

IATF 16949:2016 Audit

Template Information

Template ID	iatf-16949-2016-audit
Version	v1.0
Language	English (en)
Number of Check Items	341
Source	https://layeraudit.com
Revision Date	2026-10-27
Description	Description: This IATF audit checklist can be used by Quality Managers to assess if the company's QMS is aligned with the IATF 16949:2016 standard. It helps ensure that an automotive supplier or manufacturer's QMS promotes continuous improvement, defect prevention, and waste reduction in the automotive supply chain. Use this checklist with SafetyCulture on mobile devices to take photos and make notes of nonconformance found relevant to the question item. Use all sections of this checklist to make an internal assessment of compliance with the IATF 16949:2016 standard.

Audit Information (to be completed during audit)

Audit Date	
Auditor	
Area / Department	
Escort	

Instructions

1. This template contains 341 check items. Record results in the 'Checklist' worksheet.
2. The source does not define fixed pass/fail options. Fill in results according to your own criteria (e.g. Pass / Fail / N.A.).
3. Scores, conclusions and signatures are entered manually in the 'Scoring & Sign-off' worksheet.
4. For photos or other evidence, enter the evidence number in the 'Notes / Evidence No.' column and archive photos by number.
5. Check item numbers are renumbered consecutively. The mapping to the source rows is recorded in '编号对应表.xlsx' in the delivery package.

IATF 16949:2016 Audit — Checklist

No.	Section	Check Item	Result	Notes / Evidence No.
	Introduction	Please complete all sections starting immediately below. This IATF audit checklist will evaluate the organization's compliance with the IATF 16949:2016 standard. Remember to attach evidence to items where required, and to sign off and complete this audit in the final section.		
1	4.1 Understanding the organization and its context	Verify how the organization has determined external and internal issues relevant to its purpose and strategic direction.		
2	4.1 Understanding the organization and its context	Verify how these issues affect the ability to achieve the intended result of the QMS.		
3	4.1 Understanding the organization and its context	Verify how the organization monitors and reviews information about these internal and external issues.		
4	4.2 Understanding the needs and expectations of interested parties	Verify how organization determined relevant interested parties to QMS.		
5	4.2 Understanding the needs and expectations of interested parties	Verify how the organization has determined the relevant needs and expectations of interested parties.		
6	4.2 Understanding the needs and expectations of interested parties	Verify how the organization has determined the impact or potential impact of the interested parties.		
7	4.2 Understanding the needs and expectations of interested parties	Verify how the organization monitors and reviews information about interested parties and their relevant requirements.		
8	4.3 Determining the scope of the quality management system	Verify the QMS scope considers the following:		
8	4.3 Determining the scope of the quality management system	↳ External and internal issues.	☐	
8	4.3 Determining the scope of the quality management system	↳ The requirements of relevant interested parties.	☐	
8	4.3 Determining the scope of the quality management system	↳ The products and services of the organization.	☐	
9	4.3 Determining the scope of the quality management system	Verify how the organization has determined how the ISO 9001:2015 standard is applied within the organization.		
10	4.3 Determining the scope of the quality management system	If the organization has determined any of the requirements of the ISO 9001:2015 standard not to be applicable, show me how conformity of products and services are not affected by this.		
11	4.3 Determining the scope of the quality management system	Verify QMS scope is documented.		
12	4.3 Determining the scope of the quality management system	Verify scope states what products and services are covered by the QMS and how it justifies instances where requirements cannot be applied.		
13	4.3.1 Determining the scope of the quality management system - supplemental	Verify support functions included in scope		
14	4.3.1 Determining the scope of the quality management system - supplemental	If exemption taken, verify that it is for ISO 9001, Section 8.3. Also verify that permitted exclusion does not include manufacturing process design.		
15	4.3.2 Customer-specific requirements	Verify customer-specific requirements evaluated and included in scope		

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No.	Section	Check Item	Result	Notes / Evidence No.
16	4.4 Quality management system and its processes	Show me how the processes have been determined and how they interact.		
17	4.4 Quality management system and its processes	Verify how the processes for the QMS were determine. Verify the inputs and outputs to the processes.		
18	4.4 Quality management system and its processes	Verify the sequence and interaction of of the processes.		
19	4.4 Quality management system and its processes	Verify the criteria, methods, measurement and related performance indicators needed to operate and control the processes.		
20	4.4 Quality management system and its processes	Verify how resources are determined and allocated.		
21	4.4 Quality management system and its processes	Verify how responsibilities and authorities are determined.		
22	4.4 Quality management system and its processes	Verify how risks and opportunities are considered and what actions are taken to address them.		
23	4.4 Quality management system and its processes	Verify what methods are used to monitor, measure and evaluate processes. Verify changes, if needed, are implemented to achieve intended results.		
24	4.4 Quality management system and its processes	Verify how opportunities for improvement for the QMS and its processes are determined.		
25	4.4 Quality management system and its processes	Reviewed documented information created to support the operation of its processes.		
26	4.4.1.1 Conformance of products and processes	Verify conformance to all applicable customer, statutory and regulatory requirements		
27	4.4.1.2 Product Safety	Verify documented process		
28	4.4.1.2 Product Safety	Where applicable, shall include:		
28	4.4.1.2 Product Safety	↳ identification of statutory and regulatory product-safety requirements and customer notification	☐	
28	4.4.1.2 Product Safety	↳ special approvals for design FMEA, process FMEAs and control plans	☐	
28	4.4.1.2 Product Safety	↳ identification and controls of product safety-related characteristics (including at the point of manufacture)	☐	
28	4.4.1.2 Product Safety	↳ reaction plans	☐	
28	4.4.1.2 Product Safety	↳ definition of responsibilities, escalation process and flow of information, including top management and customer notification	☐	
28	4.4.1.2 Product Safety	↳ training required	☐	
28	4.4.1.2 Product Safety	↳ changes of product or process shall be approved prior to implementation	☐	
28	4.4.1.2 Product Safety	↳ transfer of requirements with regard to product safety throughout the supply chain, including customer-designated sources	☐	
28	4.4.1.2 Product Safety	↳ product traceability by manufactured lot (at a minimum) throughout the supply chain	☐	
28	4.4.1.2 Product Safety	↳ lessons learned for new product introductions	☐	
29	5.1 Leadership and commitment	Top management is identified		
30	5.1 Leadership and commitment	Verify top management demonstrates leadership and commitment by:		
30	5.1 Leadership and commitment	↳ Taking accountability for QMS effectiveness	☐	
30	5.1 Leadership and commitment	↳ Ensuring the QMS policy and objectives are established and are compatible with strategic direction and context of organization	☐	
30	5.1 Leadership and commitment	↳ Ensuring the QMS is integrated into organization's business processes	☐	

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No.	Section	Check Item	Result	Notes / Evidence No.
30	5.1 Leadership and commitment	↳ Promoting the use of the process approach and risk-based thinking	☐	
30	5.1 Leadership and commitment	↳ Ensuring resources are available	☐	
30	5.1 Leadership and commitment	↳ Communicating the importance of effective QMS and of conforming to its requirements	☐	
30	5.1 Leadership and commitment	↳ Ensuring intended outcomes	☐	
30	5.1 Leadership and commitment	↳ Engaging, directing and supporting persons to contribute to the effectiveness of the QMS	☐	
30	5.1 Leadership and commitment	↳ Promoting continuous improvement	☐	
30	5.1 Leadership and commitment	↳ Supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility	☐	
31	5.1 Leadership and commitment	Verify how top management demonstrates leadership and commitment with respect to customer focus by ensuring that:		
31	5.1 Leadership and commitment	↳ customer and applicable statutory and regulatory requirements are determined, understood and consistently met.	☐	
31	5.1 Leadership and commitment	↳ the risks and opportunities that affect product and service conformity and the ability to enhance customer satisfaction are determined and addressed.	☐	
31	5.1 Leadership and commitment	↳ the focus of enhancing customer satisfaction is maintained.	☐	
32	5.1 Leadership and commitment	Verify corporate responsibility policies are defined and implemented:		
32	5.1 Leadership and commitment	↳ Anti-bribery policy	☐	
32	5.1 Leadership and commitment	↳ Employee code of conduct	☐	
32	5.1 Leadership and commitment	↳ Ethics escalation policy ("whistle-blowing policy")	☐	
33	5.1 Leadership and commitment	Verify top management reviews the product realization process for effectiveness and efficiency and is input to Management Review		
34	5.1 Leadership and commitment	Verify top management has identified process owners and that the process owners understand their roles and are competent to perform those roles		
35	5.2 Policy	Verify the quality policy:		
35	5.2 Policy	↳ is appropriate to the purpose and context of the organization and supports its strategic direction.	☐	
35	5.2 Policy	↳ provides a framework for setting quality objectives.	☐	
35	5.2 Policy	↳ includes a commitment to satisfy applicable requirements.	☐	
35	5.2 Policy	↳ includes a commitment to continual improvement of the QMS.	☐	
36	5.2 Policy	Verify QMS Policy is maintained as documented information.		
37	5.2 Policy	Verify QMS Policy is communicated, understood and applied within the organization.		
38	5.2 Policy	Verify QMS Policy is available to relevant interested parties.		
39	5.3 Organizational roles, responsibilities and authorities	Verify responsibilities and authorities for relevant roles are assigned and communicated within the organization		
40	5.3 Organizational roles, responsibilities and authorities	Verify top management assigns responsibility and authority for:		
40	5.3 Organizational roles, responsibilities and authorities	↳ ensuring the QMS conforms to the ISO 9001:2015 and IATF 16949:2016 standards.	☐	
40	5.3 Organizational roles, responsibilities and authorities	↳ ensuring that processes are delivering their intended outputs.	☐	
40	5.3 Organizational roles, responsibilities and authorities	↳ reporting on the performance of the QMS and on opportunities for improvement, in particular to top management.	☐	

