Comparison Matrix

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American Systems Registrar

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<tr>
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<tbody>
<tr>
<td><strong>The text that is bolded is text from IATF 16949.</strong></td>
<td><strong>The text that is bolded is automotive text from ISO/TS 16949.</strong></td>
<td><strong>The comments that are bolded relate to the automotive requirements.</strong></td>
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<tr>
<td>The normal text is from ISO 9001:2015</td>
<td>The normal text is from ISO 9001:2008</td>
<td>The comments in normal text relate to ISO 9001:2015</td>
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### Foreword

This Automotive Quality Management System Standard, herein referred to as "Automotive QMS Standard" or "IATF 16949," along with applicable automotive customer-specific requirements, ISO 9001:2015 requirements, and ISO 9000:2015 defines the fundamental quality management system requirements for automotive production and relevant service parts organizations. As such, this Automotive QMS Standard cannot be considered a stand-alone QMS Standard but has to be comprehended as a supplement to and used in conjunction with ISO 9001:2015. ISO 9001:2015 is published as a separate ISO Standard.

IATF 16949:2016 (1st edition) represents an innovative document, given the strong orientation to the customer, with inclusion of a number of consolidated previous customer specific requirements.

Annex B is provided for guidance to implement the IATF 16949 requirements unless otherwise specified by customer specific requirements.

Annex A (Control Plan) of IATF 16949 is a normative part of IATF 16949 and therefore contains requirements that must be met.
#### 4 Context of the organization

##### 4.1 Understanding the organization and its context

The organization shall determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system.

The organization shall monitor and review information about these external and internal issues.

**NOTE 1** Issues can include positive and negative factors or conditions for consideration.

**NOTE 2** Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local.

**NOTE 3** Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge and performance of the organization.

| No equivalent clause | Generally organizations address this by developing a vision statement and a mission statement; these are developed into a long term strategic direction and a strategic plan. These further lead to shorter 3 to 5 year business development plans, which are supported by annual goals and objectives. For small to medium size organizations, these may be unstated and undocumented and be in the mind of the owner or may not exist at all. The issues can relate to: Legal (FDA, FAA, DOT, EPA, OHSA) Market & competition Technology development Cultural & social directions Economic development International Trade For automotive specifically legal issues could relate to 1. Passenger restraints 2. Engine air emissions 3. Braking systems 4. Exterior light illumination and others depending on the types of products and position in the supply chain |
4.2 Understanding the needs and expectations of interested parties

Due to their effect or potential effect on the organization’s ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, the organization shall determine:

2.a) the interested parties that are relevant to the quality management system;

2.b) the requirements of these interested parties that are relevant to the quality management system.

The organization shall monitor and review information about these interested parties and their relevant requirements.

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<tr>
<th>No equivalent clause</th>
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<tbody>
<tr>
<td>Organization’s interested parties include:</td>
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<tr>
<td>Owner(s) – individuals, investment companies, corporate ownership, stockholders</td>
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<td>Employees</td>
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<tr>
<td>Regulators</td>
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<tr>
<td>Customers</td>
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<tr>
<td>Competitors</td>
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<tr>
<td>Trade Associations</td>
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<tr>
<td>State and local business community</td>
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<tr>
<td>Owners</td>
</tr>
<tr>
<td>Suppliers</td>
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<tr>
<td>Neighbors</td>
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</tbody>
</table>

For automotive specifically, interested parties could include AIAG, SAE, DOT and EPA, ISO/TS certification body.

For Tier 2 and below, interested parties include the OEMs that their customers supply to.
### 4.3 Determining the scope of the quality management system

The organization shall determine the boundaries and applicability of the quality management system to establish its scope. When determining this scope, the organization shall consider:

- **3.a)** the external and internal issues referred to in 4.1;
- **3.b)** the requirements of relevant interested parties referred to in 4.2;
- **3.c)** the products and services of the organization.

The organization shall apply all the requirements of this International Standard if they are applicable within the determined scope of its quality management system.

The scope of the organization’s quality management system shall be available and be maintained as documented information. The scope shall state the types of products and services covered, and provide justification for any requirement of this International Standard that the organization determines is not applicable to the scope of its quality management system.

