



IATF - International Automotive Task Force

IATF 16949:2016 – Frequently Asked Questions (FAQs)

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.

FAQ 21-22 issued in month of June 2018.

Revised FAQ 18 issued in month of October 2018.

Deleted FAQ 10 and FAQ 18 in month of November 2018.

FAQ 23-26 issued in month of March 2019.

FAQ 27-29 issued in month of August 2019.

FAQ 7 revised and reissued in the month of April 2021



NUMBER	IATF 16949 REFERENCE	QUESTIONS AND ANSWERS
1	<p 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 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. 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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<p style="text-align: center;">7 Revised</p>	<p style="text-align: center;">7.1.5.3.2 External laboratory</p>	<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> See Revised SI 10, issued April 2021, effective June 2021</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 style="text-align: center;">7.5.1.1 Quality management system documentation</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 regulatory requirements of the country where the supplier is manufacturing them, the country where</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>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.</p> <p>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>



NUMBER	IATF 16949 REFERENCE	QUESTIONS AND ANSWERS
<p>10 <i>deleted</i></p>	<p>8.4.2.3.1 Automotive product-related software or automotive products with embedded software</p>	<p>See SI 15, issued November 2018, effective January 2019.</p>
<p>11</p>	<p>8.7.1.7 Nonconforming product disposition</p>	<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>

NUMBER	IATF 16949 REFERENCE	QUESTIONS AND ANSWERS
<p style="text-align: center;">11 (cont.)</p>	<p style="text-align: center;">8.7.1.7 Nonconforming product disposition</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> <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>

NUMBER	IATF 16949 REFERENCE	QUESTIONS AND ANSWERS
<p style="text-align: center;">11 (cont.)</p>	<p style="text-align: center;">8.7.1.7 Nonconforming product disposition</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>
<p style="text-align: center;">12</p>	<p style="text-align: center;">Throughout the IATF 16949 Standard</p>	<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>
<p style="text-align: center;">13</p>	<p style="text-align: center;">4.4.1.2 Product safety</p>	<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>

NUMBER	IATF 16949 REFERENCE	QUESTIONS AND ANSWERS
<p>13 (cont.)</p>	<p>4.4.1.2 Product safety</p>	<p><u>ANSWER:</u></p> <p>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> <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>



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		<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>
<p>14</p>	<p>7.1.5.3.2 External laboratory</p>	<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>
<p>15</p>	<p>8.3.2.3 Development of products with embedded software</p>	<p><u>QUESTION:</u> What is the acceptable method to assess a supplier's software development capability?</p>

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<p>15 (cont.)</p>	<p>8.3.2.3 Development of products with embedded software</p>	<p><u>ANSWER:</u></p> <p>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> <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	8.4.2.4.1 Second-party audits	<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	8.5.6.1.1 Temporary change of process controls	<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</p>



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<p>17 (cont.)</p>	<p>8.5.6.1.1 Temporary change of process controls</p>	<p>primary and alternative process controls should be defined in the process flow, PFMEA, control plan, and the standardized work available.</p> <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 <i>deleted</i></p>	<p>Quality management system audit 9.2.2.2</p>	<p>See SI 14, issued November 2018, effective January 2019.</p>
<p>19</p>	<p>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 one 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, all manufacturing processes must be audited on all shifts over a three-year cycle, the frequency depending on risk, performance, changes etc.</p>

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20	9.2.2.4 Product audit	<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>
21	8.6.2 Layout inspection and functional testing	<p><u>QUESTION:</u> Is a layout inspection different from a product requalification or functional testing?</p> <p><u>ANSWER:</u> Yes, as stated in Note 1 of 8.6.2 of IATF 16949, [Layout inspection is the complete measurement of all product dimensions shown on the design record(s)]; layout inspection is limited to dimensional measurement and requirements. Performance or materials measurements are not included in a layout inspection.</p> <p>Product requalification would normally imply full validation to all product approval requirements (e.g. PPAP or PPA) and therefore exceeds the scope of a layout inspection.</p> <p>Functional testing/verification would normally be limited to performance and material measurements such as durability or tensile strength and would not include dimensional measurements.</p> <p>Where frequency is not defined by the customer, the organization is responsible to define the frequency of layout inspection.</p>

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<p>21 (cont.)</p>	<p>8.6.2 Layout inspection and functional testing</p>	<p>Layout inspection is a part of product requalification, if product requalification is required by the customer.</p> <p>On-going layout inspection and functional testing requirements are defined in the control plan. If customer-specific requirements exist, then those requirements (including layout inspection and functional testing requirements) are also included in the control plan.</p>
<p>22</p>	<p>9.2.2.4 Product audit</p>	<p><u>QUESTION:</u> How does a product audit differ from a layout inspection?</p> <p><u>ANSWER:</u> As defined in section 3 of IATF 16949, the term product is used to represent "...any intended output..." of the manufacturing process.</p> <p>Products typically have dimensional, performance (functional) and material requirements, therefore, product audits may contain verification of dimensional, performance (functional), or material requirements. As stated in the FAQ 21 above, a layout inspection is limited to dimensional requirements.</p> <p>Product audits can be carried out on finished or partially finished product, following customer specified approaches (e.g. VDA 6.5 Product Audit), if applicable. Product audits may include packaging and labelling requirements. A product audit, like other audit types, is an independent verification of compliance to requirements. As such, the product audit has a defined frequency and scope specified within the audit programme and is based on risk.</p>

