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<tr>
<td>4.1.1</td>
<td>Determining the scope of the quality management system – supplemental 1.1 and 1.2</td>
<td></td>
<td>Supporting functions, whether on-site or remote (such as design centres, corporate headquarters and distribution centres), shall be included in the scope of the Quality Management System (QMS). The only permitted exclusion for this Automotive QMS Standard relates to the product design and development requirements within Section 8.3. The exclusion shall be justified and maintained as documented information (see Section 7.5). Permitted exclusions do not include manufacturing process design.</td>
<td>... Supporting functions, whether on-site or remote (such as design centres, corporate headquarters and distribution centres), form part of the site audit as they support the site, but cannot obtain stand-alone certification to this Technical Specification. ... The only permitted exclusions for this Technical Specification relate to 7.3 where the organization is not responsible for product design and development. Permitted exclusions do not include manufacturing process design.</td>
<td>These requirements were originally included in ISO/TS 16949:2009 Sections 1.1 and 1.2. The first requirement was slightly revised to not only address the need to include supporting functions in the audit, but also to ensure that the supporting functions are also included in the scope of the QMS.</td>
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<tr>
<td>4.3.2</td>
<td>Customer-specific requirements</td>
<td>throughout</td>
<td>Customer-specific requirements shall be evaluated and included in the scope of the organization’s quality management system.</td>
<td>Reference to customer-specific requirements were throughout ISO/TS 16949, not as a specific section.</td>
<td>Although the need to fulfill and satisfy customer-specific requirements was already mentioned throughout the whole ISO/TS 16949 document, this requirement specifically addresses the need to evaluate the customer specific requirements and include them where applicable in the organization’s quality management system.</td>
</tr>
<tr>
<td>4.4.1.1</td>
<td>Conformance of products and processes</td>
<td>throughout</td>
<td>The organization shall ensure conformance of all products and processes, including service parts and those that are outsourced, to all applicable customer, statutory, and regulatory requirements (see Section 8.4.2.2).</td>
<td>Reference to products and processes throughout ISO/TS 16949, not a specific section.</td>
<td>This requirement was adopted based on survey feedback. It ensures two things: that the organization is responsible for the conformity of outsourced processes and that all products and processes meet the requirements and expectations of all interested parties.</td>
</tr>
<tr>
<td>4.4.1.2</td>
<td>Product safety 6.4.1</td>
<td></td>
<td>The organization shall have documented processes for the management of product-safety related products and manufacturing-processes, which shall include but not be limited to the following where applicable: a) identification by the organization of statutory and regulatory product-safety requirements; b) customer notification of requirements in item a; i) special approvals for design FMEA; d) identification of product-safety related characteristics; e) identification and controls of safety related characteristics of product and at the point of manufacture; f) special approval of control plans and process FMEAs; g) reaction plans (see Section 9.1.1.1); h) defined responsibilities, definition of escalation process and flow of information, including top management, and customer notification; i) training identified by the organization or customer for personnel involved in product-safety related products and associated manufacturing processes; j) changes of product or process shall be approved prior to implementation, including evaluation of potential effects on product safety from process and product changes (see Section 8.3.5); k) transfer of requirements with regard to product safety throughout the supply chain, including customer-designated sources (see Section 8.4.3.1); l) product traceability by manufactured lot (at a minimum) throughout the supply chain (see Section 8.5.2.1); m) lessons learned for new product introduction. <strong>NOTE:</strong> Special approval is an additional approval by the function (typically the customer) that is responsible to approve such documents with safety-related content.</td>
<td>While product safety was briefly mentioned in Section 6.4.1 of ISO/TS 16949, IATF 16949 greatly expands the intent of product safety in Section 4.4.1.2.</td>
<td>This is a new section with new and enhanced requirements that address current and emerging issues the automotive industry is facing related to product and process safety. The list of items a) thru n) requires that the organization addresses them in a documented and dedicated process for the management of product-safety related products and manufacturing processes.</td>
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### IATF 16949:2016 Section 5.1.1.1 Corporate responsibility

<table>
<thead>
<tr>
<th>Former ISO/TS 16949:2009 Section Number</th>
<th>Wording</th>
<th>ISO/TS 16949 Wording (if applicable)</th>
<th>Rationale for Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.1.1.1</td>
<td>Corporate responsibility not included</td>
<td>The organization shall define and implement corporate responsibility policies, including at a minimum an anti-bribery policy, an employee code of conduct, and an ethics escalation policy (&quot;whistle-blowing policy&quot;).</td>
<td>Corporate responsibility was not included in ISO/TS 16949. ISO 9001:2015 expanded the ISO 9001:2008 concept of Management Responsibility and Commitment into a set of leadership behaviors to ensure an effective Quality Management System. The IATF supplemented the ISO requirements by adopting a Corporate Responsibility requirement to address increasing market and governmental expectations for improved integrity in social and environmental matters.</td>
</tr>
</tbody>
</table>

### IATF 16949:2016 Section 5.1.1.2 Process effectiveness and efficiency

| 5.1.1 | Top management shall review the product realization processes and support processes to evaluate and improve their effectiveness and efficiency. The results of the process review activities shall be included as input to the management review (see Section 9.3.2.1). | Top management shall review the product realization processes and the support processes to assure their effectiveness and efficiency. | The requirement to review the processes to ensure effectiveness and efficiency was covered in ISO/TS 16949, Section 5.1.1. Based on the IATF survey feedback, the IATF strengthened the requirement to ensure that the results of the review are now to be included in the management review. |

### IATF 16949:2016 Section 5.1.1.3 Process owners

| 5.1.1.3 | Process owners not included | Top management shall identify process owners who are responsible for managing the organization’s processes and related outputs. Process owners shall understand their roles and be competent to perform those roles (see Section 7.2). | Process owners were not called out in ISO/TS 16949. ISO/TS 16949:2009 addressed management responsibility and authority, but it did not explicitly mention that management ensure process owners understand their role and are competent. The IATF adopted this requirement to ensure that management understands this expectation. |

### IATF 16949:2016 Section 5.3.1 Organisational roles, responsibilities, and authorities – supplemental

| 5.3.1.1 | Top management shall assign personnel with the responsibility and authority to ensure that customer requirements are met. These assignments shall be documented. This includes, but is not limited to, the selection of special characteristics, setting quality objectives and related training, corrective and preventive actions, product design and development, capacity analysis, logistics information, customer scorecards, and customer portals. | Top management shall designate personnel with responsibility and authority to ensure that customer requirements are addressed. This includes selection of special characteristics, setting quality objectives and related training, corrective and preventive actions, product design and development. | This requirement was already part of ISO/TS 16949:2009. However based on IATF survey feedback, the IATF adopted some modifications to the requirement to address the need to document assigned personnel responsibilities and authorities. Additionally, clarifying that the goal is not just to address customer requirements but to meet customer requirements fully. |

