the controls, verify effectiveness through daily management, and then revalidate when the primary control is restored.</p> <p>Periodically, the organization shall review instances of where alternative process controls have been used and consider this as an input to update the process flow, FMEA, and control plan. (See SI 11)</p>
<p>18</p>	<p>Quality management system audit 9.2.2.2</p>	<p><u>QUESTION:</u> Why is the audit cycle increased to 3 years? Does this mean an organization can wait to do QMS audits in the 3rd year? Or are audits expected to be conducted years 1, 2, and 3?</p> <p><u>ANSWER:</u> All quality management system processes need to be audited over a three-year calendar period, with the annual audit programme addressing QMS processes, prioritized based on risk. However, it is not the intent of this requirement to allow for all processes to be audited once every three years.</p> <p>The complete audit cycle remains 3 years in length. During those 3 years of the audit cycle, all processes and all shifts are required to be audited to all applicable requirements in the IATF 16949 standard, including ISO 9001 base requirements, and any customer specific requirements.</p>

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		A typical example of the 3-year audit cycle would be to show all quality management system requirements in the organization and identify, based on risk, in which annual audit programme each process is to be audited.
<p style="text-align: center;">19</p>	<p style="text-align: center;">9.2.2.3 Manufacturing process audit</p>	<p><u>QUESTION:</u> For each manufacturing process audit do all shifts have to be covered?</p> <p><u>ANSWER:</u> Each audit does not have to cover all shifts in <u>one</u> audit (for example an audit of the pressing process could be done on shift 1 and 2, sampling shift changeover in year 1, and then in year 2 or 3 an audit undertaken on the third shift for pressing). However, <u>all</u> manufacturing processes must be audited on <u>all shifts</u> over a three-year cycle, the frequency depending on risk, performance, changes etc.</p>
<p style="text-align: center;">20</p>	<p style="text-align: center;">9.2.2.4 Product audit</p>	<p><u>QUESTION:</u> Why is there no defined audit frequency for Product audit?</p> <p><u>ANSWER:</u> The audit frequency must be determined based on the risk and product complexity (See ISO 9001, Section 9.2.2). If an organization has high risk and high product complexity, it is recommended that product audit frequency be increased.</p>