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40	5.3 Organizational roles, responsibilities and authorities	↳ ensuring the promotion of customer focus throughout the organization.	☐	
40	5.3 Organizational roles, responsibilities and authorities	↳ ensuring the integrity of the QMS is maintained when changes to the QMS are planned and implemented.	☐	
41	5.3 Organizational roles, responsibilities and authorities	Verify personnel are assigned responsibility and authority to ensure that customer requirements are met and these assignments are documented.		
42	5.3 Organizational roles, responsibilities and authorities	Verify personnel responsible for conformity have the authority to stop shipment and stop production to correct quality problems.		
43	5.3 Organizational roles, responsibilities and authorities	Verify personnel with authority and responsibility for corrective action are promptly informed of products or processes that do not conform		
44	5.3 Organizational roles, responsibilities and authorities	Verify that personnel across all shifts have responsibility for ensuring conformity to product requirements.		
45	6.1 Actions to address risks and opportunities	Verify how the internal and external issues and interested parties are considered when planning for the QMS?		
46	6.1 Actions to address risks and opportunities	Verify how risks and opportunities are determined and addressed so the QMS can achieve its intended results, prevent and reduce undesired effects and achieve continual improvement		
47	6.1 Actions to address risks and opportunities	Verify how actions are planned to address risks and opportunities.		
48	6.1 Actions to address risks and opportunities	Verify how actions are integrated and implemented into the QMS processes.		
49	6.1 Actions to address risks and opportunities	Verify how the organization evaluates the effectiveness of the actions.		
50	6.1 Actions to address risks and opportunities	Verify how actions are taken to address risks and opportunities determined as being appropriate to the potential impact on the conformity of products and services.		
51	6.1 Actions to address risks and opportunities	Verify risk analysis includes, at a minimum, lessons learned from product recalls, product audits, field returns and repairs, complaints, scrap and rework.		
52	6.1 Actions to address risks and opportunities	Verify retained documented information		
53	6.1 Actions to address risks and opportunities	Verify preventive action process		
54	6.1 Actions to address risks and opportunities	Verify contingency plans are documented		
55	6.1 Actions to address risks and opportunities	Verify contingency plans are prepared for continuity of supply in the event of:		
55	6.1 Actions to address risks and opportunities	↳ key equipment failures	☐	
55	6.1 Actions to address risks and opportunities	↳ interruption from externally provided products, processes and services	☐	
55	6.1 Actions to address risks and opportunities	↳ recurring natural disasters	☐	
55	6.1 Actions to address risks and opportunities	↳ fire	☐	
55	6.1 Actions to address risks and opportunities	↳ utility interruptions	☐	
55	6.1 Actions to address risks and opportunities	↳ labour shortages	☐	
55	6.1 Actions to address risks and opportunities	↳ infrastructure disruptions	☐	
56	6.1 Actions to address risks and opportunities	Verify validation of manufactured product after re-start		

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No.	Section	Check Item	Result	Notes / Evidence No.
57	6.2 Quality objectives and planning to achieve them	Verify top management ensures that quality objectives are defined, established and maintained at relevant functions, levels and processes.		
58	6.2 Quality objectives and planning to achieve them	Verify the quality objectives are:		
58	6.2 Quality objectives and planning to achieve them	↳ consistent with the quality policy.	☐	
58	6.2 Quality objectives and planning to achieve them	↳ measurable.	☐	
58	6.2 Quality objectives and planning to achieve them	↳ taking into account applicable requirements.	☐	
58	6.2 Quality objectives and planning to achieve them	↳ relevant to the conformity of products and services and to the enhancement of customer satisfaction.	☐	
58	6.2 Quality objectives and planning to achieve them	↳ monitored.	☐	
58	6.2 Quality objectives and planning to achieve them	↳ communicated.	☐	
58	6.2 Quality objectives and planning to achieve them	↳ updated as appropriate.	☐	
59	6.2 Quality objectives and planning to achieve them	Verify objectives are documented.		
60	6.2 Quality objectives and planning to achieve them	Verify how the organization determines what will be done, with what resources, when completed and how the results will be evaluated for quality objectives.		
61	6.2 Quality objectives and planning to achieve them	Verify annual quality objectives and related performance targets (internal and external) are established		
62	6.3 Planning of changes	Verify how QMS changes are planned systematically.		
63	6.3 Planning of changes	Verify how the organization demonstrates the purpose and potential consequences of changes.		
64	6.3 Planning of changes	Verify how the organization considers the integrity of the QMS.		
65	6.3 Planning of changes	Verify how resources are made available.		
66	6.3 Planning of changes	Verify how responsibility and authority is allocated and reallocated.		
67	7.1.1 General - 7.1.3 Infrastructure	Verify how resources are determined for the organization.		
68	7.1.1 General - 7.1.3 Infrastructure	Show me how the capabilities and constraints on internal resources are considered.		
69	7.1.1 General - 7.1.3 Infrastructure	Show me how needs from external providers are considered.		
70	7.1.1 General - 7.1.3 Infrastructure	Verify how the organization provides persons necessary to consistently meet customer, applicable statutory and regulatory requirements for the QMS including the necessary processes.		
71	7.1.1 General - 7.1.3 Infrastructure	Verify how the organization determines, provides and maintains the infrastructure for the operation of processes to achieve products and services conformity.		
72	7.1.1 General - 7.1.3 Infrastructure	Verify design layout optimizes material flow, material handling and value-added use of floor space		
73	7.1.1 General - 7.1.3 Infrastructure	Verify assessments of manufacturing feasibility and evaluation of capacity planning as inputs into Management Review		
74	7.1.4 Environment for the operation of processes	Verify how the organization determines, provides and maintains the environment for the operation of processes to achieve products and service conformity.		

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No.	Section	Check Item	Result	Notes / Evidence No.
75	7.1.4 Environment for the operation of processes	Verify premises are in a state of order, cleanliness and repair		
76	7.1.5 Monitoring and measuring resources	Verify how resources are determined to ensure valid and reliable monitoring and measuring results.		
77	7.1.5 Monitoring and measuring resources	Verify how the organization ensures that the resources provided are suitable for the specific type of monitoring and measurement activities being undertaken and that they are maintained to ensure continued fitness of purpose.		
78	7.1.5 Monitoring and measuring resources	Verify documented information that shows evidence of fitness for purpose of monitoring and measurement resources.		
79	7.1.5 Monitoring and measuring resources	Show me how measurement instruments are verified or calibrated at specific intervals against national or international standards. If no standards, show me documented information which is used as the basis for calibration or verification.		
80	7.1.5 Monitoring and measuring resources	Show me how measurement instruments are identified.		
81	7.1.5 Monitoring and measuring resources	Show me how measurement instruments are safeguarded from adjustments, damage and deterioration.		
82	7.1.5 Monitoring and measuring resources	Verify how the organization determines the validity of previous measurements if you find an instrument to be defective during verification or calibration. Verify any actions taken.		
83	7.1.5 Monitoring and measuring resources	Verify MSA		
84	7.1.5 Monitoring and measuring resources	Verify criteria used conforms to those in reference manuals on MSA		
85	7.1.5 Monitoring and measuring resources	Verify documented process for managing calibration/verification records		
86	7.1.5 Monitoring and measuring resources	Verify calibration/verification activities and records shall include:		
86	7.1.5 Monitoring and measuring resources	↳ revisions following engineering changes that impact measurement systems	☐	
86	7.1.5 Monitoring and measuring resources	↳ any out-of-spec readings as received for calibration/verification	☐	
86	7.1.5 Monitoring and measuring resources	↳ risk assessment caused by out-of-spec condition	☐	
86	7.1.5 Monitoring and measuring resources	↳ documented information on the validity of previous measurement results when a piece of inspection measurement and test equipment is found to be out of calibration or defective during its planned verification or calibration or during its use	☐	
86	7.1.5 Monitoring and measuring resources	↳ customer notification if product or material has been shipped	☐	
86	7.1.5 Monitoring and measuring resources	↳ statements of conformity to spec after calibration/verification	☐	
86	7.1.5 Monitoring and measuring resources	↳ verification of software version	☐	
86	7.1.5 Monitoring and measuring resources	↳ records of the calibration and maintenance activities for all gauging, including employee-owned, customer-owned or on-site supplier-owned equipment	☐	
86	7.1.5 Monitoring and measuring resources	↳ production-related software verification used for product and process control	☐	
87	7.1.5 Monitoring and measuring resources	Verify defined scope for internal laboratory is documented		
88	7.1.5 Monitoring and measuring resources	Verify laboratory requirements for:		
88	7.1.5 Monitoring and measuring resources	↳ adequacy of the laboratory technical procedures	☐	
88	7.1.5 Monitoring and measuring resources	↳ competency of laboratory personnel	☐	