### IATF 16949:2016 Section 5.3.2 Responsibility and authority for product requirements and corrective actions

<p>| 5.3.2.1 | Top management shall ensure that: a) personnel responsible for conformity to product requirements have the authority to stop shipment and stop production to correct quality problems; NOTE: Due to the process design in some industries, it might not always be possible to stop production immediately. In this case, the affected batch must be contained and shipment prevented. b) personnel with authority and responsibility for corrective action are promptly informed of products or processes that do not conform to requirements; this includes selection of special characteristics, setting quality objectives and related training, corrective and preventive actions, product design and development. c) production operations across all shifts are staffed with personnel in charge of, or delegated responsibility for, ensuring conformity to product requirements. | Managers with responsibility and authority for corrective action shall be promptly informed of products or processes which do not conform to requirements. Personnel responsible for conformity to product requirements shall have the authority to stop production to correct quality problems. Production operations across all shifts shall be staffed with personnel in charge of, or delegated responsibility for, ensuring conformity to product requirements. | The IATF adopted some enhancements to the requirement originally included in ISO/TS 16949 based on IATF survey feedback to address the need to explicitly make Top Management responsible for ensuring conformity to product requirements and to corrective actions taken. |</p>
<table>
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<tr>
<th>IATF 16949:2016 Section Number</th>
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<tr>
<td>6.1.2.1</td>
<td>5.4.1.1</td>
<td>The organization shall include in its risk analysis, at a minimum, lessons learned from product recalls, product audits, field returns and repairs, complaints, scrap, and rework. The organization shall retain documented information as evidence of the results of risk analysis.</td>
<td>Reference to risk analysis was in Section 7.2.2.2 of ISO/TS 16949, however, risk analysis was not a specific section.</td>
<td>The need to identify, analyze, and consider actual and potential risks was already covered in various areas of ISO/TS 16949. The IATF adopted the additional requirements for risk analysis recognizing the continual need to analyze and respond to risk and to have organizations consider specific risks associated with the automotive industry.</td>
</tr>
<tr>
<td>6.1.2.2</td>
<td>6.1.2.3</td>
<td>Preventive action</td>
<td>The organization shall determine and implement action(s) to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the severity of the potential issues. The organization shall establish a process to lessen the impact of negative effects of risk including the following: a) determining potential nonconformities and their causes; b) evaluating the need for action to prevent occurrence of nonconformities; c) determining and implementing action needed; d) documented information of action taken; e) reviewing the effectiveness of the preventive action taken.</td>
<td>Preventive action was in the ISO 9001:2008 portion of ISO/TS 16949. The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems. A documented procedure shall be established to define requirements for a) determining potential nonconformities and their causes, b) evaluating the need for action to prevent occurrence of nonconformities, c) determining and implementing action needed, d) records of results of action taken (see 4.2.4), and e) reviewing the effectiveness of the preventive action taken.</td>
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<tr>
<td>6.1.2.3</td>
<td>5.4.1.1</td>
<td>Contingency plans</td>
<td>The organization shall: a) identify and evaluate internal and external risks to all manufacturing processes and infrastructure equipment essential to maintain production output and to ensure that customer requirements are met; b) define contingency plans according to risk and impact to the customer; c) prepare contingency plans for continuity of supply in the event of any of the following: key equipment failures (also see Section 8.5.6.1.1); interruption from externally provided products, processes, and services; recurring natural disasters; fire; utility interruptions; labour shortages; or infrastructure disruptions; d) include, as a supplement to the contingency plans, a notification process to the customer and other interested parties for the extent and duration of any situation impacting customer operations; e) periodically test the contingency plans for effectiveness (e.g., simulations, as appropriate); f) conduct contingency plan reviews (at a minimum annually) using a multidisciplinary team including top management, and update as required; g) document the contingency plans and retain documented information describing any revision(s), including the person(s) who authorized the change(s).</td>
<td>The organization shall prepare contingency plans to satisfy customer requirements in the event of an emergency such as utility interruptions, labour shortages, key equipment failure and field returns.</td>
</tr>
<tr>
<td>6.2.2.1</td>
<td>5.4.1.1</td>
<td>Quality objectives and planning to achieve them – supplemental</td>
<td>Top management shall ensure quality objectives to meet customer requirements are defined, established, and maintained for relevant functions, processes, and levels throughout the organization. The results of the organization’s review regarding interested parties and their relevant requirements shall be considered when the organization establishes its annual (at a minimum) quality objectives and related performance targets (internal and external).</td>
<td>Top management shall define quality objectives and measurements that shall be included in the business plan and used to deploy the quality policy. Quality objectives should address customer expectations and be achievable within a defined time period.</td>
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### Notes
- **Preventive action**
  - The IATF enhanced the requirement found in ISO/TS 16949 by comprehending what is considered to be best practice in the automotive industry. The expanded requirement ensures the organization defines and prepares contingency plans along with a notification process to the customer or other interested parties.

- **Contingency plans**
  - The organization shall prepare contingency plans to satisfy customer requirements in the event of an emergency such as utility interruptions, labour shortages, key equipment failure and field returns.

- **Quality objectives and planning to achieve them – supplemental**
  - Top management shall define quality objectives and measurements that shall be included in the business plan and used to deploy the quality policy. Quality objectives should address customer expectations and be achievable within a defined time period.
### 7.1.3 Plant, facility, and equipment planning

#### 7.1.3.1 Calibration/verification records

The organization shall have a documented process for developing and improving plant, facility, and equipment plans. In designing plant layouts, the organization shall:

- Optimize material flow, material handling, and value-added use of floor space including control of non-conforming product, and
- Facilitate a synchronized material flow, as applicable.

Methods shall be developed and implemented to evaluate manufacturing feasibility for new product or new operation. Manufacturing feasibility assessments shall include capacity planning. These methods shall also be applicable for evaluating proposed changes to existing operations. The organization shall maintain process effectiveness, including periodic re-evaluation relative to risk, to incorporate any changes made during process approval, control plan maintenance (see Section 8.1.1.1), and verification of job set-up (see Section 8.1.1.2).

Assessments of manufacturing feasibility and evaluation of capacity planning shall be inputs to management reviews (see Section 9.2).

**NOTE 1**: These requirements should include the application of lean-manufacturing principles.

**NOTE 2**: Three requirements should apply to on-site supplier activities, as applicable.

- Records of calibration/verification activity for all gauges and measuring and test equipment (including employee-owned equipment relevant for measuring, customer-owned equipment, or on-site supplier-owned equipment) needed to provide evidence of conformity to internal requirements, legislative, and regulatory requirements, and customer defined requirements shall be retained.

The organization shall ensure that calibration/verification activities and records include the following details:

- Revisions following engineering changes that impact measurement systems;
- Any use of specification rounding or round-off for calibration/verification;
- An assessment of the risk of the intended use of the product caused by the out of specification condition;
- 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, documented information on the validity of previous measurement results obtained with this piece of inspection measurement and test equipment shall be retained, including the associated standards test calibration date and the next due date on the calibration report, notification to the customer if suspect product or material has been shipped, statements of conformity after calibration/verification, and notification to the customer if suspect product or material has been shipped.

### 7.1.4 Environment for the operation of processes—supplementary

#### 7.1.4.1 Measurement system analysis

**NOTE**: Prioritization of MSA studies should focus on critical or special product or process characteristics.

- If the organization shall have a documented process for managing calibration/verification, records of the calibration/verification activity for all gauges and measuring and test equipment (including employee-owned equipment relevant for measuring, customer-owned equipment, or on-site supplier-owned equipment) needed to provide evidence of conformity to determined requirements, including software installed on employee-owned or customer-owned equipment.

- The organization shall have a documented process for developing and improving plant, facility, and equipment plans. The laboratory shall specify and implement a methodology to verify measurement system capability, and ensure that customer requirements are met, enhanced calibration/verification record retention requirements, including software installed on employee-owned or customer-owned equipment.

### 7.1.5.1 Internal laboratory

**NOTE**: An organization's internal laboratory facility shall have a defined scope that includes its capability to perform the required inspection, test, or calibration services. The laboratory scope shall be included in the quality management system documentation. The laboratory shall specify and implement, as a minimum, requirements for:

- Adequacy of the laboratory technical procedure;
- Competency of the laboratory personnel;
- Testing of the product;
- Capability to perform these services correctly, traceable to the relevant process standard (such as ASTM, EN, etc., when no national or international standard(s) is/are available, the organization shall define and implement a methodology to verify measurement system capability;)
- Customer requirements, if any;
- Review of the system records.

**NOTE**: Third-party accreditations to AS/EN/ISO 17025 (or equivalent) may be used to demonstrate the organization's in-house laboratory conformity to this requirement.

**NOTE**: Added requirement to have the organization (client) define a methodology to verify measurement system capability if no national or international standard(s) exist.
7.1.5.2 External laboratory

7.6.2.2 Internal/Commercial/Independent laboratory facilities used for inspection, test, or calibration services by the organization shall have a defined laboratory scope that includes the capability to perform the required inspection, test, or calibration, and either:
- the laboratory shall be accredited to ISO/IEC 17025 or national equivalent; and include the relevant inspection, test, or calibration service in the scope of the accreditation (certificate); the certificate of calibration or test report shall include the mark of national accreditation body, or
- there shall be evidence that the external laboratory is acceptable to the customer.
NOTE: Such evidence may be demonstrated by customer assessment, for example, by customer-approved second-party assessment that the laboratory meets the intent of ISO/IEC 17025 or national equivalent.

The second-party assessment may be the organization assessing the laboratory using a customer-supplied method of assessment. Calibration services may be performed by the equipment manufacturer when a qualified laboratory is not available for a given piece of equipment. In such cases, the organization shall ensure that the requirements listed in Section 7.1.5.1 have been met. Use of calibration services, other than by qualified (or customer accepted) laboratories, may be subject to customer regulatory confirmation, if required.

NOTE 1: Such evidence may be demonstrated by customer assessment, for example, by customer-approved second-party assessment that the laboratory meets the intent of ISO/IEC 17025 or national equivalent.

NOTE 2: When a qualified laboratory is not available for a given piece of equipment, calibration services may be performed by the equipment manufacturer. In such cases, the organization should ensure that the requirements listed in 7.6.2.1 have been met.

The organization shall have internal auditors who are qualified to audit the requirements of this technical specification (see 6.2.2.2). Enhanced requirements for the organization’s internal auditor competency requirements to ensure a more robust internal audit process.

7.2.1 Competence - supplemental

7.2.1.2 The organization shall establish and maintain documented procedures for identifying training needs and achieving competence of all personnel performing activities affecting conformity to product and process requirements. Personnel performing specific assigned tasks shall be qualified, as required, with particular attention to the satisfaction of customer requirements.

The organization shall provide the on-the-job training for personnel in any new or modified job affecting conformity to product requirements, including contract or agency personnel. Personnel whose work can affect quality shall be informed about the consequences of nonconformity to quality requirements.

Enhanced emphasis of on-the-job training and its importance in meeting customer requirements, including customer-interested parties.