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23	8.5.1.3 Verification of job set-ups	<p><u>QUESTION:</u> If first-off/last-off part validation is not performed or appropriate for a specific type of manufacturing process, are such records to be maintained per 8.5.1.3 e)?</p> <p><u>ANSWER:</u> As stated in 8.5.1.3 d), first-off/last-off part validation is performed only when it is applicable and appropriate. Where the validation is not performed because it is not applicable or appropriate, there is no requirement to maintain records.</p>
24	8.4.2.2 Statutory and regulatory requirements	<p><u>QUESTION 1:</u> If the organization is not responsible for product design and is therefore only manufacturing products as per the customer’s design, is the organization then exempt from the requirements in 8.4.2.2?</p> <p><u>ANSWER:</u> No, all organizations regardless of their responsibility for product design must satisfy the applicable requirements of 8.4.2.2. The applicable requirements address purchased products, processes, and services for which the organization is responsible.</p>

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<p style="text-align: center;">24 (cont.)</p>	<p style="text-align: center;">8.4.2.2 Statutory and regulatory requirements (cont.)</p>	<p><u>QUESTION 2:</u> Is the organization required to request a complete list of countries of destination from the customer if the list was not provided by the customer?</p> <p><u>ANSWER:</u> Yes, the organization is required to request a complete list of the countries of destination from the customer if the list was not provided by the customer.</p> <p>NOTE:</p> <ul style="list-style-type: none"> ○ The “country of receipt” is where the organization is located. (Country of the manufacturing site) ○ The “country of shipment” is the customer’s receiving location. (Country where the manufacturing site ships to) ○ The “country of destination” is the country where the vehicle is sold. (Country where the final product is initially sold) <p><u>QUESTION 3:</u> What is the consequence if the customer does not provide the information on the countries of destination to the organization? What is the organization required to document in this situation?</p> <p><u>ANSWER:</u> If the organization claims that the customer did not provide the necessary information on the countries of destination, the organization should be able to produce written evidence (e.g. letters, emails, meeting minutes, etc.) of their efforts to obtain it.</p>

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<p>24 (cont.)</p>	<p>8.4.2.2 Statutory and regulatory requirements (cont.)</p>	<p><u>QUESTION 4:</u> What level of detail should be provided by the customer regarding the countries of destination? Would a generic statement like “every country globally” be an appropriate response?</p> <p><u>ANSWER:</u> No, a generic statement such as “every country globally” is not acceptable. The customer is expected to provide to the organization a specific list of countries where the vehicle(s) are initially sold.</p> <p><u>QUESTION 5:</u> Applicable statutory and regulatory requirements are often linked to the relevant use of a product. Some parts might become a safety-related product, depending on its use. Based on the before mentioned statement, is the customer required to provide the organization with detailed information about the intended use?</p> <p><u>ANSWER:</u> It is expected that the customer will provide to the organization information of the characteristics that are relevant for the identification of required controls to meet applicable statutory and regulatory requirements (e.g. special characteristics).</p>

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25	8.3 Design and Development of products and services	<p><u>QUESTION</u> What constitutes product design responsibility for an organization?</p> <p><u>ANSWER</u> If an organization receives from its customer a fully defined engineering specification for the parts it is making (make to print), the organization would not be product design responsible. Where the organization does not receive a fully defined engineering specification for the parts it is making, the organization is product design responsible. In all cases, the organization is responsible for manufacturing process design.</p>
26	8.5.1.5 Total Productive Maintenance	<p><u>QUESTION</u> What is the intent of including the term “periodic overhaul” in the requirements for Total Productive Maintenance?</p> <p><u>ANSWER</u> The intent of all the line items in section 8.5.1.5 is to include the minimum steps to maintain manufacturing equipment over a long period of usage so it can consistently produce product to specification. “Periodic overhaul” is rework of manufacturing tooling and equipment needed when regular maintenance steps are no longer enough to keep the tooling and equipment in a condition where it can continue to make product to specification, as detected using Mean Time Between Repairs or other similar metrics.</p>