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88	7.1.5 Monitoring and measuring resources	↳ testing of the product	☐	
88	7.1.5 Monitoring and measuring resources	↳ traceability to relevant process standard (such as ASTM, EN, etc.) or when no national standard(s) is available, the organization shall define and implement a methodology to verify measurement system capability	☐	
88	7.1.5 Monitoring and measuring resources	↳ customer requirements, if any	☐	
88	7.1.5 Monitoring and measuring resources	↳ review of related records	☐	
89	7.1.5 Monitoring and measuring resources	Verify external laboratories are accredited to ISO/IEC 17025 or national equivalent and or is acceptable to the customer		
90	7.1.5 Monitoring and measuring resources	Verify scope includes relevant inspection, test or calibration service and the certificate of calibration or test report includes the mark of a national accreditation body		
91	7.1.6 Organizational knowledge	Verify how the organization determines the necessary knowledge for the operation of processes and achieves conformity of products and services.		
92	7.1.6 Organizational knowledge	Verify how knowledge is maintained and made available to the extent necessary.		
93	7.1.6 Organizational knowledge	Verify how the organization determines current knowledge and how its acquires additional knowledge when addressing changing needs and trends.		
94	7.2 Competence	Show me how you determine the necessary competence of people doing work under your control that affects quality performance.		
95	7.2 Competence	Show me how you determine competence on the basis of appropriate education, training or experience.		
96	7.2 Competence	Show me how you take actions to acquire necessary competence where applicable and how do you evaluate the effectiveness of those actions.		
97	7.2 Competence	Verify documented information as evidence of competence where appropriate.		
98	7.2 Competence	Verify documented process(es) for identifying training needs including awareness and achieving competence		
99	7.2 Competence	Verify on-the-job training process		
100	7.2 Competence	Verify documented process(es) to verify internal and second-party auditors are competent and can demonstrate:		
100	7.2 Competence	↳ understanding of the automotive process approach for auditing, including risk-based thinking	☐	
100	7.2 Competence	↳ understanding of applicable customer and organization specific requirements	☐	
100	7.2 Competence	↳ understanding of applicable ISO 9001 and IATF 16949 requirements	☐	
100	7.2 Competence	↳ applicable manufacturing process(es) to be audited, including PFMEA and control plan (second-party auditor only)	☐	
100	7.2 Competence	↳ understanding of the applicable core tool requirements	☐	
100	7.2 Competence	↳ understanding how to plan, conduct, report and close out audit findings	☐	
101	7.2 Competence	Verify how manufacturing process auditors demonstrate technical understanding of the relevant manufacturing process(es) to be audited, including process risk analysis (PFMEA) and control plan		
102	7.2 Competence	Verify product auditors demonstrate competence in understanding product requirements and use of relevant measuring and test equipment to verify product conformity		
103	7.2 Competence	Verify maintenance of and improvement in internal auditor competence by:		
103	7.2 Competence	↳ executing minimum number of audits per year, as defined by organization	☐	
103	7.2 Competence	↳ maintaining knowledge of relevant requirements based on internal or external changes	☐	
104	7.3 Awareness	Verify people doing work under the organization's control are aware of:		
104	7.3 Awareness	↳ the quality policy.	☐	
104	7.3 Awareness	↳ the relevant quality objectives.	☐	
104	7.3 Awareness	↳ their contribution to the effectiveness of the QMS, including the benefits of improved performance.	☐	

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104	7.3 Awareness	↳ the implications of not conforming with the QMS requirements.	☐	
105	7.3 Awareness	Verify that the organization documents process for employee motivation and empowerment:		
105	7.3 Awareness	↳ to achieve quality objectives	☐	
105	7.3 Awareness	↳ to make continual improvements	☐	
105	7.3 Awareness	↳ to create an environment that promotes innovation	☐	
106	7.3 Awareness	Verify that the organization promotes quality and technological awareness in the whole organization		
107	7.4 Communication	Verify internal and external communication process (what, when, with whom and how to communicate).		
108	7.5 Documented information	Verify documented information required by the ISO 9001:2015 standard.		
109	7.5 Documented information	Verify documented information that shows the effectiveness of the QMS.		
110	7.5 Documented information	Show me that your documented information contains appropriate identification, format (language, software version, graphics, ...) and media (paper, electronic, ...).		
111	7.5 Documented information	Show me how the documented information is reviewed and approved for suitability and adequacy.		
112	7.5 Documented information	Show me how you control documented information and make it available and suitable for use. Tell me how you protect your documented information.		
113	7.5 Documented information	Verify how the organization controls the distribution, access, retrieval, use, storage, preservation, legibility, control of changes, retention and disposition of documented information.		
114	7.5 Documented information	Verify documented information of external origin is identified, as appropriate, and controlled.		
115	7.5 Documented information	Verify quality manual and it includes, at a minimum:		
115	7.5 Documented information	↳ Scope of the QMS, including details of and justification for any exclusions	☐	
115	7.5 Documented information	↳ documented processes established for the QMS or reference to them	☐	
115	7.5 Documented information	↳ the organization's processes and their sequence and interactions (inputs and outputs), including type and extent of control of any outsourced processes	☐	
115	7.5 Documented information	↳ a document indicating where within the QMS their customer-specific requirements are addressed	☐	
116	7.5 Documented information	Verify record retention policy		
117	7.5 Documented information	Verify production part approvals, tooling records, product and process design records, purchase orders (if applicable) or contracts and amendments are maintained for the length of time that the product is active for production/service plus one calendar year		
118	7.5 Documented information	Verify documented process describing the review, distribution and implementation of all customer engineering standards/specifications and related revisions		
119	7.5 Documented information	Verify records of dates engineering standard/spec change implemented in production (implementation shall include updated documents)		
120	7.5 Documented information	Verify review is completed within 10 working days of receipt of notification of engineering standards/spec changes		
121	8.1 Operational planning and control	Verify how the organization has planned, implemented and controlled processes needed to meet the requirements of products and services.		
122	8.1 Operational planning and control	Verify how requirements for products and services are determined.		
123	8.1 Operational planning and control	Verify how criteria for processes and acceptance for products and services are determined.		
124	8.1 Operational planning and control	Verify how resources are determined.		
125	8.1 Operational planning and control	Verify how process control is implemented.		

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126	8.1 Operational planning and control	Show me documented information that demonstrates processes have been carried out as planned and can demonstrate conformity of products and services.		
127	8.1 Operational planning and control	Determine how output from the planning process is suitable for operations.		
128	8.1 Operational planning and control	Verify how planned changes are controlled. Verify how unintended changes are reviewed and what actions are taken to mitigate any adverse effects, as necessary.		
129	8.1 Operational planning and control	Verify how outsourced processes are controlled.		
130	8.1 Operational planning and control	Verify topics shall be included in planning for product realization:		
130	8.1 Operational planning and control	↳ customer product requirements and technical specifications	☐	
130	8.1 Operational planning and control	↳ logistics requirements	☐	
130	8.1 Operational planning and control	↳ manufacturing feasibility	☐	
130	8.1 Operational planning and control	↳ project planning	☐	
130	8.1 Operational planning and control	↳ acceptance criteria	☐	
131	8.1 Operational planning and control	Verify organization ensures confidentiality		
132	8.2 Determination of requirements for products and services	Verify processes created for communicating with customers on information relating to products, services, enquiries, contracts, order handling, customer views, perceptions and complaints, handling or treatment of customer property and specific requirements for contingency actions.		
133	8.2 Determination of requirements for products and services	Verify process to determine the requirements for products and services to be offered to potential customers and how the process is established, implemented and maintained.		
134	8.2 Determination of requirements for products and services	Verify how product and service requirements including statutory and regulatory requirements are defined. Verify that the organization has the ability to meet the defined requirements and substantiate any claims for its products and services.		
135	8.2 Determination of requirements for products and services	Verify how the organization reviews:		
135	8.2 Determination of requirements for products and services	↳ customer requirements for delivery and post-delivery.	☐	
135	8.2 Determination of requirements for products and services	↳ requirements necessary for customer's specified or intended use, where known.	☐	
135	8.2 Determination of requirements for products and services	↳ statutory and regulatory requirements applicable to the products and services.	☐	
135	8.2 Determination of requirements for products and services	↳ other contract or order requirements.	☐	
136	8.2 Determination of requirements for products and services	Verify retained documented evidence of customer-authorized waiver of above requirements for a formal review		
137	8.2 Determination of requirements for products and services	Verify organization's manufacturing processes are capable (capability analysis, Cp, Cpk, Pp, Ppk)		
138	8.2 Determination of requirements for products and services	Show me that the review is conducted prior to the organization's commitment to supply products and services to the customer.		