7.3.2 Competence - on-the-job training

7.3.2.2 The organization shall provide the on-the-job training (which shall include customer requirements training) for personnel in any new or modified responsibilities affecting conformity to quality requirements, internal requirements, regulatory or legislative requirements; this shall include contractor or agency personnel. The level of detail required for on-the-job training shall be commensurate with the level of education the personnel possess and the complexity of the tasks they are required to perform for their daily work. Persons whose work can affect quality shall be informed about the consequences of nonconformity to quality requirements.

Additionally, manufacturing process auditors shall demonstrate technical understanding of the relevant manufacturing processes to be audited, including process risk analysis (such as FMEA) and control plan. Product auditors shall demonstrate competence in understanding product requirements and use of relevant measuring and test equipment to verify product conformity. Where training is provided to achieve competency, documented information shall be retained to demonstrate the trainer’s competency with the above requirements. Maintenance of and improvement in internal auditor competence shall be demonstrated through:
- a) executing a minimum number of audits per year, as defined by the organization; and
- b) maintaining knowledge of relevant requirements based on internal and external changes (e.g., process, technology, product technology) and external changes (e.g., ISO 9001, IATF 16949 core tools, and customer specific requirements).

7.2.4 Second-party auditor competency

7.2.4.2 The organization shall demonstrate the competence of the auditors undertaking the second-party audits. Second-party auditors shall meet customer-specific requirements for auditor qualification and demonstrate the minimum following core competencies, including understanding of:
- a) the automotive process approach to auditing, including risk-based thinking;
- b) applicable customer-organization specific requirements;
- c) applicable ISO 9001 and IATF 16949 requirements related to the scope of the audit;
- d) applicable manufacturing processes to be audited, including FMEA and control plan;
- e) applicable core tool requirements related to the scope of the audit;
- f) the use of the audit plan, conduct, prepare audit reports, and close-out audit findings.

Second-party auditor competency was not included in ISO/TS 16949.

New requirements for second-party auditors to meet in order to be properly qualified to conduct those types of audits with customer-specific requirements being a main focus.

7.3.1 Awareness - supplemental

7.3.1.2 The organization shall maintain documented information that demonstrates all employees are aware of their impact on product quality and the importance of their activities in achieving, maintaining, and improving quality, including customer requirements and the risks involved for the customer with non-conforming product.

The organization shall have a process to measure the extent to which its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives (see 6.2.2). The organization shall have a process to motivate employees to achieve quality objectives, to make continual improvements, and to create an environment that promotes innovation. The process shall include the promotion of quality and technological awareness throughout the whole organization.

Additional requirements to ensure all employees are aware of their impact on the organization’s success in product quality, customer-specific requirements, and risks involved for the customer with non-conforming product.

7.3.2 Employee motivation and empowerment

7.3.2.2 The organization shall maintain documented procedures for motivating employees to achieve quality objectives, to make continual improvements, and to create an environment that promotes innovation. The process shall include the promotion of quality and technological awareness throughout the whole organization.

Set a major change, just-in-time reprocessing and maintenance of a “documented process” for employee motivation and empowerment.
| 7.5.1.1 | Quality management system documentation | 4.2.2 | The organization’s quality management system shall be documented and include a quality manual, which can be a series of documents (electronic or hard copy). The format and structure of the quality manual is at the discretion of the organization and will depend on the organization's size, culture, and complexity. If a series of documents are used, then a list shall be retained of the documents that compose the quality manual for the organization. The quality manual shall include, at a minimum, the following:
- The scope of the quality management system, including details of and justification for any exclusions;
- Documented processes established for the quality management system, or reference to them;
- The organization’s processes and their sequence and interactions (inputs and outputs), including type and extent of control of any out-sourced processes;
- A document (i.e., matrix) indicating where within the organization’s quality management system their customer-specific requirements are addressed.

**NOTE:** A matrix of how the requirements of this Automotive QMS standard are addressed by the organization’s processes may be used to assist with linkages of the organization’s processes and this Automotive QMS.

The requirement for the organization to have a quality manual was in the ISO 9001:2008 portion of ISO/TS 16949 (Section 4.2.2). The IATF retained the quality manual requirement; however, this can be one main document or a series of multiple documents (hard copy or electronic). Also requires that the organization’s processes and interactions are documented as part of their QMS. |

| 7.5.3.2.1 | Record retention | 4.2.4.1 | The organization shall define, document, and implement a record retention policy. The control of records shall satisfy statutory, regulatory, organizational, and customer requirements. Production part approval, tooling records (including maintenance and ownership), product and process design records, purchase orders (if applicable), or contracts and amendments shall be retained for the length of time that the product is active for production and service requirements, plus one calendar year, unless otherwise specified by the customer or regulatory agency.

**NOTE:** Production part approval documented information may include approved product, applicable test equipment records, or approved test data. |

| 7.5.3.2.2 | Engineering specifications | 4.2.3.1 | The organization shall have a documented process describing the review, distribution, and implementation of all customer engineering standards/specifications and related revisions based on customer schedules, as required. When an engineering standard/specification change results in a product design change, refer to the requirements in Section 8.5.6. When an engineering standard/specification change results in a product realization process change, refer to the requirements in Section 8.5.8. The organization shall maintain a record of the date on which each change is implemented in production. Review should be completed within 50 working days of receipt of notification of engineering standards/specifications changes. A change in these standards/specifications may require an updated record of customer production part approval when these specifications are referenced on the design record or if they affect documents of the production part approval process, such as control plan, risk analysis (such as FMEAs), etc. |

The organization shall have a process to assure the timely review, distribution and implementation of all customer engineering standards/specifications and changes based on customer-required schedule. Timely review should be as soon as possible, and shall not exceed two working weeks. The organization shall maintain a record of the date on which each change is implemented in production. Implementation shall include updated documents. Review should be completed within 10 working days of receipt of notification of engineering standards/specifications changes. A change in these standards/specifications may require an updated record of customer production part approval when these specifications are referenced on the design record or if they affect documents of production part approval process, such as control plan, risk analysis (such as FMEAs), etc. |
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<tr>
<th>AT4 10049:2016 Section Number</th>
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<th>ISO/TS 16949:2009 Section Number</th>
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<th>Wording</th>
<th>Relevant for Change</th>
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<tbody>
<tr>
<td>7.1.1</td>
<td>Operational planning and control — supplemental</td>
<td>7.3.1</td>
<td>When planning for product realization, the following topics shall be included:</td>
<td>Customer requirements and references to its technical specifications shall be included in the planning of product realization as a component of the quality plan.</td>
<td>Enhanced detail to ensure key processes are included and considered when planning for product realization.</td>
</tr>
<tr>
<td>7.1.1</td>
<td>Customer communication — supplemental</td>
<td>7.2.1.1</td>
<td>Written or verbal communication shall be in the language agreed with the customer.</td>
<td>The organization shall have the ability to communicate necessary information, including data, to a customer-designated language or format (e.g. computer-aided design data, electronic data exchange).</td>
<td>Minor editing, no major change in the intent of this section.</td>
</tr>
<tr>
<td>7.2.1 (Note 2 and 3)</td>
<td>Determining the requirements for products and services — supplemental</td>
<td>7.2.1</td>
<td>These requirements shall include recycling, environmental impact, and characteristics identified as a result of the organization's knowledge of the product and manufacturing processes.</td>
<td>Determination of requirements related to the product was in the ISO 9001:2008 portion of ISO/TS 16949 (Section 7.2.1 NOTE 1 and NOTE 2). NOTE 1 Post-delivery activities include any after-sales customer service provided as part of the customer contract or purchase order. NOTE 2 This requirement includes recycling, environmental impact and characteristics identified as a result of the organization’s knowledge of the product and manufacturing processes (see 7.3.2.3).</td>
<td>Strengthened the standard by elevating rules into requirements.</td>
</tr>
<tr>
<td>7.2.2.1</td>
<td>Review of the requirements for products and services — supplemental</td>
<td>7.2.1.1</td>
<td>The organization shall conform to customer requirements for designation, approval documentation, and control of special characteristics.</td>
<td>The organization shall ensure the confidentiality of customer-contracted products and projects and are skilled in applicable product design tools and techniques. Applicable tools and techniques shall be identified by the organization.</td>
<td>Enhanced requirements for manufacturing feasibility analysis.</td>
</tr>
<tr>
<td>7.3.1</td>
<td>Design and development of products and services — supplemental</td>
<td>7.3.1</td>
<td>The requirements of ISO 9001:2015, Section 8.3.1.1, shall apply to product and manufacturing process design and development and shall focus on error prevention rather than detection.</td>
<td>The organization shall ensure that personnel with product design responsibility are competent to achieve design requirements and are skilled in applicable product design tools and techniques. Applicable tools and techniques shall be identified by the organization.</td>
<td>Certification of whether the multi-disciplinary approach is to be used and who should be involved.</td>
</tr>
<tr>
<td>7.3.2</td>
<td>Development of products with embedded software</td>
<td>7.3.2.1</td>
<td>The organization shall use a process for quality assurance for their products with internally developed embedded software. A software development assessment methodology shall be utilized to assess the organization's software development process. Using prioritization based on risk and potential impact to the customer, the organization shall retain documented information of a software development capability self-assessment. The organization shall include software development within the scope of their internal audit programme (see Section 9.2.2.1).</td>
<td>Embedded software was not included in ISO/TS 16949.</td>
<td>Added requirements for organization-responsible embedded software development and software development capability self-assessments.</td>
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6.3.1.1 Product design input

7.3.2.1 The organization shall identify, document, and review product design input requirements as a result of contract review. Product design input requirements include, but are not limited to, the following:

- Product specifications including, but not limited to, special characteristics (see Section 7.3.3.2);
- Boundary and interface requirements;
- Identification, traceability, and packaging;
- Consideration of design alternatives;
- Assessment of risks with the input requirements and the organization's ability to mitigate/manage the risks, including from the feasibility analysis;
- Identification, traceability, and packaging.