Conformity to this International Standard may only be claimed if the requirements determined as not being applicable do not affect the organization’s ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction.

#### 4.3.1 Determining the scope of the quality management system

**Supporting functions, whether on-site**

### 4.2.2 Quality manual

The organization shall establish and maintain a quality manual that includes:

- **2.2.a)** the scope of the quality management system, including details of and justification for any exclusions (see 1.2).

**Scope requirements are more explicit**

#### Required Content

**Types of products & services**

Application of all requirements from ISO 9001 that are applicable – if they have activities/processes they are to be included Boundaries of the QMS

Justification for any exclusions

Scope determined by considering external & internal issues, requirements of interested parties & products & services

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**Automotive Specific:**

Scope must include supporting functions, (remote and on-site).

Only permitted exclusion is product design and development and this...
### 4.4 Quality management system

The organization shall establish, implement, maintain and continually improve a quality management system, including the processes needed and their interactions, in accordance with the requirements of this International Standard.

The organization shall determine the processes needed for the quality management system and their application throughout the organization, and shall:

| 4.1.a) | determine the inputs required and the outputs expected from these processes; |
| 4.1.b) | determine the sequence and interaction of these processes; |
| 4.1.c) | determine and apply the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes; |
| 4.1.d) | determine the resources needed for these processes and ensure their availability; |
| 4.1.e) | assign the responsibilities and authorities for these processes; |
| 4.1.f) | address the risks and opportunities as determined in accordance with the requirements of 6.1; |
| 4.1.g) | evaluate these processes and implement any changes |

### 4.1 General requirements

The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard. The organization shall

- a) determine the processes needed for the quality management system and their application throughout the organization (see 1.2),
- b) determine the sequence and interaction of these processes,
- c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective,
- d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes,
- e) monitor, measure where applicable, and analyse these processes, and
- f) implement actions necessary to achieve planned results and continual improvement of these processes by the organization in accordance with the requirements of this International Standard. Where an organization chooses to outsource any process that affects product conformity to requirements, the organization shall ensure control over such processes. The type and extent of control to be applied to these outsourced processes shall be defined within the quality management system.

**NOTE 1** Processes needed for the quality management system referred to above include:

**Process Approach additions/changes**

Assign responsibilities & authorities for the processes

Address risks and opportunities with link to 6.1

Discussion of outsourced processes moved to a reference in clause 8.1 which refers to control described in clause 8.4 basically the purchasing requirements

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**Automotive has added specific wording requiring the QMS to lead to conformance of the product to requirements including customer.**
needed to ensure that these processes achieve their intended results;

4.1.h) improve the processes and the quality management system.

4.4.1.1 Conformance of products and processes
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).

4.4.1.2 Product safety
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 requirements in item a);
c) 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;

Now need a documented process for the management of product – safety related products and processes. Identification of safety related requirements and inclusion in FMEAs, control plans, controls such as work instructions, flow down to suppliers, training. This clause requires more detailed control over safety related products, processes and characteristics. This control includes special approvals for FMEAs and control plans and any changes.

There is a lot more detail relating to the control of these safety related requirements.

NOTE See also 7.4.1 and 7.4.1.3.
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 ISO 9001, Section 8.3.6);

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.

NOTE: Special approval is an additional approval by the function (typically the customer) that is responsible to approve such documents with safety-related content.

4.4.2 To the extent necessary, the organization shall:

4.2.a) maintain documented information to support the operation of its processes;

4.2.b) retain documented information to have confidence that the processes are being carried out as planned.
### 5 Leadership

#### 5.1 Leadership and commitment

**5.1.1 General**

Top management shall demonstrate leadership and commitment with respect to the quality management system by:

1.1.a) taking accountability for the effectiveness of the quality management system;

1.1.b) ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization;

1.1.c) ensuring the integration of the quality management system requirements into the organization’s business processes;

1.1.d) promoting the use of the process approach and risk-based thinking;

1.1.e) ensuring that the resources needed for the quality management system are available;

1.1.f) communicating the importance of effective quality management and of conforming to the quality management system requirements;

#### 5.1 Management commitment

Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by

- a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements,

- b) establishing the quality policy,

- c) ensuring that quality objectives are established,

- d) conducting management reviews, and

- e) ensuring the availability of resources.