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139	8.2 Determination of requirements for products and services	Verify how the organization resolves differences in the contract or order requirements from those previously defined.		
140	8.2 Determination of requirements for products and services	Verify how the organization confirms customer requirements where the customer doesn't provide a documented statement.		
141	8.2 Determination of requirements for products and services	Verify documented information of reviews describing new or changed requirements to products and services.		
142	8.2 Determination of requirements for products and services	Verify documented information of amended reviews and how relevant personnel are made aware of those changes.		
143	8.2 Determination of requirements for products and services	Verify written or verbal communication is in language agreed to with the customer		
144	8.3.1 General	Verify how the design and development process is established, implemented and maintained.		
145	8.3.1 General	Verify product and manufacturing design is focused on error prevention rather than detection		
146	8.3.1 General	Verify that the organization documents the design and development process		
147	8.3.2 Design and development planning	In determining the stages and control for design and development, verify the organization considers:		
147	8.3.2 Design and development planning	↳ the nature, duration and complexity of the activities.	☐	
147	8.3.2 Design and development planning	↳ the requirements that specify particular process stages including applicable reviews.	☐	
147	8.3.2 Design and development planning	↳ required verification and validation.	☐	
147	8.3.2 Design and development planning	↳ responsibilities and authorities.	☐	
147	8.3.2 Design and development planning	↳ how interfaces are controlled between individuals and parties.	☐	
147	8.3.2 Design and development planning	↳ the need for involvement of customer and user groups.	☐	
148	8.3.2 Design and development planning	Verify documented information that confirms design and development requirements have been met.		
149	8.3.2 Design and development planning	Verify design and development planning includes a multidisciplinary approach of all affected stakeholders within its organization and its supply chain (as appropriate).		
150	8.3.2 Design and development planning	Verify product design personnel are competent to achieve design requirements and are skilled in applicable product design tools and techniques.		
151	8.3.2 Design and development planning	Verify process for quality assurance for their products with internally developed embedded software.		
152	8.3.3 Design and development inputs	In determining requirements essential for the type of products and services being designed and developed, the organization shall consider:		
152	8.3.3 Design and development inputs	↳ functional and performance requirements.	☐	
152	8.3.3 Design and development inputs	↳ information derived from previous similar design and development activities.	☐	
152	8.3.3 Design and development inputs	↳ statutory and regulatory requirements.	☐	
152	8.3.3 Design and development inputs	↳ standard or codes of practice that the organization has committed to implement.	☐	
152	8.3.3 Design and development inputs	↳ potential consequences of failure due to the nature of the products and services.	☐	
153	8.3.3 Design and development inputs	Verify that the inputs are complete and unambiguous.		

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No.	Section	Check Item	Result	Notes / Evidence No.
154	8.3.3 Design and development inputs	Verify documented information on design and development inputs are retained.		
155	8.3.3 Design and development inputs	Verify design input requirements as a result of contract review:		
155	8.3.3 Design and development inputs	↳ product specs including but not limited to special characteristics	☐	
155	8.3.3 Design and development inputs	↳ boundary and interface requirements	☐	
155	8.3.3 Design and development inputs	↳ identification, traceability and packaging	☐	
155	8.3.3 Design and development inputs	↳ consideration of design alternatives	☐	
155	8.3.3 Design and development inputs	↳ assessment of risks with the input requirements and the organization's ability to mitigate/manage the risks, including from the feasibility analysis	☐	
155	8.3.3 Design and development inputs	↳ targets for conformity to product requirements	☐	
155	8.3.3 Design and development inputs	↳ applicable statutory and regulatory requirements	☐	
155	8.3.3 Design and development inputs	↳ embedded software requirements	☐	
156	8.3.3 Design and development inputs	Verify manufacturing process design inputs include (but not limited to):		
156	8.3.3 Design and development inputs	↳ product design output data including special characteristics	☐	
156	8.3.3 Design and development inputs	↳ targets for productivity, process capability, timing and cost	☐	
156	8.3.3 Design and development inputs	↳ manufacturing technology alternatives	☐	
156	8.3.3 Design and development inputs	↳ customer requirements	☐	
156	8.3.3 Design and development inputs	↳ experience from previous developments	☐	
156	8.3.3 Design and development inputs	↳ new materials	☐	
156	8.3.3 Design and development inputs	↳ product handling and ergonomic requirements	☐	
156	8.3.3 Design and development inputs	↳ design for manufacturing and design for assembly	☐	
157	8.3.3 Design and development inputs	Verify error-proofing included in manufacturing process design as appropriate		
158	8.3.3 Design and development inputs	Verify multi-disciplinary approach to identify special characteristics:		
158	8.3.3 Design and development inputs	↳ documentation of all special characteristics in the drawings, risk analysis (FMEA), control plans and standard work/instructions	☐	
158	8.3.3 Design and development inputs	↳ verify special characteristics are identified with specific markings and are cascaded through each of the documents	☐	
158	8.3.3 Design and development inputs	↳ development of control and monitoring strategies	☐	
158	8.3.3 Design and development inputs	↳ customer-specified approvals	☐	
158	8.3.3 Design and development inputs	↳ compliance with customer-specified definitions and symbols (can be organization's equivalent as defined by conversion table)	☐	
159	8.3.4 Design and development controls	Verify the organization includes all products and services that affect customer requirements such as sub- assembly, sequencing, sorting, rework, and calibration services in the scope of their definition of externally provided products, processes, and services		
160	8.3.4 Design and development controls	Verify the organization applies controls to the design and development process to ensure that:		

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No.	Section	Check Item	Result	Notes / Evidence No.
160	8.3.4 Design and development controls	↳ the results to be achieved are defined.	☐	
160	8.3.4 Design and development controls	↳ reviews are conducted to evaluate the ability of the results of design and development to meet requirements.	☐	
160	8.3.4 Design and development controls	↳ verification activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use.	☐	
160	8.3.4 Design and development controls	↳ validation activities are conducted to ensure that the resulting products and services meet the requirements of the specified application or intended use.	☐	
160	8.3.4 Design and development controls	↳ any necessary actions are taken on problems determined during the reviews, or verification and validation activities.	☐	
161	8.3.4 Design and development controls	Verify documented information of these activities are retained.		
162	8.3.4 Design and development controls	Verify measurement results summary are an input to management review		
163	8.3.4 Design and development controls	Verify measurements are reported to customer, if required		
164	8.3.4 Design and development controls	Verify validation performed in accordance to customer requirements, including industry and government regulation standards.		
165	8.3.4 Design and development controls	Verify interaction of organization's product, including embedded software, within the system of the final customer's product (if contractually agreed with customer)		
166	8.3.4 Design and development controls	Verify prototype program and control plan (if required)		
167	8.3.4 Design and development controls	Verify prototype performance testing is monitored for timely completion		
168	8.3.4 Design and development controls	Verify product and manufacturing approval process conforming to customer requirements		
169	8.3.4 Design and development controls	Verify approval of external provided parts and services prior to submission of part approval to customer		
170	8.3.4 Design and development controls	Verify product approval is documented prior to shipment (if required) and retained.		
171	8.3.5 Design and development outputs	Verify the organization ensures the design and development outputs:		
171	8.3.5 Design and development outputs	↳ meet the input requirements.	☐	
171	8.3.5 Design and development outputs	↳ are adequate for the subsequent processes for the provision of products and services.	☐	
171	8.3.5 Design and development outputs	↳ include or reference monitoring and measuring requirements, as appropriate , and acceptance criteria.	☐	
171	8.3.5 Design and development outputs	↳ specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision.	☐	
171	8.3.5 Design and development outputs	↳ design risk analysis (FMEA)	☐	
171	8.3.5 Design and development outputs	↳ reliability study results	☐	
171	8.3.5 Design and development outputs	↳ product special characteristics	☐	
171	8.3.5 Design and development outputs	↳ results of product design error-proofing, such as DFSS, DFMA and FTA	☐	
171	8.3.5 Design and development outputs	↳ product definition including 3D models, technical data packages, product manufacturing information and geometric dimensioning & tolerancing (GD&T)	☐	
171	8.3.5 Design and development outputs	↳ product design review results	☐	
171	8.3.5 Design and development outputs	↳ service diagnostic guidelines and repair and serviceability instructions	☐	
171	8.3.5 Design and development outputs	↳ service part requirements	☐	

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No.	Section	Check Item	Result	Notes / Evidence No.
171	8.3.5 Design and development outputs	↳ packaging and labeling requirements for shipping	☐	
172	8.3.5 Design and development outputs	Verify documented information on design and development outputs are retained.		
173	8.3.5 Design and development outputs	Verify manufacturing process design output is documented		
174	8.3.5 Design and development outputs	Verify manufacturing process design output versus input		
175	8.3.5 Design and development outputs	Verify manufacturing process design output includes:		
175	8.3.5 Design and development outputs	↳ specifications and drawings	☐	
175	8.3.5 Design and development outputs	↳ special characteristics for product and manufacturing process	☐	
175	8.3.5 Design and development outputs	↳ identification of process input variables that impact characteristics	☐	
175	8.3.5 Design and development outputs	↳ tooling and equipment for production and control, including capability studies of equipment and process(es)	☐	
175	8.3.5 Design and development outputs	↳ manufacturing process flow charts/layout, including linkage of product, process and tooling	☐	
175	8.3.5 Design and development outputs	↳ capacity analysis	☐	
175	8.3.5 Design and development outputs	↳ manufacturing process FMEA	☐	
175	8.3.5 Design and development outputs	↳ maintenance plans and instructions	☐	
175	8.3.5 Design and development outputs	↳ control plan	☐	
175	8.3.5 Design and development outputs	↳ standard work and work instructions	☐	
175	8.3.5 Design and development outputs	↳ process approval acceptance criteria	☐	
175	8.3.5 Design and development outputs	↳ data for quality, reliability, maintainability and measurability	☐	
175	8.3.5 Design and development outputs	↳ results of error-proofing identification and verification, as appropriate	☐	
175	8.3.5 Design and development outputs	↳ methods of rapid detection, feedback and correction of product/manufacturing process nonconformities	☐	
176	8.3.6 Design and development changes	Verify the organization identifies, reviews and controls changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements.		
177	8.3.6 Design and development changes	Verify documented information on design and development changes, the result of reviews, the authorization of changes and the actions taken to prevent adverse impacts are retained.		
178	8.3.6 Design and development changes	Verify organization evaluates design changes after initial product approval		
179	8.3.6 Design and development changes	Verify documented approval or waiver from the customer prior to production implementation (if required)		
180	8.3.6 Design and development changes	Verify revision level of embedded software and hardware		
181	8.4 Control of externally provided processes, products and services	Verify the organization has a documented supplier selection process and it includes:		
181	8.4 Control of externally provided processes, products and services	↳ an assessment of the selected supplier's risk to product conformity and uninterrupted supply of the organization's product to their customers	☐	
181	8.4 Control of externally provided processes, products and services	↳ relevant quality and delivery performance	☐	