7.3.2.2 The organization shall identify, document, and review manufacturing process design input requirements including, but not limited to, the following:

- Product design output data including special characteristics;
- Targets for productivity, process capability, timing, and cost;
- Manufacturing technology alternatives;
- Customer's requirements, if any;
- Experience from previous developments;
- New materials;
- Product handling and ergonomic requirements; and
- Design for manufacturing and design for assembly.

7.3.3 Special characteristics

7.3.2.3 The organization shall use a multidisciplinary approach to establish, document, and implement its process(es) to identify special characteristics, including those determined by the customer and the risk analysis performed by the organization, and shall include the following:

- Documentation of all special characteristics in the drawings, risk analysis (such as FMEA), control plans, and standard work/operator instructions; special characteristics are identified with specific markings and preceded, through each of these documents;
- Development of control and monitoring strategies for special characteristics of products and production processes;
- Customer-specific approvals, when required;
- Compliance with customer-specific definitions and symbols on the organization's equivalent symbols or notations, as defined in a symbols conversion table. The symbols conversion table shall be submitted to the customer, if required.

7.4.1 Monitoring

7.4.1.1 Measurements at specified stages during the design and development of products and processes shall be defined, analyzed, and reported with summary results as an input to management review (see Section 9.3.2.1). When required by the customer, measurements of the product and process development activity shall be reported to the customer at stages specified, or agreed to, by the customer.

7.4.1.2 Measurements at specified stages of design and development shall be defined, analyzed, and reported with summary results as an input to management review. The measurements may include quality risks, costs, lead times, critical paths, and other measurements.

7.4.2 Design and development validation

7.4.2.1 Design and development validation shall be performed in accordance with customer requirements, including any applicable industry and governmental agency-regulated standards. The timing of design and development validation shall be planned in alignment with customer-specified timing, as applicable.

7.4.2.2 When contracted with the customer, the measurements shall be performed in accordance with customer requirements, including programme timing.

7.4.3 Prototype program

7.4.3.2 When required by the customer, the organization shall have a prototype programme and control plan. The organization shall use, whenever possible, the same suppliers, tooling, and manufacturing processes as will be used in production.

7.4.3.3 All performance testing activities shall be monitored for timely completion and conformity to requirements. When services are outsourced, the organization shall include the type and extent of control in the scope of its quality management system to ensure that outsourced services conform to requirements (see ISO 9001:2015, Section 8.4.6). When required by the customer, the organization shall have a prototype programme and control plan. The organization shall use, whenever possible, the same suppliers, tooling, and manufacturing processes as will be used in production.

7.4.4 Product approval process

7.4.4.1 The organization shall establish, implement, and maintain a product and manufacturing process approval procedure conforming to requirements defined by the customer(s). The organization shall approve externally provided products and services per ISO 9001:2015, Section 8.4.3, prior to submission of their part approval to the customer.

7.4.4.2 The organization shall obtain documented product approval prior to shipment, if required by the customer. Records of such approval shall be retained.

7.4.4.3 The organization shall conform to a product and manufacturing process approval procedure recognized by the customer. NOTE: Product approval should be subsequent to the verification of the manufacturing process. The product and manufacturing process approval procedure shall also be applied to suppliers. The organization shall identify, document and review the product design input requirements, including:

- Product specifications including, but not limited to, special characteristics (see Section 7.3.3.2);
- Identification, traceability, and packaging.

7.4.4.4 Use of information: the organization shall have a process to deploy information gained from previous design projects, competitive product analysis (benchmarking), supplier feedback, internal input, field data, and other relevant sources for current and future projects of a similar nature.

NOTE One approach for considering design alternatives is the use of trade-off curves. The organization shall identify special characteristics (see 7.3.3.2) and identify process control documents including drawings, FMEAs, control plans, and operator instructions with the customer's special characteristic symbol or the organization's equivalent symbol or notation to include those process steps that affect special characteristics.

NOTE Special characteristics can include product characteristics and process parameters.

6.3.2 Manufacturing process design input

7.3.2.3 The organization shall obtain documented product approval to the customer. The organization shall approve externally provided products and services per ISO 9001:2015, Section 8.4.3, prior to submission of their part approval to the customer.

7.3.6.1 The organization shall have a process to deploy information gained from previous design projects, competitive product analysis (benchmarking), supplier feedback, internal input, field data, and other relevant sources for current and future projects of a similar nature.

NOTE One approach for considering design alternatives is the use of trade-off curves. The organization shall identify special characteristics (see 7.3.3.2) and identify process control documents including drawings, FMEAs, control plans, and operator instructions with the customer's special characteristic symbol or the organization's equivalent symbol or notation to include those process steps that affect special characteristics.

NOTE Special characteristics can include product characteristics and process parameters.

6.3.3 Special characteristics

7.3.3.2 The organization shall review the manufacturing process design input requirements, including:

- Product design output data, including special characteristics;
- Targets for productivity, process capability, timing, and cost;
- Customer's requirements, if any;
- Experience from previous developments;
- New materials;
- Product handling and ergonomic requirements; and
- Design for manufacturing and design for assembly.

The manufacturing process design shall include the use of error-proofing methods to a degree appropriate to the magnitude of the problems and commensurate with the risks encountered.
3.3.1 Design and development changes - supplemental

The product design output shall be expressed in terms that can be verified and validated against product design input requirements. The product design output shall include, but is not limited to the following, as applicable:
- design risk analysis (for example, FMEA)
- reliability study results
- proof-of-concept prototype
- product special characteristics
- results of product design error-proofing, such as DFSS, DFMA, and FTA
- product definition including 3D models, technical data packages, product manufacturing information, and geometric dimensioning & tolerancing (GD&T)
- 2D drawings, product manufacturing information, and geometric dimensioning & tolerancing (GD&T)
- product design review results
- service diagnostic guidelines and repair and serviceability instructions
- service part requirements
- packaging and labeling requirements for shipping

NOTE: Interim design outputs should include any engineering problems being resolved through a trade-off process.

3.3.2 Manufacturing process design output

The organization shall document the manufacturing process design output in a manner that enables verification against the manufacturing process design inputs. The organization shall verify the outputs against manufacturing process design input requirements. The manufacturing process design output shall include, but is not limited to the following:
- specifications and drawings
- special characteristics for product and manufacturing process
- identification of process input variables that impact characteristics
- tooling and equipment for production and control, including capability studies of equipment and process(ues)
- manufacturing process flow charts/layout, including linkage of product, process, and tooling
- capacity analysis
- manufacturing process FMEA
- maintenance plans and instructions
- control plan (see Annex A)
- standard work and work instructions
- process approval acceptance criteria
- data for quality, reliability, maintainability, and measurability
- results of error-proofing identification and verification, as appropriate
- methods of rapid detection, feedback, and correction of product/manningufacturing process nonconformities.

3.3.3 Design and development changes - supplemental

The product design output shall be expressed in terms that can be verified and validated against product design input requirements. The product design output shall include design FMEA, reliability results, product special characteristics and specifications, product error-proofing, as appropriate, product definition including drawings or mathematically based data, product design review results, and diagnostic guidelines, where applicable.

Recognition of the use of 3D models; inclusion of service parts and packaging.

3.4.1 General - supplemental

The organization shall include 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.

NOTE 1: Purchased products above include all products and services that affect customer requirements such as sub-assembly, sequencing, sorting, rework and calibration services.

3.4.2 Supplier selection process

The organization shall have a documented supplier selection process. The selection process shall include:
- an assessment of the selected supplier’s risk to product conformity and uninterrupted supply of the organization’s product to their customers;
- relevant quality and delivery performance;
- an evaluation of the supplier’s quality management system;
- multidisciplinary decision-making; and
- an assessment of software development capabilities, if applicable.

Other supplier selection criteria that should be considered include the following:
- volume of automotive business (absolute and as a percentage of total business);
- financial stability;
- purchased product, material, or service complexity;
- required technology (product or process);
- adequacy of available resources (e.g., people, infrastructure);
- design and development capabilities (including project management);
- manufacturing capability;
- change management process;
- business continuity planning (e.g., disaster preparedness, contingency planning);
- logistics process;
- customer service.

Supplier selection is to address supplier selection in the ISO 9001:2008 boxed text via the Purchasing Process (see Section 7.4.1). Supplier Selection Process was not as detailed.