**Top Management – new/now explicit commitments and accountabilities:**

- Accountability for effectiveness of the QMS

- Ensuring QMS achieves intended results

- Compatible with Strategic Direction of organization

- Integration with business processes (interpreted in context of nature of organization – for profit; not for profit; private, public)
g) ensuring that the quality management system achieves its intended results;

h) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;

i) promoting improvement;

j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

NOTE Reference to “business” in this International Standard can be interpreted broadly to mean those activities that are core to the purposes of the organization’s existence, whether the organization is public, private, for profit or not for profit.

5.1.1.1 Corporate responsibility
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 ("whistle-blowing policy").

5.1.1.2 Process effectiveness and efficiency
Top management shall review the product realization processes and support processes to assure 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).

5.1.1.3 Process owners
Top management shall identify process owners.
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 ISO 9001, Section 7.2).
<table>
<thead>
<tr>
<th>5.1.2 Customer Focus</th>
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<tbody>
<tr>
<td>Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that:</td>
<td>Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1).</td>
</tr>
<tr>
<td>1.2.a) customer and applicable statutory and regulatory requirements are determined, understood and consistently met;</td>
<td>Customer focus tie to regulatory requirements as well as customer requirements</td>
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<tr>
<td>1.2.b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;</td>
<td>Customer focus tie to risk as affecting products &amp; services</td>
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<td>1.2.c) the focus on enhancing customer satisfaction is maintained.</td>
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<table>
<thead>
<tr>
<th>5.2 Policy</th>
<th>5.3 Quality policy</th>
<th>5.5.2 Management representative</th>
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<tbody>
<tr>
<td><strong>5.2.1 Developing the quality policy</strong></td>
<td>Top management shall ensure that the quality policy</td>
<td>Top management shall ensure that responsibilities and authorities are defined and communicated within the organization.</td>
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<tr>
<td>Top management shall establish, implement and maintain a quality policy that:</td>
<td>a) is appropriate to the purpose and context of the organization and supports its strategic direction;</td>
<td>There is no longer a position of &quot;management representative&quot;</td>
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<tr>
<td>a) is appropriate to the purpose and context of the organization and supports its strategic direction;</td>
<td>b) provides a framework for setting quality objectives;</td>
<td>There are now 5 responsibilities and authorities that need to be assigned.</td>
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<tr>
<td>b) provides a framework for setting quality objectives;</td>
<td>c) includes a commitment to satisfy applicable requirements;</td>
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<td>c) includes a commitment to satisfy applicable requirements;</td>
<td>d) includes a commitment to continual improvement of the quality management system,</td>
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<tr>
<td>d) includes a commitment to continual improvement of the quality management system.</td>
<td>c) provides a framework for establishing and reviewing quality objectives,</td>
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<tr>
<td><strong>5.2.2 Communicating the quality policy</strong></td>
<td>d) is communicated and understood within the organization, and</td>
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<tr>
<td>The quality policy shall:</td>
<td>e) is reviewed for continuing suitability.</td>
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<tr>
<td>a) be available and be maintained as documented information;</td>
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<td>b) be communicated, understood and applied within the organization;</td>
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<tr>
<td>c) be available to relevant interested parties, as appropriate.</td>
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<tr>
<td>5.3 Organizational roles, responsibilities and authorities</td>
<td>5.5.1 Responsibility and authority</td>
<td>Top management shall appoint a member of the organization's management who, irrespective of other responsibilities, shall have responsibility and authority that</td>
</tr>
<tr>
<td>Top management shall ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization.</td>
<td>Top management shall ensure that responsibilities and authorities are defined and communicated within the organization.</td>
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<tr>
<td>Top management shall assign the responsibility and authority for:</td>
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<tr>
<td>a) ensuring that the quality management system conforms to the requirements</td>
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of this International Standard;
b) ensuring that the processes are delivering their intended outputs;
c) reporting on the performance of the quality management system and on opportunities for improvement (see 10.1), in particular to top management;
d) ensuring the promotion of customer focus throughout the organization;
e) ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

5.3.1 Organizational roles, responsibilities, and authorities — supplemental
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.

5.3.2 Responsibility and authority for product requirements and corrective actions
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.