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No.	Section	Check Item	Result	Notes / Evidence No.
181	8.4 Control of externally provided processes, products and services	↳ an evaluation of the supplier's QMS	☐	
181	8.4 Control of externally provided processes, products and services	↳ multidisciplinary decision making	☐	
181	8.4 Control of externally provided processes, products and services	↳ an assessment of software development capabilities (if applicable)	☐	
182	8.4 Control of externally provided processes, products and services	Verify "Directed-Buy" external providers meet all requirement		
183	8.4 Control of externally provided processes, products and services	Verify how the organization ensures externally provided processes, products and services conform to specified requirements.		
184	8.4 Control of externally provided processes, products and services	Verify controls applied to externally provided processes, products and services when products and services are intended for incorporation into the organization's own products and services, products and services are provided directly to the customer or a process, or part of a process, is provided by an external provider as a result of a decision by the organization.		
185	8.4 Control of externally provided processes, products and services	Verify how the organization determines and applies criteria for the evaluation, selection, monitoring of performance and re-evaluation of external providers.		
186	8.4 Control of externally provided processes, products and services	Verify documented information of activities and actions arising from the evaluations.		
187	8.4 Control of externally provided processes, products and services	Verify how the organization determines controls applied to the external provision of processes, products and services and the resulting output.		
188	8.4 Control of externally provided processes, products and services	Verify how the organization considers the potential impact of the external provided processes, products and services on its ability to meet customer and applicable statutory and regulatory requirements.		
189	8.4 Control of externally provided processes, products and services	Verify the effectiveness of the controls applied by the external provider.		
190	8.4 Control of externally provided processes, products and services	Verify how the organization determines the verification, or other activities, necessary to ensure the externally provided processes, products and services meet requirements.		
191	8.4 Control of externally provided processes, products and services	Verify the organization has a documented process to identify outsourced processes and to select the types and extent of controls used to verify conformity (shall include criteria and actions to escalate or reduce controls based on supplier performance and assessment of product, material or service risk		
192	8.4 Control of externally provided processes, products and services	Verify the organization has a documented process that purchased products, processes and services conform to the current applicable statutory and regulatory requirements		
193	8.4 Control of externally provided processes, products and services	Verify the organization ensures special controls defined by the customer are implemented and maintained, including at suppliers		
194	8.4 Control of externally provided processes, products and services	Verify supplier's QMS is certified to ISO 9001 with the ultimate objective of becoming certified to IATF 16949		
195	8.4 Control of externally provided processes, products and services	Verify process for software quality assurance for suppliers of automotive product-related software or automotive products with embedded software		
196	8.4 Control of externally provided processes, products and services	Verify organization has documented process and criteria to evaluate supplier performance		

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No.	Section	Check Item	Result	Notes / Evidence No.
197	8.4 Control of externally provided processes, products and services	Verify organization monitors the following supplier performance indicators:		
197	8.4 Control of externally provided processes, products and services	↳ delivered product conformity to requirements	☐	
197	8.4 Control of externally provided processes, products and services	↳ customer disruptions at the receiving plant, including yard holds and stop ships	☐	
197	8.4 Control of externally provided processes, products and services	↳ delivery schedule performance	☐	
197	8.4 Control of externally provided processes, products and services	↳ number of occurrences of premium freight	☐	
197	8.4 Control of externally provided processes, products and services	↳ special status customer notifications related to quality or delivery issues (if provided by customer)	☐	
197	8.4 Control of externally provided processes, products and services	↳ dealer returns, warranty, field actions and recalls (if provided by customer)	☐	
198	8.4 Control of externally provided processes, products and services	Verify the organization has documented the criteria for determining the need, type, frequency and scope of second-party audit		
199	8.4 Control of externally provided processes, products and services	Verify second-party audit reports are retained		
200	8.4 Control of externally provided processes, products and services	Verify inputs to supplier development includes:		
200	8.4 Control of externally provided processes, products and services	↳ performance issues	☐	
200	8.4 Control of externally provided processes, products and services	↳ second-party audit findings	☐	
200	8.4 Control of externally provided processes, products and services	↳ third-part quality management system certification status	☐	
200	8.4 Control of externally provided processes, products and services	↳ risk analysis	☐	
201	8.4 Control of externally provided processes, products and services	Verify the organization communicates to external providers its requirements for:		
201	8.4 Control of externally provided processes, products and services	↳ the processes, products and services to be provided.	☐	
201	8.4 Control of externally provided processes, products and services	↳ the approval of product and services; methods, processes and equipment; and the release of products and services.	☐	
201	8.4 Control of externally provided processes, products and services	↳ competence, including any required qualification of persons.	☐	
201	8.4 Control of externally provided processes, products and services	↳ the external providers' interactions with the organization.	☐	
201	8.4 Control of externally provided processes, products and services	↳ control and monitoring of the external providers' performance to be applied by the organization.	☐	

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No.	Section	Check Item	Result	Notes / Evidence No.
201	8.4 Control of externally provided processes, products and services	└ verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises.	☐	
202	8.4 Control of externally provided processes, products and services	Verify all applicable statutory and regulatory requirements and special product and process characteristics are passed down to suppliers		
203	8.5.1 Control of production and service provision	Verify the organization has documented information that defines the characteristics of the products to be produced, the services to be provided or the activities to be performed and the results to be achieved.		
204	8.5.1 Control of production and service provision	Verify the availability and use of suitable monitoring and measuring resources.		
205	8.5.1 Control of production and service provision	Verify the implementation of monitoring and measuring activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met.		
206	8.5.1 Control of production and service provision	Verify the use of suitable infrastructure and environment for the operation of processes.		
207	8.5.1 Control of production and service provision	Verify the appointment of competent persons, including any required qualification.		
208	8.5.1 Control of production and service provision	Verify the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement.		
209	8.5.1 Control of production and service provision	Verify the implementation of actions to prevent human error (i.e. poke yoke, visual locations, checklist, emergency stops, templates, document control, ...)		
210	8.5.1 Control of production and service provision	Verify the implementation of release, delivery and post-delivery activities.		
211	8.5.1.1 Control Plan	Verify control plans (in accordance with Annex A) include:		
211	8.5.1.1 Control Plan	└ controls used for the manufacturing process control, including verification of job set-ups	☐	
211	8.5.1.1 Control Plan	└ first-off/last-off part validation (as applicable)	☐	
211	8.5.1.1 Control Plan	└ methods for monitoring of control exercised over special characteristics defined by both the customer and the organization	☐	
211	8.5.1.1 Control Plan	└ the customer-required information (if any)	☐	
211	8.5.1.1 Control Plan	└ specified reaction plan (see Annex A)	☐	
212	8.5.1.1 Control Plan	Verify the control plans shall be reviewed and updated:		
212	8.5.1.1 Control Plan	└ if the organization determines it has shipped nonconforming product to the customer	☐	
212	8.5.1.1 Control Plan	└ when any change occurs affecting product, manufacturing process, measurement, logistics, supply sources, production volume changes or risk analysis (FMEA) (see Annex A)	☐	
212	8.5.1.1 Control Plan	└ after a customer complaint and implementation of the associated corrective action (as applicable)	☐	
212	8.5.1.1 Control Plan	└ at a set frequency based on a risk analysis	☐	
213	8.5.1.1 Control Plan	Verify if the customer requires approval of Control Plan after review or revision		
214	8.5.1.2 Standardized work - operator instructions and visual standards	Verify standardized work documents are:		
214	8.5.1.2 Standardized work - operator instructions and visual standards	└ communicated to and understood by the employees who are responsible for performing the work	☐	
214	8.5.1.2 Standardized work - operator instructions and visual standards	└ legible	☐	