3.4.3 Customer-directed sources (also known as "Directed-Buy")

When specified by the customer, the organization shall purchase products, materials, or services from customer-directed sources. All requirements of ISO 9001:2015, Section 8.4 (except the requirements in IATF 16949, Section 8.4.1.2), are applicable to the organization’s control of customer-directed sources unless specific agreements are otherwise defined by the contract between the organization and the customer.

Where specified by the contract (e.g., customer engineering drawing, specification), the organization shall purchase products, materials or services from approved sources. The use of customer-designated sources, including tool/gauge suppliers, does not relieve the organization of the responsibility for ensuring the quality of purchased products.

Clarification of organization’s responsibilities for customer directed sources, even for Directed-Buy.
6.4.1 Type and extent of control (supplemental)

7.4.3.1 The organization shall have a documented process to identify outsourced processes and to select the types and extent of controls used to verify conformity of externally provided products, processes, and services to internal (organizational) and external customer requirements.

The process shall include the criteria and actions to escalate or reduce the types and extent of controls and development activities based on supplier performance and assessment of product, material, or service risk.

The organization shall have a process to assure the quality of purchased product (see 7.4.3) utilizing one or more of the following methods:
- receipt of, and evaluation of, statistical data by the organization;
- receiving inspection and/or testing, such as sampling based on performance, second- or third-party assessments or audits of supplier sites, when coupled with records of acceptable delivered product conformity to requirements;
- part evaluation by a designated laboratory; or
- another method agreed with the customer.

6.4.2 Statutory and regulatory requirements

7.4.1.1 The organization shall document their process to ensure that purchased products, processes, and services conform to the current applicable statutory and regulatory requirements in the country of receipt, the country of shipment, and of the customer-identified country of destination, if provided. In the event the customer defines special controls for certain products with statutory and regulatory requirements, the organization shall ensure they are implemented and maintained as defined, including all suppliers.

7.4.1.2 The organization shall pass down all applicable statutory and regulatory requirements and special product and process characteristics to their suppliers and require the suppliers to cascade all applicable requirements down the supply chain to the point of manufacture.

The organization shall have a documented process and criteria to evaluate their suppliers to ensure all purchased products or materials used in product conform to applicable statutory and regulatory requirements.

Further strengthened the requirement for control of outsourced processes, including the assessment of risk.

6.4.3 Supplier quality management system development

7.4.12 The organization shall require their suppliers of automotive products and services to develop, implement, and improve a quality management system certified to ISO 9001, unless otherwise authorized by the customer (i.e., item a) below), with the ultimate objective of becoming certified to this Automotive QMS Standard. Unless otherwise specified by the customer, the following sequence should be applied to achieve this requirement:
- compliance to ISO 9001 through 3rd party audits;
- certification to ISO 9001 through 3rd party audits; unless otherwise specified by the customer, suppliers to the organization shall demonstrate conformity to ISO 9001 by maintaining a third-party certification issued by a certification body bearing the accreditation mark of a recognized IAF MLA member and where the accreditation body's main scope includes management system certification to ISO/IEC 17021.
- certification to ISO 9001 with compliance to other customer defined QMS requirements (such as Minimum Automotive Quality Management System Requirements for Safe Tier Suppliers [MAQMS] or equivalent) through 2nd party audits;
- certification to ISO 9001 with compliance to IATF 16949 through 2nd party audits;
- certification to IATF16949 through 3rd party audits (based third-party certification of the supplier to IATF 16949, by an IATF-recognized certification body).

The organization shall perform supplier quality management system development with the goal of supplier conformity with this Technical Specification. Conformity with ISO 9001:2008 is the first step toward achieving this goal.

NOTE The prioritization of suppliers for development depends upon, for example, the supplier’s quality performance and the importance of the product supplied.

Unless otherwise specified by the customer, suppliers to the organization shall be third party, registered to ISO 9001:2008 by an accredited third-party certification body.

Providing a method to strengthen ISO 9001 certification; alignment of customer specific requirements; clarification of acceptable third-party certification bodies (recognized by the IATF).

6.4.4 Supplier monitoring

7.4.13 The organization shall have a documented and process to determine performance in order to ensure conformity of externally provided products, processes, and services to internal and external customer requirements.

At a minimum, the following supplier performance indicators shall be monitored:
- delivered product conformity to requirements;
- customer disruptions, including field returns;
- special status of customer notifications related to quality or delivery issues;
- dealer returns, warranty, field actions, and recalls.

Supplier performance shall be monitored through the following indicators:
- delivery performance monitoring:
- customer disruptions, including field returns;
- delivery schedule performance (including incidents of premium freight)
- special status of customer notifications related to quality or delivery issues;
- dealer returns, warranty, field actions, and recalls.

The organization shall implement actions necessary to resolve open (unsatisfactory) performance issues and pursue opportunities for continual improvement.

NOTE Guidance may be found in the IATF Auditor Guide and ISO 19011.

Strengthened requirements for supplier monitoring.

6.4.5 Supplier development

7.4.14 The organization shall determine the priority, type, extent, and timing of required supplier development actions for its suppliers. Determination inputs shall include, but are not limited to, the following:
- performance issues identified through supplier monitoring (see Section 8.4.2.4); and
- supplier-QMS development (see Section 8.4.2.1.2);
- third-party quality management system certification status;
- risk analysis.

The organization shall implement actions necessary to resolve open (unsatisfactory) performance issues and pursue opportunities for continual improvement.

The organization shall have a process to assure the quality of purchased product (see 7.4.3) utilizing one or more of the following methods:
- receipt of, and evaluation of, statistical data by the organization;
- receiving inspection and/or testing, such as sampling based on performance, second- or third-party assessments or audits of supplier sites, when coupled with records of acceptable delivered product conformity to requirements; and
- part evaluation by a designated laboratory; or
- another method agreed with the customer.

Emphasis on performance based supplier development actions.

6.4.6 Information for external providers - supplemental

7.4.15 The organization shall pass down applicable statutory and regulatory requirements and special product and process characteristics to their suppliers and require the suppliers to cascade all applicable requirements down the supply chain to the point of manufacture.

Information for external providers were not previously included in ISO/TS 16949.

Require organization to provide key information to their supply chain.
7.5.1.1 Control plan

The organization shall develop control plans (in accordance with Annex A) at the system, subsystem, component, and/or material level for the relevant manufacturing site and all product supplied, including those for processes producing bulk materials as well as parts. Freely control plans are acceptable for bulk material and similar parts using a common manufacturing process.

The organization shall have a control plan for pre-launch and production that shows linkage and incorporates information from the design risk analysis (if provided by the customer), process flow diagram, and manufacturing risk analysis outputs (such as FMEA). The organization shall, if required by the customer, provide measurement and conformity data collected during execution of either the pre-launch or production control plans. The organization shall include in the control plans:

- a) controls used for the manufacturing process control, including verification of job set-ups;
- b) first-off/last-off part validation, as applicable;
- c) methods for monitoring of control exercised over special characteristics (see Annex A) defined by both the customer and the organization;
- d) the customer-required information, if any;
- e) specified reaction plan (see Annex A); when nonconforming product is detected, or when the process becomes statistically unstable or not statistically capable.

The organization shall review control plans, and update as required, for any of the following:

- a) the organization determines it has shipped nonconforming product to the customer;
- b) when any change occurs affecting product, manufacturing process, measurement, logistics, supply sources, production volume changes, or risk analysis (FMEA) (see Annex A);
- c) after a customer complaint and implementation of the associated corrective action, if applicable;
- d) at a set frequency based on a risk analysis;
- e) if required by the customer, the organization shall obtain customer approval after review or revision of the control plan.

7.5.1.4 Verification after shutdown

The organization shall verify job set-ups when performed, such as an initial run of a job, material changeover, or job change that requires a new set-up;

- maintain documented information for set-up personnel;
- use statistical methods of verification, where applicable;
- perform first-off/last-off part validation, as applicable; where appropriate, first-off parts should be retained for comparison with the last-off parts; where appropriate, last-off parts should be retained for comparison with first-off parts in subsequent runs;
- retain records of process and product approval following set-up and first-off/last-off part validations.

7.5.2 Standardised work – operator instructions and visual standards

The organization shall ensure that standardised work documents are:

- a) communicated to and understood by the employees who are responsible for performing the work;
- b) legible;
- c) presented in the language(s) understood by the personnel responsible to follow them;
- d) accessible for use at the designated work area(s);
- e) presented in the language(s) understood by the personnel responsible to follow them;
- f) presented in a manner that is easily accessible at the work station.

The standardised work documents shall also include rules for operator safety.

The organization shall implement a system to monitor these activities if any work is outsourced.