5.5.1.1 RESPONSIBILITY FOR QUALITY
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.

5.5.2.1 CUSTOMER REPRESENTATIVE
These are the responsibilities of the customer representative in ISO/TS 16949 and have been expanded a bit.
All these responsibilities should be documented somewhere for example job descriptions or quality manual or procedures.

NOTE The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.
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 to the customer prevented.

  - **b)** personnel with authority and responsibility for corrective action are promptly informed of products or processes that do not conform to requirements to ensure that nonconforming product is not shipped to the customer and that all potential nonconforming product is identified and contained;

  - **c)** production operations across all shifts are staffed with personnel in charge of, or delegated responsibility for, ensuring conformity to product requirements.

**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.**
| 6 Planning |  |  |
6.1 Actions to address risks and opportunities

6.1.1 When planning for the quality management system, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to:
   a) give assurance that the quality management system can achieve its intended result(s);
   b) enhance desirable effects;
   c) prevent, or reduce, undesired effects;
   d) achieve improvement.

6.1.2 The organization shall plan:
   a) actions to address these risks and opportunities;
   b) how to:
      1) integrate and implement the actions into its quality management system processes (see 4.4);
      2) evaluate the effectiveness of these actions.

Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services.

NOTE 1 Options to address risks can include avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.

NOTE 2 Opportunities can lead to the adoption of new practices, launching new products, opening new markets, addressing new clients, building partnerships, using new raw materials, and saving time and resources.

5.4.2 Quality management system planning

Top management shall ensure that

4.2.a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and

4.2.b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

There is not a comparable clause in 2008 version; only the very general that planning of the QMS should meet the process approach requirements and quality objectives.

This revision expects that the QMS addresses identified risks arising from the consideration of the context of the organization and the requirements of interested parties.

The context of the organization might lead to risks such as:

Product risks – FDA, DOT, EPA (examples gas mileage requirements on vehicles; Product shipping risks-hazardous materials; vehicle lighting requirements; food and drug risks)

The requirements of interested parties may lead to risks identified during contract review such as short delivery times or difficult product requirements or suppliers ability to provide raw materials or components.

Most of our clients will identify risks during contract review and take actions such as negotiating delivery dates or taking exception to product requirements or evaluating risks during design activities (especially design reviews, verification and validation) or identifying risks when selecting and evaluating suppliers.
<table>
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<th>technology and other desirable and viable possibilities to address the organization's or its customers’ needs</th>
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6.1.2.1 Risk analysis
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.

6.1.2.2 Preventive action
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;
f) utilizing lessons learned to prevent recurrence in similar processes (see ISO 9001, Section 7.1.6).

6.1.2.3 Contingency plans
The organization shall:

f.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;
f.b) define contingency plans according to

<table>
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<tr>
<th>6.3.2 CONTINGENCY PLANS</th>
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<tbody>
<tr>
<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>
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</table>

IATF 16949 expects that performance data/indicators such recalls, audit results, returns & repairs, complaints, scrap & rework to be tied into the risk analysis. Similar to the expectation that returns, scrap and complaints were expected to be tied to the FMEAs in ISO/TS 16949, but this is broader and ties to all of the risk analyses mechanisms used by the organization.

This clause adds in the previous preventive action requirements but in the context of requiring specific actions to address risks.

This clause includes the ISO/TS 16949 contingency plan requirements which is now tied to and based on the risk analysis. There should be consistency between the risk analysis and the contingency plans.

These requirements now include:

1. A process to notify customers of any incidents (extent & duration) affecting
| f.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; |
| f.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; |
| f.e | periodically test the contingency plans for effectiveness (e.g., simulations, as appropriate); |
| f.f | conduct contingency plan reviews (at a minimum annually) using a multidisciplinary team including top management, and update as required; |
| f.g | document the contingency plans and retain documented information describing any revision(s), including the person(s) who authorized the change(s). |

The contingency plans shall include provisions to validate that the manufactured product continues to meet customer specifications after the re-start of production following an emergency in which production was stopped and if the regular shutdown processes were not followed.