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No.	Section	Check Item	Result	Notes / Evidence No.
214	8.5.1.2 Standardized work - operator instructions and visual standards	↳ presented in language(s) understood by personnel who follow them	☐	
214	8.5.1.2 Standardized work - operator instructions and visual standards	↳ accessible for use at the designated work area(s)	☐	
215	8.5.1.2 Standardized work - operator instructions and visual standards	Verify standardized work documents include rules for operator safety		
216	8.5.1.3 Verification of job set-ups / 8.5.1.4 Verification after shutdown	Verify organization verifies job setups		
217	8.5.1.3 Verification of job set-ups / 8.5.1.4 Verification after shutdown	Verify documentation is maintained for set-up personnel		
218	8.5.1.3 Verification of job set-ups / 8.5.1.4 Verification after shutdown	Verify organization uses statistical methods of verification, where applicable		
219	8.5.1.3 Verification of job set-ups / 8.5.1.4 Verification after shutdown	Verify first-off/last-off part validation		
220	8.5.1.3 Verification of job set-ups / 8.5.1.4 Verification after shutdown	Verify records are retained for process and product approval following set-up and first-off/last-off validations		
221	8.5.1.3 Verification of job set-ups / 8.5.1.4 Verification after shutdown	Verify organization ensure compliance with requirements after a planned or unplanned production shutdown period		
222	8.5.1.5 Total productive maintenance	Verify total productive maintenance system is documented and includes:		
222	8.5.1.5 Total productive maintenance	↳ identification of process equipment	☐	
222	8.5.1.5 Total productive maintenance	↳ availability of replacement parts	☐	
222	8.5.1.5 Total productive maintenance	↳ provision of resource for machine, equipment and facility maintenance	☐	
222	8.5.1.5 Total productive maintenance	↳ packaging and preservation of equipment, tooling and gauging	☐	
222	8.5.1.5 Total productive maintenance	↳ applicable customer-specific requirements	☐	
222	8.5.1.5 Total productive maintenance	↳ documented maintenance objectives (i.e. OEE, MTBF, MTTR and preventive maintenance compliance metrics)	☐	
222	8.5.1.5 Total productive maintenance	↳ regular review of maintenance plan and objectives and documented action plan to address corrective actions where objectives are not met	☐	
222	8.5.1.5 Total productive maintenance	↳ use of preventive maintenance methods	☐	
222	8.5.1.5 Total productive maintenance	↳ use of predictive maintenance methods (as applicable)	☐	
222	8.5.1.5 Total productive maintenance	↳ periodic overhaul	☐	

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No.	Section	Check Item	Result	Notes / Evidence No.
223	8.5.1.6 Management of production tooling and manufacturing, test, inspection tooling and equipment	Verify production tooling management system (customer-owned or organization-owned) includes:		
223	8.5.1.6 Management of production tooling and manufacturing, test, inspection tooling and equipment	↳ maintenance and repair facilities and personnel	☐	
223	8.5.1.6 Management of production tooling and manufacturing, test, inspection tooling and equipment	↳ storage and recovery	☐	
223	8.5.1.6 Management of production tooling and manufacturing, test, inspection tooling and equipment	↳ set-up	☐	
223	8.5.1.6 Management of production tooling and manufacturing, test, inspection tooling and equipment	↳ tool-change programs for perishable tools	☐	
223	8.5.1.6 Management of production tooling and manufacturing, test, inspection tooling and equipment	↳ tool design modification documentation, including engineering change level of the product	☐	
223	8.5.1.6 Management of production tooling and manufacturing, test, inspection tooling and equipment	↳ tool modification and revision to documentation	☐	
223	8.5.1.6 Management of production tooling and manufacturing, test, inspection tooling and equipment	↳ tool identification, such as serial or asset number; the status, such as production, repair or disposal; ownership; and location	☐	
224	8.5.1.6 Management of production tooling and manufacturing, test, inspection tooling and equipment	Verify customer-owned tools and equipment are permanently marked in a visible location		
225	8.5.1.6 Management of production tooling and manufacturing, test, inspection tooling and equipment	Verify system implemented to monitors these activities		
226	8.5.1.7 Production scheduling	Verify production is scheduled to meet customer orders/demands such as JIT		
227	8.5.1.7 Production scheduling	Verify production scheduling is supported by an information system		
228	8.5.2 Identification and traceability	Verify how organization identifies outputs from the process to ensure conformity.		
229	8.5.2 Identification and traceability	How does the organization identify the status of process outputs.		
230	8.5.2 Identification and traceability	Verify how the organization controls the unique identification of process outputs when traceability is required. Verify documented information of traceability, where required.		

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No.	Section	Check Item	Result	Notes / Evidence No.
231	8.5.2 Identification and traceability	Verify traceability plans:		
231	8.5.2 Identification and traceability	↳ enable the organization to identify nonconforming and/or suspect product	☐	
231	8.5.2 Identification and traceability	↳ enable the organization to segregate nonconforming and/or suspect product	☐	
231	8.5.2 Identification and traceability	↳ ensure the ability to meet the customer and/or regulatory response time requirements	☐	
231	8.5.2 Identification and traceability	↳ ensure documented information is retained in the format (electronic, hardcopy, archive) that enables the organization to meet the response time requirements	☐	
231	8.5.2 Identification and traceability	↳ ensure serialized identification of individual products, if specified by the customer or regulatory standards	☐	
231	8.5.2 Identification and traceability	↳ ensure the identification and traceability requirements are extended to externally provided products with safety/regulatory characteristics	☐	
232	8.5.3 Property belonging to customers or external providers	What care is provided to customers' or external providers' property?		
233	8.5.3 Property belonging to customers or external providers	Verify how the organization identifies, verifies, protects and safeguards customers' or external providers' property which is provided for use or incorporation into the organization's products or services.		
234	8.5.3 Property belonging to customers or external providers	Verify retained documented information for property that is damaged or otherwise found to be unsuitable for use.		
235	8.5.4 Preservation	Verify how the organization ensures preservation of the process outputs to ensure conformity to requirements.		
236	8.5.4 Preservation	Verify organization assesses product in stock, the place/type of storage container and the storage environment at planned intervals		
237	8.5.4 Preservation	Verify organization uses inventory management system to optimize inventory turns over time and ensure stock rotation (i.e. FIFO)		
238	8.5.4 Preservation	Verify obsolete product is controlled similar to that of nonconforming product		
239	8.5.4 Preservation	Verify organization complies with customer requirements for preservation, packaging, shipping and labeling		
240	8.5.5 Post-delivery activities	Verify the organization considers the following to meet post-delivery activities:		
240	8.5.5 Post-delivery activities	↳ statutory and regulatory requirements	☐	
240	8.5.5 Post-delivery activities	↳ potential undesired consequences associated with its products and services	☐	
240	8.5.5 Post-delivery activities	↳ the nature, use and intended lifetime of its products and services	☐	
240	8.5.5 Post-delivery activities	↳ customer requirements	☐	
240	8.5.5 Post-delivery activities	↳ customer feedback	☐	
241	8.5.5 Post-delivery activities	Verify organization has process for communication of information on service concerns to manufacturing, material handling, logistics, engineering and design		
242	8.5.5 Post-delivery activities	Verify the following if a service agreement with the customer exists:		
242	8.5.5 Post-delivery activities	↳ relevant service centers comply with applicable requirements	☐	
242	8.5.5 Post-delivery activities	↳ effectiveness of any special purpose tools or measurement equipment	☐	
242	8.5.5 Post-delivery activities	↳ service personnel are trained in applicable requirements	☐	
243	8.5.6 Control of changes	Verify how the organization reviews and controls changes for production or service provision.		

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No.	Section	Check Item	Result	Notes / Evidence No.
244	8.5.6 Control of changes	Verify retained documented information describing the results of the review of changes, the person(s) authorizing the change and any necessary actions arising from the review.		
245	8.5.6.1 Control of changes - Supplemental	Verify documented process		
246	8.5.6.1 Control of changes - Supplemental	Verify that the organization:		
246	8.5.6.1 Control of changes - Supplemental	↳ defines verification and validation activities	☐	
246	8.5.6.1 Control of changes - Supplemental	↳ validates changes before implementation	☐	
246	8.5.6.1 Control of changes - Supplemental	↳ documents evidence of related risk analysis	☐	
246	8.5.6.1 Control of changes - Supplemental	↳ retains records of verification and validation	☐	
246	8.5.6.1 Control of changes - Supplemental	↳ notifies the customer of any planned product realization changes after the most recent product approval (if required)	☐	
246	8.5.6.1 Control of changes - Supplemental	↳ obtains documented approval, prior to implementation of the change (if required)	☐	
246	8.5.6.1 Control of changes - Supplemental	↳ completes additional verification or identification requirements, such as production trial run and new product validation (if required)	☐	
247	8.5.6.1 Control of changes - Supplemental	Verify production trial run for verification of changes made a supplier		
248	8.5.6.1.1 Temporary change of process controls	Verify organization has a list of primary and approved back-up/alternate process controls		
249	8.5.6.1.1 Temporary change of process controls	Verify alternate method is documented		
250	8.5.6.1.1 Temporary change of process controls	Verify alternate control method is approved internally prior to production implementation and by the customer (if required)		
251	8.5.6.1.1 Temporary change of process controls	Verify alternative control methods are identified in the Control Plan and are reviewed periodically		
252	8.5.6.1.1 Temporary change of process controls	Verify standard work instructions are created for alternative control methods		
253	8.5.6.1.1 Temporary change of process controls	Verify alternative process controls are reviewed on a daily basis (at a minimum)		
254	8.5.6.1.1 Temporary change of process controls	Verify restart verification is documented for a defined period		
255	8.5.6.1.1 Temporary change of process controls	Verify traceability of all product produced with alternative process control devices or processes		
256	8.6 Release of products and services	Verify at appropriate stages product and service requirements have been met.		
257	8.6 Release of products and services	Verify products and services are not released to the customer until the planned arrangements have been satisfactorily completed, unless otherwise approved by relevant authority and, as applicable, by the customer.		
258	8.6 Release of products and services	Verify retained documented information that shows evidence of conformity with acceptance criteria and traceability to person(s) authorizing the release.		
259	8.6 Release of products and services	Verify verification of product and service requirements are documented as specified in the Control Plan		
260	8.6 Release of products and services	Verify a layout inspection and functional inspection is performed per the Control Plan and are available for customer review		
261	8.6 Release of products and services	For appearance items, verify the organizations provides:		
261	8.6 Release of products and services	↳ appropriate resources, including lighting, for evaluation	☐	
261	8.6 Release of products and services	↳ masters for color, grain, gloss, metallic brilliance, texture, distinctness of image (DOI) and haptic technology, as appropriate	☐	
261	8.6 Release of products and services	↳ maintenance and control of appearance masters and evaluation equipment	☐	