7.5.3 Total productive maintenance

The organization shall develop, implement, and maintain a documented total productive maintenance system. As a minimum, the system shall include the following:

- a) identification of process equipment necessary to produce conforming product at the required volume;
- b) availability of replacement parts for the equipment identified in item a; provision of resource for machine, equipment, and facility maintenance;
- c) packaging and preservation of equipment, tooling, and gauging;
- d) applicable customer-specific requirements;
- e) documented maintenance objectives, for example: OEE (Overall Equipment Effectiveness), MTBF (Mean Time Between Failure), and MTTR (Mean Time To Repair), and Preventive Maintenance compliance metrics. Performance between Failure), and MTTR (Mean Time To Repair), and Preventive Maintenance compliance metrics. Performance to the maintenance objectives shall be an input into management review (see ISO 9001:2015, Section 9.3); regular review of maintenance plan and objectives and a documented action plan to address corrective actions where objectives are not achieved;
- f) use of preventive maintenance methods;
- g) use of predictive maintenance methods, as applicable;
- h) periodic overload.

The organization shall verify that customer-owned tools, manufacturing equipment, and test/inspection equipment are permanently marked in a visible location so that the ownership and application of each item can be determined.

The organization shall implement a system to monitor these activities if any work is outsourced.

7.5.4 Management of production tools and manufacturing, test, inspection tooling and equipment

The organization shall provide resources for tool and gauge design, fabrication, and verification activities for production and service materials and for bulk materials, as applicable.

The organization shall establish and implement a system for production tooling management, whether owned by the organization or the customer, including:

- a) maintenance and repair facilities and personnel;
- b) storage and recovery;
- c) setup;
- d) tool-change programmes for perishable tools;
- e) tool design modification documentation, including engineering change level of the product;
- f) tool identification, such as serial or asset number; the status, such as production, repair or disposal; ownership at location.

The organization shall verify that customer-owned tools, manufacturing equipment, and test/inspection equipment are permanently marked in a visible location so that the ownership and application of each item can be determined.

The organization shall implement a system to monitor these activities if any work is outsourced.

- a) verify tool setups when performed, such as an initial run of a job, material changeover, or job change that requires a new setup;
- e) identified reaction plan (see Annex A); when nonconforming product is detected, or when the process becomes statistically unstable or not statistically capable.

8.5.1.6 Verification after shutdown

The organization shall verify that customer-owned tools, manufacturing equipment, and test/inspection equipment are permanently marked in a visible location so that the ownership and application of each item can be determined.

The organization shall implement a system to monitor these activities if any work is outsourced.

The organization shall establish and implement a system for production tooling management, including:

- a) maintenance and repair facilities and personnel;
- b) storage and recovery;
- c) setup;
- d) tool-change programmes for perishable tools;
- e) tool design modification documentation, including engineering change level of the product;
- f) tool identification, such as serial or asset number; the status, such as production, repair or disposal; ownership at location.

The organization shall verify that customer-owned tools, manufacturing equipment, and test/inspection equipment are permanently marked in a visible location so that the ownership and application of each item can be determined.

The organization shall implement a system to monitor these activities if any work is outsourced.

The organization shall develop control plans (see Annex A) at the system, subsystem, component and/or material level for the product supplied, including those for processes producing bulk materials as well as parts, using a common manufacturing process.

The organization shall, if required by the customer, provide measurement and conformity data collected during execution of either the pre-launch or production control plans. The organization shall define the control plan for pre-launch and production that shows linkage and incorporates information from the design risk analysis (if provided by the customer), process flow diagram, and manufacturing risk analysis outputs (such as FMEA).

The control plan shall:

- list the controls used for the manufacturing process control,
- include methods for monitoring of control exercised over special characteristics (see 7.1.4) defined by both the customer and the organization;
- include the customer-required information, if any;
- initiate the specified reaction plan (see 7.1.4) when the process becomes unstable or not statistically capable.

The control plan shall be reviewed and updated when any change occurs affecting product, manufacturing process, measurement, logistics, supply sources or FMEA (see 7.1.4).

NOTE: Customer approval may be required after review or update of the control plan.

8.5.1.2 Standardised work – operator instructions and visual standards

The organization shall ensure that standardised work documents are:

- a) communicated to and understood by the employees who are responsible for performing the work;
- b) legible;
- c) presented in the languages understood by the personnel responsible to follow them;
- d) accessible for use at the designated work area(s);
- e) communicated to and understood by the employees who are responsible for performing the work;
- f) presented in a manner that is easily accessible at the work station.

The standardised work documents shall also include rules for operator safety.

The organization shall prepare documented work instructions for all employees having responsibilities for the operation of processes that impact conformity to product requirements. These instructions shall be accessible for use at the work station. These instructions shall be derived from sources such as the quality plan, the control plan and the product realization process.

NOTE: Customer approval may be required after review or update of the control plan.

Annex A

Strengthened control plan requirements and aligned IATF OEM customer requirements into the IATF 16949 standard. Updated NOTE to a requirement; strengthened control plan review and update criteria and added to FMEA update.

Elevated requirements for standardised work, including the requirement to address specific language needs.

Elevated Note to a requirement, clarified record-retention.

Updated requirement for verification after shutdown, integration of industry section on tool and equipment.
Production scheduling

The organization shall ensure that production is scheduled in order to meet customer orders/demands such as just-in-time (JIT) supported by an information system that permits access to production information at key stages of the process and is order driven.

The organization shall include relevant planning information, e.g. customer orders, supplier on-time delivery, performance, capacity, shared loading (multi-part station), lead time, inventory level, preventive maintenance, and validation, during production scheduling.

Production shall be scheduled in order to meet customer requirements, such as just-in-time supported by an information system that permits access to production information at key stages of the process and is order driven.

Emphasized importance of planning information; integrated IATF OEM customer lessons learned.

Identification and traceability — supplemental

The purpose of traceability is to support identification of clear start and stop points for product received by the customer or in the field that may contain quality and/or safety-related nonconformities; therefore, the organization shall implement identification and traceability processes as described below.

The organization shall conduct an analysis of internal, customer, and regulatory traceability requirements for all automotive products, including developing and documenting traceability plans, based on the levels of risk or failure severity for employees, customers, and consumers. These plans shall define the appropriate traceability systems, processes, and methods by product, process, and manufacturing location that:

- enable the organization to identify nonconforming and/or suspect product;
- enable the organization to segregate nonconforming and/or suspect product;
- ensure the ability to meet the customer and/or regulatory response time requirements;
- ensure documented information is retained in the format (electronic, hardcopy, archive) that enables the organization to meet the response time requirements;
- ensure serialized identification of individual products, if specified by the customer or regulatory standards;
- ensure the identification and traceability requirements are extended to externally provided products with safety/regulatory characteristics.

The words "where appropriate" in 7.5.3 shall not apply.

Strengthening requirements for traceability to support industry lessons learned related to field issues.

Preservation — supplemental

Preservation shall include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection.

Preservation shall apply to materials and components from external and/or internal providers from receipt through processing, including receipt and until delivery/acceptance by the customer.

In order to detect deterioration, the organization shall assess at appropriate planned intervals the condition of product in stock, the place/type of storage container, and the storage environment.

The organization shall use an inventory management system to optimize inventory turns over time and ensure stock rotation, such as "first-in-first-out" (FIFO). Obsolete product shall be controlled in a manner similar to that of nonconforming product.

Organizations shall comply with preservation, packaging, shipping, and labeling requirements as provided by their customers.

In order to detect deterioration, the condition of product in stock shall be assessed at appropriate planned intervals.

The organization shall use an inventory management system to optimize inventory turns over time and assure stock rotation, such as "first-in-first-out" (FIFO). Obsolete product shall be controlled in a manner similar to that of nonconforming product.

Adding specificity to preservation controls and included application to internal and/or external providers.

Feedback of information to customer

The organization shall ensure that a process for communication of information on service concerns to manufacturing, material handling, logistics, engineering, and design activities is established, implemented, and maintained.

NOTE 1 The intent of the addition of "service concerns" to this sub-clause is to ensure that the organization is aware of nonconforming product(s) and material(s) that may be identified at the customer location or in the field.

NOTE 2 "Service concerns" should include the results of field failure test analysis (see Section 10.2.5) where applicable.

The organization shall use an inventory management system to optimize inventory turns over time and assure stock rotation, such as "first-in-first-out" (FIFO). Obsolete product shall be controlled in a manner similar to that of nonconforming product.

Organizations shall comply with preservation, packaging, shipping, and labeling requirements as provided by their customers.

The process for communication of information on service concerns to manufacturing, engineering and design activities shall be established, implemented, and maintained.

Expanded scope to include material handling and logistics.

Service agreement with customer

When there is a service agreement with the customer, the organization shall:

- verify the relevant service centres comply with applicable requirements;
- verify the effectiveness of any special purpose tools or measurement equipment;
- ensure all service personnel are trained in applicable requirements.

When there is a service agreement with the customer, the organization shall verify the effectiveness of any organization service centres, any special purpose tools or measurement equipment, and the training of service personnel.

Clarification of service agreement requirements.

Control of changes — supplemental

The organization shall have a documented process to control and react to changes that impact product realization. The effects of any change, including those changes caused by the organization, the customer, or any supplier, shall be assessed.

The organization shall:

- define verification, validation activities to ensure compliance with customer requirements;
- validate changes before implementation;
- document the evidence of related risk analysis;
- retain records of verification and validation.

Changes, including those made at suppliers, should require a production trial run for verification of changes (such as changes to part design, manufacturing location, or manufacturing process) to validate the impact of any changes on the manufacturing process.