2. Included specifically are key equipment failure, supply chain (externally provided product & services), natural disasters; fire; utility interruption; labor shortages or infrastructure disruption

3. Periodically testing the plans for effectiveness

4. Review of the plans annually

The contingency plan needs to include the validation of product following an emergency and if the regular shutdown process was not followed
6.2 Quality objectives and planning to achieve them

6.2.1 The organization shall establish quality objectives at relevant functions, levels and processes needed for the quality management system. The quality objectives shall:

- a) be consistent with the quality policy;
- b) be measurable;
- c) take into account applicable requirements;
  - d) be relevant to conformity of products and services and to enhancement of customer satisfaction;
- e) be monitored;
- f) be communicated;
- g) be updated as appropriate.

The organization shall maintain documented information on the quality objectives.

6.2.2 When planning how to achieve its quality objectives, the organization shall determine:

- a) what will be done;
- b) what resources will be required;
- c) who will be responsible;
- d) when it will be completed;
- e) how the results will be evaluated.

5.4 Planning

5.4.1 Quality objectives

Top management shall ensure that quality objectives, including those needed to meet requirements for product (see 7.1 a)), are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.

Some additional requirements for example relevance to product conformity and customer satisfaction

An action plan is now expected for the quality objectives
6.2.2.1 Quality objectives and planning to achieve them — supplemental
Top management shall ensure that 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).

5.4.1.1 Quality objectives — Supplemental
Top management shall define quality objectives and measurements that shall be included in the business plan and used to deploy the quality policy.

**NOTE** Quality objectives should address customer expectations and be achievable within a defined time period.

<table>
<thead>
<tr>
<th>IATF 16949 requires annual objectives</th>
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<tbody>
<tr>
<td>IATF 16949 also ties the establishment of objectives to the interested parties and their requirements, which ties objectives to OEMs for tier 2 suppliers and below.</td>
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</table>
6.3 Planning of changes
When the organization determines the need for changes to the quality management system, the changes shall be carried out in a planned manner (see 4.4). The organization shall consider:

3.a) the purpose of the changes and their potential consequences;
3.b) the integrity of the quality management system;
3.c) the availability of resources;
3.d) the allocation or reallocation of responsibilities and authorities.

5.4.2 Quality management system planning
Top management shall ensure that
4.2.a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and
4.2.b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

QMS change control more detailed

7 Support
7.1 Resources
7.1.1 General
The organization shall determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system.

The organization shall consider:

a) the capabilities of, and constraints on, existing internal resources;
b) what needs to be obtained from external providers.

7.1.2 People
The organization shall determine and provide the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes.

6.1 Provision of resources
The organization shall determine and provide the resources needed
1.a) to implement and maintain the quality management system and continually improve its effectiveness, and
1.b) to enhance customer satisfaction by meeting customer requirements.

No essential changes; some explanation wording added
### 7.1.3 Infrastructure

The organization shall determine, provide and maintain the infrastructure necessary for the operation of its processes and to achieve conformity of products and services.

**NOTE** Infrastructure can include:

- a) buildings and associated utilities;
- b) equipment, including hardware and software;
- c) transportation resources;
- d) information and communication technology.

#### 7.1.3.1 Plant, facility, and equipment planning

The organization shall use a multidisciplinary approach including risk identification and risk mitigation methods for developing and improving plant, facility, and equipment plans. In designing plant layouts, the organization shall:

- a) optimize material flow, material handling, and value-added use of floor space including control of nonconforming product, and
- b) facilitate synchronous material flow, as applicable.

Methods shall be developed and implemented to evaluate manufacturing feasibility for new product or new operations. 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

<table>
<thead>
<tr>
<th>Infrastructure</th>
<th>Infrastructure</th>
<th>No essential changes; some word smithing</th>
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<tbody>
<tr>
<td>The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable,</td>
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<tr>
<td>3.a) buildings, workspace and associated utilities,</td>
<td>3.b) process equipment (both hardware and software), and</td>
<td></td>
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<tr>
<td>3.c) supporting services (such as transport, communication or information systems).</td>
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</table>

#### PLANT, FACILITY, AND EQUIPMENT PLANNING

The organization shall use a multidisciplinary approach (see 7.3.1) for developing plant, facility and equipment plans. Plant layouts shall optimize material travel, handling and value-added use of floor space, and shall facilitate synchronous material flow. Methods shall be developed and implemented to evaluate and monitor the effectiveness of existing operations. These requirements should focus on lean manufacturing principles and the link to the effectiveness of the quality management system.