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No.	Section	Check Item	Result	Notes / Evidence No.
261	8.6 Release of products and services	↳ verification that personnel making appearance evaluations are competent and qualified	☐	
262	8.6 Release of products and services	For externally provided processes, products, services, verify the organization utilizes one or more of the following methods:		
262	8.6 Release of products and services	↳ receipt and evaluation of statistical data	☐	
262	8.6 Release of products and services	↳ receiving inspection and/or testing, such as sampling based on performance	☐	
262	8.6 Release of products and services	↳ second-party or third-party assessments or audits of supplier sites when coupled with records of acceptable delivered product conformance to requirements	☐	
262	8.6 Release of products and services	↳ part evaluation by a designated laboratory	☐	
262	8.6 Release of products and services	↳ another method agreed with the customer	☐	
263	8.6 Release of products and services	Verify organization confirms and is able to provide evidence that externally provided processes, products and services conform to the latest applicable statutory, regulatory and other requirements in the countries where they are manufactured and in the customer-identified countries of destination, if provided		
264	8.6 Release of products and services	Verify acceptance criteria defined by organization		
265	8.7 Control of nonconforming outputs	Verify that outputs that do not conform to requirements are identified and controlled.		
266	8.7 Control of nonconforming outputs	Verify appropriate action is taken for nonconforming products and services (also include after delivery of product or during/after the provision of services):		
266	8.7 Control of nonconforming outputs	↳ Correction	☐	
266	8.7 Control of nonconforming outputs	↳ Segregation, containment, return or suspension of provision of products and services	☐	
266	8.7 Control of nonconforming outputs	↳ Informing the customer	☐	
266	8.7 Control of nonconforming outputs	↳ Obtaining authorization for acceptance under concession	☐	
267	8.7 Control of nonconforming outputs	Verify conformity to the requirements when nonconforming outputs are corrected.		
268	8.7 Control of nonconforming outputs	Verify retained documented information that describes the nonconformity, describes actions taken, describes any concessions obtained and identifies the authority deciding the action in respect of the nonconformity.		
269	8.7.1.1 Customer authorization for concession - 8.7.1.3 Control of suspect product	Verify concession or deviation permit approved by customer prior to further processing from what is currently approved		
270	8.7.1.1 Customer authorization for concession - 8.7.1.3 Control of suspect product	Verify organization obtains customer authorization prior to further processing for "use as is" and rework dispositions of nonconforming product (including sub-components)		
271	8.7.1.1 Customer authorization for concession - 8.7.1.3 Control of suspect product	Verify records are maintained of expiration date and quantity authorized under concession		
272	8.7.1.1 Customer authorization for concession - 8.7.1.3 Control of suspect product	Verify material shipped under concession is appropriately identified		
273	8.7.1.1 Customer authorization for concession - 8.7.1.3 Control of suspect product	Verify product with unidentified or suspect status is classified and controlled as nonconforming product		

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No.	Section	Check Item	Result	Notes / Evidence No.
274	8.7.1.1 Customer authorization for concession - 8.7.1.3 Control of suspect product	Verify appropriate manufacturing personnel are trained for containment of suspect and nonconforming product		
275	8.7.1.4 Control of reworked product - 8.7.1.5 Control of repaired product	Verify documented process for rework confirmation		
276	8.7.1.4 Control of reworked product - 8.7.1.5 Control of repaired product	Verify instructions for disassembly or rework, including re-inspection and traceability requirements		
277	8.7.1.4 Control of reworked product - 8.7.1.5 Control of repaired product	Verify documented process for repair confirmation		
278	8.7.1.4 Control of reworked product - 8.7.1.5 Control of repaired product	Verify instructions for disassembly or repair, including re-inspection and traceability requirements		
279	8.7.1.4 Control of reworked product - 8.7.1.5 Control of repaired product	Verify documented customer authorization for concession for the product to be repaired		
280	8.7.1.4 Control of reworked product - 8.7.1.5 Control of repaired product	Verify retained documentation on the disposition of rework including quantity, disposition, disposition date and applicable traceability information		
281	8.7.1.6 Customer notification - 8.7.1.7 Nonconforming product disposition	Verify customer is immediately notified if nonconforming product is shipped		
282	8.7.1.6 Customer notification - 8.7.1.7 Nonconforming product disposition	Verify detailed documentation of the event followed initial communication		
283	8.7.1.6 Customer notification - 8.7.1.7 Nonconforming product disposition	Verify documented process for disposition of nonconforming product not subject to rework or repair		
284	8.7.1.6 Customer notification - 8.7.1.7 Nonconforming product disposition	Verify nonconforming product is rendered unusable prior to disposal		
285	9.1 Monitoring, measurement, analysis and evaluation	Verify the organization has determined what needs to be monitored and measured, the methods to be used, when it will be performed, analyzed and evaluated.		
286	9.1 Monitoring, measurement, analysis and evaluation	Verify the organization evaluates the performance and effectiveness of its QMS.		
287	9.1 Monitoring, measurement, analysis and evaluation	Review retained appropriate documented information		
288	9.1 Monitoring, measurement, analysis and evaluation	Verify the organization performs process studies on all new manufacturing processes to verify process capability		
289	9.1 Monitoring, measurement, analysis and evaluation	Verify the organization's adherence to:		
289	9.1 Monitoring, measurement, analysis and evaluation	^L measurement techniques	□	

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No.	Section	Check Item	Result	Notes / Evidence No.
289	9.1 Monitoring, measurement, analysis and evaluation	↳ sampling plans	☐	
289	9.1 Monitoring, measurement, analysis and evaluation	↳ acceptance criteria	☐	
289	9.1 Monitoring, measurement, analysis and evaluation	↳ records of actual measurement values and/or test results for variable data	☐	
289	9.1 Monitoring, measurement, analysis and evaluation	↳ reaction plans and escalation process when acceptance criteria are not met	☐	
290	9.1 Monitoring, measurement, analysis and evaluation	Verify significant process events (i.e. tool change, machine repair) are retained documented information		
291	9.1 Monitoring, measurement, analysis and evaluation	Verify reaction plans created for processes that are either not statistically capable or are unstable. Reaction plans shall include containment of product and 100% inspection (as appropriate)		
292	9.1 Monitoring, measurement, analysis and evaluation	Verify records of effective dates of process changes		
293	9.1 Monitoring, measurement, analysis and evaluation	Verify that organization has determined the appropriate use of statistical tools		
294	9.1 Monitoring, measurement, analysis and evaluation	Verify statistical concepts are understood and used by employees involved in the collection, analysis and management of statistical data		
295	9.1 Monitoring, measurement, analysis and evaluation	Verify the organization monitors customers' perceptions and satisfaction based on performance indicators that include but not limited to:		
295	9.1 Monitoring, measurement, analysis and evaluation	↳ delivered part quality performance	☐	
295	9.1 Monitoring, measurement, analysis and evaluation	↳ customer disruptions	☐	
295	9.1 Monitoring, measurement, analysis and evaluation	↳ field returns, recalls and warranty (where applicable)	☐	
295	9.1 Monitoring, measurement, analysis and evaluation	↳ delivery schedule performance (including incidents of premium freight)	☐	
295	9.1 Monitoring, measurement, analysis and evaluation	↳ customer notifications related to quality or delivery issues, including special status	☐	
296	9.1 Monitoring, measurement, analysis and evaluation	Verify organization monitors customer portals and customer scorecards (where provided)		
297	9.1 Monitoring, measurement, analysis and evaluation	Verify the organization analyzes and evaluates:		
297	9.1 Monitoring, measurement, analysis and evaluation	↳ conformity of products and services.	☐	
297	9.1 Monitoring, measurement, analysis and evaluation	↳ the degree of customer satisfaction.	☐	
297	9.1 Monitoring, measurement, analysis and evaluation	↳ the performance and effectiveness of the QMS.	☐	