When required by the customer, the organization shall:

- notify the customer of any planned product realization changes after the most recent product approval;
- obtain documented approval, prior to implementation of the change;
- complete additional verification or identification requirements, such as production trial run and new product validation.

The organization shall have a process to control and react to changes that impact product realization. The effects of any change, including those changes caused by any supplier, shall be assessed, and verification and validation activities shall be defined, to ensure compliance with customer requirements. Changes shall be validated before implementation.

For proprietary designs, impact on form, fit and function (including performance and/or durability) shall be reviewed with the customer so that all effects can be properly evaluated.

When required by the customer, additional verification/identification requirements, such as those required for new product introduction, shall be met.

NOTE 1 Any product realization change affecting customer requirements requires notification to, and agreement from, the customer.

NOTE 2 The above requirement applies to product and manufacturing process changes.

Strengthen the standard to align with existing IATF OEM requirements.
Temporary change of process controls

The organization shall identify, document, and maintain a list of the process controls, including inspection, measuring, testing, and error-proofing devices that includes the primary process control and the approved back-up or alternate methods. The organization shall document the process that manages the use of alternate control methods. The organization shall include in this process, based on risk analyses (such as FMEA), severity and the internal approvals to be obtained prior to production implementation of the alternate control method. Prior to shipment of product that was inspected or tested using the alternate method, if required, the organization shall obtain approval from the customer(s). The organization shall maintain and periodically review a list of approved alternate process control methods that are referenced in the control plan. Standard work instructions shall be available for each alternate process control method. The organization shall review the operation of alternate process controls on a daily basis, at a minimum, to verify implementation of standard work with the goal to return to the standard process as defined by the control plan as soon as possible. Example methods include, but are not limited to, the following:

- daily quality focused audits (e.g., layered process audits, as applicable)
- daily leadership meetings
- restant verification is documented for a defined period on severity and confirmation that all features of the error-proofing device or process are effectively reinstated.

The organization shall implement traceability of all product produced while any alternate process control devices or processes are being used (e.g., verification and retention of first piece and last piece from every shift).

Release of products and services – supplemental

The organization shall ensure that the planned arrangements to verify that the product and service requirements have been met encompass the control plan and are documented as specified in the control plan (see Annex A). The organization shall ensure that the planned arrangements for initial release of products and services encompass product or service approval. The organization shall ensure that product or service approval is accomplished after changes following initial release, according to ISO 9001:2015, Section 8.5.6.

Layout inspection and functional testing

A layout inspection and a functional verification to applicable customer engineering material and performance standards shall be performed for each product as specified in the control plan. Results shall be available for customer review. NOTE 1 Layout inspection is the complete measurement of all product dimensions shown on the design record(s). NOTE 2 The frequency of layout inspection is determined by the customer.

Appearance items

For organizations manufacturing parts designated by the customer as “appearance items,” the organization shall provide the following:

- appropriate resources, including lighting, for evaluation;
- masters for colour, grain, gloss, metallic brilliance, texture, distinctness of image (DOI), and haptic technology, as appropriate;
- maintenance and control of appearance masters and evaluation equipment;
- verification that personnel making appearance evaluations are competent and qualified to do so.

For organizations manufacturing parts designated by the customer as “appearance items,” the organization shall provide appropriate resources, including lighting, for evaluation, masters for colour, grain, gloss, metallic brilliance, texture, distinctness of image (DOI), and haptic technology, as appropriate, maintenance and control of appearance masters and evaluation equipment, and verification that personnel making appearance evaluations are competent and qualified to do so.

Verification and acceptance of conformity of externally provided products and services

The organization shall have a process to ensure the quality of externally provided processes, products, and services utilizing one or more of the following methods:

- receipt of and evaluation of statistical data provided by the supplier to the organization;
- receiving inspection and/or testing, such as sampling based on performance;
- second- or third-party assessments or audits of supplier sites, when coupled with records of acceptable delivered product conformance to requirements;
- part evaluation by a designated laboratory;
- appropriate, second- or third-party assessments of customer design records.

The organization shall have a process to ensure the quality of purchased product (see 7.4.3) utilizing one or more of the following methods:

- receipt of, and evaluation of, statistical data by the organization;
- receiving inspection and/or testing, such as sampling based on performance;
- second- or third-party assessments or audits of supplier sites, when coupled with records of acceptable delivered product conformity to requirements;
- part evaluation by a designated laboratory;
- another method agreed with the customer.

Statutory and regulatory conformity

Prior to release of externally provided products into production flow, the organization shall confirm and be 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-specified countries of destination, if provided.

All purchased products or materials used in product shall conform to applicable statutory and regulatory requirements.

Acceptance criteria

Acceptance criteria shall be defined by the organization and, where appropriate or required, approved by the customer. For attribute data sampling, the acceptance level shall be zero defects (see Section 8.9.1.1). For attribute data sampling, the acceptance level shall be zero defects (see 8.2.3.1).

Customer authorization for concession

The organization shall obtain a customer concession or deviation permit prior to further processing whenever the product or manufacturing process is different from that which is currently approved.

The organization shall obtain customer authorization prior to further processing for “as is in” and “as customer desires” nonconforming product. If sub-components are reused in the manufacturing process, that sub-component usage shall be clearly communicated to the customer in the concession or deviation permit. The organization shall maintain a record of the expiration date or authority under concession.

The organization shall also ensure compliance with the original or superseding specifications and requirements when the authorization expires. Material shipped under concession shall be properly identified on each shipping container (this applies equally to purchased products). The organization shall approve any requests from suppliers before submission to the customer.

Control of nonconforming product – customer specified process

The organization shall comply with applicable customer specific controls for nonconforming product(s).

Product with unidentified or suspect status shall be classified as nonconforming product (see 7.5.3). Ensures customer Controlled Shipping requirements are followed.

Control of suspect product

The organization shall ensure that product with unidentified or suspect status is classified and controlled in nonconforming product. The organization shall ensure that all appropriate manufacturing personnel receive training for containment of suspect and nonconforming product.

Product with unidentified or suspect status shall be classified as nonconforming product (see 7.5.3). Strengthening requirements by ensuring containment training is implemented.
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<th>Section</th>
<th>Title</th>
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<th>Expanded Scope</th>
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<tr>
<td>8.7.1.4</td>
<td>Control of reworked product</td>
<td>The organization shall utilize risk analysis (such as FMEA) methodology to assess risks in the rework process prior to a decision to rework the product.  If required by the customer, the organization shall obtain approval from the customer prior to commencing rework of the product.  The organization shall have a documented process for rework confirmation in accordance with the control plan or other relevant documented information to verify compliance to original specifications.  Instructions for disassembly or rework, including re-inspection and traceability requirements, shall be accessible to and utilized by the appropriate personnel.  The organization shall retain documented information on the disassembly of reworked product including quantity, disposition, disposition date, and applicable traceability information.  Instructions for rework, including re-inspection requirements, shall be accessible to and utilized by the appropriate personnel.</td>
<td>Expanded scope to include: customer approval, risk assessment, rework confirmation, traceability, and retention of documented information.</td>
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<tr>
<td>8.7.1.5</td>
<td>Control of repaired product</td>
<td>The organization shall utilize risk analysis (such as FMEA) methodology to assess risks in the repair process prior to a decision to repair the product.  The organization shall obtain approval from the customer prior to commencing repair of the product.  The organization shall have a documented process for repair confirmation in accordance with the control plan or other relevant documented information.  Instructions for disassembly or repair, including re-inspection and traceability requirements, shall be accessible to and utilized by the appropriate personnel.  The organization shall obtain a documented customer authorization for concession for the product to be repaired.  The organization shall retain documented information on the disposition of repaired product including quantity, disposition, disposition date, and applicable traceability information.  Customers shall be informed promptly in the event that nonconforming product has been shipped.</td>
<td>Customers shall be informed promptly in the event that nonconforming product has been shipped.</td>
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<tr>
<td>8.7.1.6</td>
<td>Customer notification</td>
<td>The organization shall immediately notify the customer(s) in the event that nonconforming product has been shipped.  Initial communication shall be followed with detailed documentation of the event.  While customer notification is mentioned twice in ISO/TS 16949:2009 (see Section 7.4.3.2 and Section 8.2.1.1), it did not address customer notification in a standalone section.  New automotive requirement to address modifications in ISO 9001 requirements and address customer issues for IATF OEM concerns.</td>
<td>New automotive requirement to address modifications in ISO 9001 requirements and address customer issues for IATF OEM concerns.</td>
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<tr>
<td>8.7.1.7</td>
<td>Nonconforming product</td>
<td>The organization shall have a documented process for disposition of nonconforming product not subject to rework or repair.  For product not meeting requirements, the organization shall verify that the product to be scrapped is rendered unusable prior to disposal.  The organization shall not divert nonconforming product to service or other use without prior customer approval.  Product with unverified or suspect status shall be classified as nonconforming product (see 7.9.1).  Strengthened the requirement of disposition of nonconforming product.</td>
<td>Strengthened the requirement of disposition of nonconforming product.</td>
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</table>
The organization shall have a documented internal audit process. The process shall include:

- The organization shall determine the characteristics that are either not statistically capable or are unstable. These reaction plans shall include containment of product and 100% inspection, as appropriate. A corrective action plan shall be developed and implemented by the organization indicating specific actions, timing, and assigned responsibilities to ensure that the process becomes stable and capable. The plans shall be reviewed with and approved by the customer, when required. The organization shall maintain records of effective dates of process changes.