NUMBER	IATF 16949 REFERENCE	QUESTIONS AND ANSWERS
<p style="text-align: center;">26 (cont.)</p>	<p style="text-align: center;">8.5.1.5 Total Productive Maintenance</p>	<p>Periodic overhaul is already defined in section 3 of the standard: “maintenance methodology to prevent a major unplanned breakdown where, based on fault or interruption history, a piece of equipment, or subsystem of the equipment, is proactively taken out of service and disassembled, repaired, parts replaced, reassembled, and then returned to service.”</p> <p>Perhaps periodic overhaul is not applicable to some types of tooling and equipment. Perhaps some tooling is simply replaced with a new tool at the end of its useful life. However, all tooling and equipment does have a limited life based on usage, time or other known factors. The tooling and equipment manufacturer would be a good source to determine which factors and to estimate when such major work needs to be completed. Periodic overhaul or its appropriate equivalent (e.g. replacement) would need to be accounted for in the steps of the organization’s maintenance plan.</p>
<p style="text-align: center;">27</p>	<p style="text-align: center;">8.5.1.5 Total Productive Maintenance</p>	<p><u>QUESTION</u></p> <p>What is the intent of using the term “Total Productive Maintenance” for this clause, is there a connection to the industry term “Total Productive Maintenance”?</p> <p><u>ANSWER</u></p> <p>The term “Total Productive Maintenance” (TPM) used in the IATF 16949 standard refers to various similar approaches that focus on proactive and preventive techniques for improving tooling and equipment reliability through the machines, equipment, processes and employees that add manufacturing value to an organization. For example, the industry approach for TPM places the responsibility for routine maintenance, such as cleaning, lubricating and inspection in the hands of the operators.</p> <p>Clause 8.5.1.5 of IATF 16949 has some requirements which align with some of the pillars of industry TPM. However, the individual requirements of 8.5.1.5 [a) through j)] are as stated in IATF 16949. The use of the term “Total Productive Maintenance” in IATF 16949 gives organizations an</p>



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<p>27 (cont.)</p>	<p>8.5.1.5 Total Productive Maintenance</p>	<p>opportunity to adopt the underlying principles of industry Total Productive Maintenance while meeting the listed requirements of 8.5.1.5 in IATF 16949.</p>
<p>28</p>	<p>9.2.2.3 Manufacturing process audit</p>	<p><u>QUESTION</u></p> <p>What is intended frequency and coverage of Manufacturing Process Audits?</p> <p><u>ANSWER</u></p> <p>Effective assessment of each manufacturing process is vital to ensure continued manufacturing of product meeting customer, statutory and regulatory requirements. However, aligned with the risk approach of ISO 9001 and IATF 16949, some manufacturing processes or aspects of manufacturing processes may need higher frequency of assessment than others.</p> <p>The organization determines the audit frequency, if not defined by the customer, by using the appropriate risk management approach, including consideration of new technologies and customer measured performance. Manufacturing processes demonstrated to be low risk by the organization may be audited less frequently than high risk processes; however, all manufacturing processes are audited within the 3-year audit cycle.</p> <p>Evidence for risk analysis includes continued compliance with all relevant requirements, (for example: statutory and regulatory, customer, process, and internal requirements). If any one of the relevant requirements is not met, the manufacturing processes is audited at a higher frequency than every 3 years. The 3-year frequency as per clause 9.2.2.3 is a minimum requirement intended for low risk and fully compliant manufacturing processes.</p>

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<p>29</p>	<p>6.1.2.3 Contingency Plans</p>	<p><u>QUESTION</u></p> <p>What is meant by the use of the term “cyber-attack” for contingency plan testing?</p> <p><u>ANSWER</u></p> <p>A Cyber-attack is an attempt to gain illegal access to a computer or computer system for the purpose of causing damage or harm. A cyberattack is often a deliberate exploitation of weaknesses in the security of computer systems or networks to gain access to data, alter computer code, logic or data. These actions may have disruptive consequences that can compromise confidential data and lead to cybercrimes, such as information and identity theft, automation-caused operational interruptions, encryption of company critical data or illegal remote controlling of systems or data.</p> <p>Cyber-attacks and cybercrimes are not always a result of a sophisticated series of actions to guess passwords using powerful computer programs run by teams of people from a remote location. They are often actions designed to convince individual persons to release sensitive or private information through email notes (typically phishing), pretexting (impersonating a trusted person or government official), phone calls announcing fake emergencies getting personal information, visual reading of typed passwords, infecting popular websites with malware, text messages with links to sites installing malware, USB drives left on desks, appearing to be legitimate, which are plugged into PCs, and theft of discarded materials containing confidential computer information, etc. Additionally, a cyber-criminal, after gaining access to a company's system, could encrypt company's critical data and demand a ransom to unencrypt the data.</p> <p>Also, GDPR (General Data Protection Regulation) in Europe or similar requirements in other regions specify that organizations are responsible to ensure that personal data retained by the organization is protected and kept secure at all times, reinforcing the importance of being prepared in the case of cyber-attacks.</p> <p>Additional details regarding information technology security techniques is available through ISO/IEC 27001.</p>