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No.	Section	Check Item	Result	Notes / Evidence No.
297	9.1 Monitoring, measurement, analysis and evaluation	↳ if planning has been implemented effectively.	☐	
297	9.1 Monitoring, measurement, analysis and evaluation	↳ the effectiveness of actions taken to address risks and opportunities.	☐	
297	9.1 Monitoring, measurement, analysis and evaluation	↳ the performance of external providers.	☐	
297	9.1 Monitoring, measurement, analysis and evaluation	↳ the need for improvements the the QMS.	☐	
298	9.1 Monitoring, measurement, analysis and evaluation	Verify organization compares trends in quality and operational performance with progress toward objectives and leads to improving customer satisfaction		
299	9.2 Internal audit	Verify internal audit process is documented		
300	9.2 Internal audit	Verify audits are conducted at planned intervals		
301	9.2 Internal audit	Verify organization has established, implemented, and maintains an internal audit program		
302	9.2 Internal audit	Verify the importance of the process, changes affecting the organization and the results of previous audits are considered		
303	9.2 Internal audit	Verify audit criteria and scope are created for each audit		
304	9.2 Internal audit	Auditors are objective and impartial		
305	9.2 Internal audit	Audit results reported to relevant management		
306	9.2 Internal audit	Verify appropriate correction and corrective actions are taken without delay		
307	9.2 Internal audit	Review retained documented information		
308	9.2 Internal audit	Verify QMS processes are audited over three-year calendar period		
309	9.2 Internal audit	Verify manufacturing processes are audited over three-year calendar period		
310	9.2 Internal audit	Verify all shifts are audited		
311	9.2 Internal audit	Verify products are audited using customer-specific required approaches		
312	9.3 Management review (go through entire standard and add to inputs)	Verify management reviews QMS at least annually		
313	9.3 Management review (go through entire standard and add to inputs)	Verify inputs to management review includes:		
313	9.3 Management review (go through entire standard and add to inputs)	↳ status of actions from previous management reviews	☐	
313	9.3 Management review (go through entire standard and add to inputs)	↳ changes in external and internal issues relevant to the QMS	☐	
313	9.3 Management review (go through entire standard and add to inputs)	↳ customer satisfaction and feedback from relevant interested parties	☐	
313	9.3 Management review (go through entire standard and add to inputs)	↳ the extent to which quality objectives have been met	☐	
313	9.3 Management review (go through entire standard and add to inputs)	↳ process performance and conformity of products and services	☐	
313	9.3 Management review (go through entire standard and add to inputs)	↳ nonconformities and corrective actions	☐	
313	9.3 Management review (go through entire standard and add to inputs)	↳ monitoring and measurement results	☐	
313	9.3 Management review (go through entire standard and add to inputs)	↳ audit results	☐	

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No.	Section	Check Item	Result	Notes / Evidence No.
313	9.3 Management review (go through entire standard and add to inputs)	↳ effectiveness of the audit program	☐	
313	9.3 Management review (go through entire standard and add to inputs)	↳ the performance of external providers	☐	
313	9.3 Management review (go through entire standard and add to inputs)	↳ adequacy of resources	☐	
313	9.3 Management review (go through entire standard and add to inputs)	↳ effectiveness of actions taken to address risks and opportunities	☐	
313	9.3 Management review (go through entire standard and add to inputs)	↳ opportunities for improvement	☐	
313	9.3 Management review (go through entire standard and add to inputs)	↳ cost of poor quality (cost of internal and external nonconformance)	☐	
313	9.3 Management review (go through entire standard and add to inputs)	↳ measures of process effectiveness	☐	
313	9.3 Management review (go through entire standard and add to inputs)	↳ measures of process efficiency	☐	
313	9.3 Management review (go through entire standard and add to inputs)	↳ product conformity	☐	
313	9.3 Management review (go through entire standard and add to inputs)	↳ assessments of manufacturing feasibility made for changes to existing operations and for new facilities or new product	☐	
313	9.3 Management review (go through entire standard and add to inputs)	↳ review of performance against maintenance objectives	☐	
313	9.3 Management review (go through entire standard and add to inputs)	↳ warranty performance (where applicable)	☐	
313	9.3 Management review (go through entire standard and add to inputs)	↳ review of customer scorecards (where applicable)	☐	
313	9.3 Management review (go through entire standard and add to inputs)	↳ identification of potential field failures identified through risk analysis (such as FMEA)	☐	
313	9.3 Management review (go through entire standard and add to inputs)	↳ actual field failures and their impact on safety or the environment	☐	
314	9.3 Management review (go through entire standard and add to inputs)	Verify outputs to management review includes:		
314	9.3 Management review (go through entire standard and add to inputs)	↳ opportunities for improvement	☐	
314	9.3 Management review (go through entire standard and add to inputs)	↳ any need for changes to the QMS	☐	
314	9.3 Management review (go through entire standard and add to inputs)	↳ resource needs	☐	
314	9.3 Management review (go through entire standard and add to inputs)	↳ action plan when customer performance targets are not met	☐	

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No.	Section	Check Item	Result	Notes / Evidence No.
315	9.3 Management review (go through entire standard and add to inputs)	Verify retained documented information		
316	10.1 General	Verify the organization determines and selects opportunities for improvement to improve products and services, corrects, prevents or reduces undesired effects and improves the performance and effectiveness of the QMS.		
317	10.2 Nonconformity and corrective action	Verify how organization reacts to nonconformity, including complaints, by evaluating how its takes action to control and correct it and how it deals with the consequences.		
318	10.2 Nonconformity and corrective action	Verify how the organization evaluates the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere.		
319	10.2 Nonconformity and corrective action	Verify how organization implements necessary actions.		
320	10.2 Nonconformity and corrective action	Verify how organization evaluates the effectiveness of actions taken.		
321	10.2 Nonconformity and corrective action	Verify the organization updates risks and opportunities determined during planning, if necessary.		
322	10.2 Nonconformity and corrective action	Verify any changes made to the QMS, if necessary.		
323	10.2 Nonconformity and corrective action	Verify retained documented information that provides evidence of the nature of the nonconformity and any subsequent actions taken and the results of any corrective actions		
324	10.2.3 Problem solving	Verify that the organization has documented process for problem solving including:		
324	10.2.3 Problem solving	↳ defined approaches for various types and scales of problems	☐	
324	10.2.3 Problem solving	↳ containment, interim actions and related activities necessary for controlling nonconforming outputs	☐	
324	10.2.3 Problem solving	↳ root cause analysis, methodology used, analysis and results	☐	
324	10.2.3 Problem solving	↳ implementation of systemic corrective actions, including consideration of the impact on similar processes and products	☐	
324	10.2.3 Problem solving	↳ verification of the effectiveness of implemented corrective actions	☐	
324	10.2.3 Problem solving	↳ reviewing and updating appropriate documented information (where necessary)	☐	
325	10.2.4 Error-proofing	Verify documented process to determine the use of appropriate error-proofing methodologies		
326	10.2.4 Error-proofing	Verify details of error-proofing method used is documented in the process risk analysis (PFMEA) and test frequencies documented in the Control Plan		
327	10.2.4 Error-proofing	Verify records of testing of error-proofing devices		
328	10.2.4 Error-proofing	Verify challenge parts are identified, controlled, verified and calibrated (where feasible)		
329	10.2.4 Error-proofing	Verify reaction plans for error-proofing device failures		
330	10.2.5 Warranty management systems - 10.2.6 Customer complaints and field failure test analysis	Verify warranty management process (if required)		
331	10.2.5 Warranty management systems - 10.2.6 Customer complaints and field failure test analysis	Verify method for warranty part analysis, including NTF (no trouble found)		
332	10.2.5 Warranty management systems - 10.2.6 Customer complaints and field failure test analysis	Verify that the organization has performed analysis on customer complaints and field failures (include embedded software)		

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No.	Section	Check Item	Result	Notes / Evidence No.
333	10.2.5 Warranty management systems - 10.2.6 Customer complaints and field failure test analysis	Verify problem solving and corrective action initiated		
334	10.2.5 Warranty management systems - 10.2.6 Customer complaints and field failure test analysis	Verify the organization communicates the results of testing/analysis to the customer and also within the organization		
335	10.3 Continual improvement	Verify how the organization continually improves. Does it consider the results of analysis and evaluation and the outputs from management review to determine if there are needs or opportunities that shall be addressed as part of continual improvement?		
336	10.3 Continual improvement	Verify that the organization's documented process for continual improvement includes:		
336	10.3 Continual improvement	↳ identification of methodology used, objectives, measurement, effectiveness and documented information	☐	
336	10.3 Continual improvement	↳ a manufacturing process improvement action plan with emphasis on the reduction of process variation and waste	☐	
336	10.3 Continual improvement	↳ risk analysis (such as FMEA)	☐	
		【表格】 IATF 16949:2016 Risk Assessment Register		
	10.3 Continual improvement	Table		
	10.3 Continual improvement	Process		
	10.3 Continual improvement	Risk Title		
	10.3 Continual improvement	Risk Category		
337	10.3 Continual improvement	Issue Type		
	10.3 Continual improvement	Interested Party		
	10.3 Continual improvement	Impact		
	10.3 Continual improvement	Existing Controls		
338	10.3 Continual improvement	Risk Level		
339	10.3 Continual improvement	Action required?		
	10.3 Continual improvement	Action Summary		
	10.3 Continual improvement	Owner		
	10.3 Continual improvement	Target Date		
340	10.3 Continual improvement	Status		
341	10.3 Continual improvement	Residual Risk		
	10.3 Continual improvement	Review Date		
	Sign Off	I, the undersigned, have completed this IATF 16949:2016 audit in an accurate manner. I have attached evidence as required and declare this audit complete.		

IATF 16949:2016 Audit — Scoring & Sign-off

Sign-off

Full name and signature of auditor	
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