- The organization shall have a documented internal audit process. The process shall include:  
  - determination of key customer-related trends and correlation for status review, decision-making and lead to action to support the following:
    - customer notifications related to quality or delivery issues.
    - customer disruptions, including field returns, delivery schedule performance (including incidents of premium freight), and customer notifications related to quality or delivery issues.
  
- The organization shall monitor the performance of manufacturing processes to demonstrate compliance with customer requirements for product quality and efficiency of the process. The monitoring shall include the review of customer performance data including online customer complaint management systems, where possible.

- The organization shall have a documented internal audit process. The process shall include:
  - trends in quality and operational performance shall be compared with progress toward objectives and lead to action to support prioritization of actions for improving customer satisfaction.

Internal audits shall cover all quality management related processes, activities and shifts, and shall be scheduled according to an annual plan. When internal/external nonconformities or customer complaints occur, the audit frequency shall be appropriately increased.

Prioritization

Trends in quality and operational performance shall be compared with progress toward objectives and lead to action to support prioritization of actions for improving customer satisfaction.

NOTE Data should be compared with those of competitors and/or appropriate benchmarks.

Clarification of the requirement for targeting process effectiveness and efficiency. Extension of the requirement to have effective and efficient processes instead of just a process. Ensures that organizations support the manufacturing process through defined roles, responsibilities, and effective escalation processes to drive process capability and stability.

Clarification regarding documented deployment of the use of statistical tools from DFMEA, PFMEA, and the APQP (or equivalent) process.

Clarification regarding requirements for these involved in capturing and analyzing data; previously drawn across all employees regardless of relevance.

Clarification of customer satisfaction monitoring criteria and introduction of additional focus on warranty management. Additional focus of the requirement to ensure all customer performance measures are regularly reviewed to reduce the risk of failure to achieving customer satisfaction.

Clarification of the requirement for targeting process effectiveness and efficiency. Extension of the requirement to have effective and efficient processes instead of just a process. Ensures that organizations support the manufacturing process through defined roles, responsibilities, and effective escalation processes to drive process capability and stability.

Clarification of customer satisfaction monitoring criteria and introduction of additional focus on warranty management. Additional focus of the requirement to ensure all customer performance measures are regularly reviewed to reduce the risk of failure to achieving customer satisfaction.

Clarification of the requirement for targeting process effectiveness and efficiency. Extension of the requirement to have effective and efficient processes instead of just a process. Ensures that organizations support the manufacturing process through defined roles, responsibilities, and effective escalation processes to drive process capability and stability.
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<td>8.2.2.2</td>
<td>Quality management system audit</td>
<td>The organization shall audit all quality management system processes over each 3 year calendar period, according to an annual programme, using the process approach to verify compliance with this Technical Specification and any additional quality management system requirements. The organization shall audit its quality management system to verify compliance with this Technical Specification and any additional quality management system requirements. Strengthening the quality management system audit and the use of process approach, further drive process improvements organization wide.</td>
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<tr>
<td>8.2.2.3</td>
<td>Manufacturing process audit</td>
<td>The organization shall audit all manufacturing processes over each 3 year calendar period to determine their effectiveness and efficiency using customer-specific required approach for process audits. Where not defined by the customer, the organization shall determine the approach to be used. Within each individual audit plan, each manufacturing process shall be audited on all shifts where it occurs, including the appropriate sampling of the shift handover. The manufacturing process audit shall include an audit of the effective implementation of the process risk analysis (such as PMFQA), control plan, and associated documents. The organization shall audit each manufacturing process to determine its effectiveness. Strengthening the formal approaches to ensure the benefits of effective manufacturing process audits are achieved by organizations.</td>
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<tr>
<td>8.2.2.4</td>
<td>Product audit</td>
<td>The organization shall audit products using customer-specific required approaches at appropriate stages of production and delivery to verify conformity to specified requirements. Where not defined by the customer, the organization shall define the approach to be used. The manufacturing process audit shall include an audit of the effective implementation of the process risk analysis (such as PFMEA), control plan, and associated documents. The organization shall audit products at appropriate stages of production and delivery to verify conformity to all specified requirements, such as product dimensions, functionality, packaging and labelling, at a defined frequency. Strengthening the product audit requirements to include customer-specified approaches.</td>
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<tr>
<td>9.3.1.1</td>
<td>Management review - supplemental</td>
<td>Management review shall be conducted at least annually. The frequency of management review(s) shall be increased based on risk to compliance with customer requirements resulting from internal or external changes impacting the quality management system and performance related issues. These reviews shall include all requirements of the quality management system and its performance trends as an essential part of the continual improvement process. Part of the management review shall be the monitoring of quality objectives, and the regular reporting and evaluation of the cost of poor quality (see 8.4.1 and 8.5.1). These results shall be recorded to provide, as a minimum, evidence of the achievement of - the quality objectives specified in the business plan, and - customer satisfaction with product supplied. Strengthening the organization’s management review requirements, including assessment of risk and compliance to customer requirements.</td>
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<td>9.3.2.1</td>
<td>Management review inputs - supplemental</td>
<td>Input to management review shall include: a) cost of poor quality (cost of internal and external non-conformance); b) measures of process effectiveness; c) measures of process efficiency; d) assessments of manufacturing feasibility made for changes to existing operations and for new facilities or new product (see Section 7.1.3.1); e) customer satisfaction (see ISO 9001:2015, Section 9.1.2); g) review of performance against maintenance objectives; h) warranty performance (where applicable); i) review of customer scorecards (where applicable); j) identification of potential field failures identified through risk analysis (such as PMFQA); k) actual field failures and their impact on quality, safety or the environment. Input to management review shall include an analysis of actual and potential field-failures and their impact on quality, safety or the environment. Enhanced details for management review input requirements.</td>
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<tr>
<td>9.3.3.1</td>
<td>Management review outputs – supplemental</td>
<td>Top management shall document and implement an action plan when customer performance targets are not met. While ISO/TS 16949 did address management review output in the ISO 9001:2008 based test via the Review Output (see Section 5.6.5), it was not as detailed. Enhanced to ensure action is taken where customer requirements are not achieved; support continual analysis of process performance and risk.</td>
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The organization shall have a documented process for problem solving including:

- defined approaches for various types and scales of problems (e.g., new product development, current manufacturing issues, field failures, audit findings);
- containment, interim actions, and related activities necessary for control of nonconforming outputs (see ISO 9001:2015, Section 8.7);
- root cause analysis, methodology used, analysis, and results;
- implementation of systemic corrective actions, including consideration of the impact on similar processes and products;
- verification of the effectiveness of implemented corrective actions;
- review, and where necessary, update the appropriate documented information (e.g., PFMEA, control plan).

Where the customer has specific prescribed processes, tools, or systems for problem solving, the organization shall use those processes, tools, or systems unless otherwise approved by the customer.

The organization shall have a defined process for problem solving leading to root cause identification and elimination. If a customer-prescribed problem-solving format exists, the organization shall use the prescribed format.

Consolidation of IATF OEM customer specific minimum requirements.

The organization shall use error-proofing methods in their corrective action process.

Previously only mentioned the use of error-proofing methods in corrective action, new requirements strengthen the approach to error-proofing and consolidated customer specific requirements.

When the organization is required to provide warranty for their product(s), the organization shall implement a warranty management process. The organization shall include in the process a method for warranty part analysis, including NTF (no trouble found). When specified by the customer, the organization shall implement the required warranty management process.

Warranty management systems were not previously included in ISO/TS 16949.

The organization shall analyze parts rejected by the customer's manufacturing plants, engineering facilities and dealerships. The organization shall minimize the cycle time of this process. Records of these analyses shall be kept and made available upon request. The organization shall perform analysis and initiate corrective action to prevent recurrence.

New requirement based on the increasing importance of warranty management and consolidates IATF OEM customer specific requirements.

The organization shall perform analysis on customer complaints and field failures, including any returned parts, and shall initiate problem solving and corrective action to prevent recurrence. Where requested by the customer, this shall include analysis of the interaction of embedded software of the organization's product within the system of the final customer's product. The organization shall communicate the results of testing/analysis to the customer and also within the organization.

New requirement regarding embedded software and identification of preferred approaches.

The organization shall have a documented process for continual improvement. The organization shall include in this process the following:

- identification of the methodology used, objectives, measurement, effectiveness, and documented information;
- a manufacturing process improvement action plan with emphasis on the reduction of process variation and waste;
- risk analysis (such as FMEA).

NOTE Continual improvement is implemented once manufacturing processes are statistically capable and stable or when product characteristics are predictable and meet customer requirements.

Clarification of the minimum process requirements.