The connection between new product and new operations/changes to operations and manufacturing feasibility and capacity planning were added.

The connection between process effectiveness and risks was added.
any changes made during process approval, control plan maintenance (see Section 8.5.1.1), and verification of job set-ups (see Section 8.5.1.3).

Assessments of manufacturing feasibility and evaluation of capacity planning shall be inputs to management reviews (see ISO 9001, Section 9.3).

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

NOTE 2 These requirements should apply to on-site supplier activities, as applicable.

7.1.4 Environment for the operation of processes
The organization shall determine, provide and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services.

NOTE A suitable environment can be a combination of human and physical factors, such as:
   a) social (e.g. non-discriminatory, calm, non-confrontational);
   b) psychological (e.g. stress-reducing, burnout prevention, emotionally protective);
   c) physical (e.g. temperature, heat, humidity, light, airflow, hygiene, noise).

These factors can differ substantially depending on the products and services provided.

NOTE Where third-party certification to ISO 45001 (or equivalent) is recognized, it may be used to demonstrate the organization’s conformity to the personnel safety aspects of this.

6.4 Work environment
The organization shall determine and manage the work environment needed to achieve conformity to product requirements.

NOTE The term “work environment” relates to those conditions under which work is performed including physical, environmental and other factors (such as noise, temperature, humidity, lighting or weather).

6.4.1 PERSONNEL SAFETY TO ACHIEVE CONFORMITY TO PRODUCT REQUIREMENTS
Product safety and means to minimize potential risks to employees shall be addressed by the organization, especially in the design and development process and in manufacturing process activities.

6.4.2 CLEANLINESS OF PREMISES

The assessments of manufacturing feasibility and capacity planning are now inputs to management review.

Work environment as it applies to operation of the processes as well as the product.

This was added to the ISO 9001:2015 wording.
7.1.4.1 Environment for the operation of processes — supplemental
The organization shall maintain its premises in a state of order, cleanliness, and repair that is consistent with the product and manufacturing process needs.
### 7.1.5 Monitoring and measuring resources

#### 7.1.5.1 General

The organization shall determine and provide the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements. The organization shall ensure that the resources provided:

1. are suitable for the specific type of monitoring and measurement activities being undertaken;
2. are maintained to ensure their continuing fitness for their purpose.

The organization shall retain appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources.

#### 7.1.5.1.1 Measurement systems analysis

Statistical studies shall be conducted to analyse the variation present in the results of each type of inspection, measurement, and test equipment system identified in the control plan. The analytical methods and acceptance criteria used shall conform to those in reference manuals on measurement systems analysis. Other analytical methods and acceptance criteria may be used if approved by the customer.

Records of customer acceptance of alternative methods shall be retained along with results from alternative measurement systems analysis (see Section 9.1.1.1).

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

### 7.6 Control of monitoring and measuring equipment

The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements.

The organization shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

Where necessary to ensure valid results, measuring equipment shall

1. be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded (see 4.2.4);
2. be adjusted or re-adjusted as necessary;
3. have identification in order to determine its calibration status;
4. be safeguarded from adjustments that would invalidate the measurement result;
5. be protected from damage and deterioration during handling, maintenance and storage.

**The measurement systems analysis requirements are the same; there is an added note about prioritization of MSA studies to focus on critical/special characteristics.**

Calibration moved under resources clause. It at first appears, that software is not covered anymore but the wording was changed from “equipment” to “resources” so it still is covered.
7.1.5.2 Measurement traceability

When measurement traceability is a requirement, or is considered by the organization to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be:

a) calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification shall be retained as documented information;

b) identified in order to determine their status;

c) safe guarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

The organization shall determine if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and shall take appropriate action as necessary.

NOTE A number or another identifier traceable to the device calibration record meets the intent of the requirements in ISO 9001:2015.

7.1.5.2.1 Calibration/verification records

The organization shall have a documented process for managing calibration/verification records.

Records of the calibration/verification

Statistical studies shall be conducted to analyse the variation present in the results of each type of measuring and test equipment system. This requirement shall apply to measurement systems referenced in the control plan. The analytical methods and acceptance criteria used shall conform to those in customer reference manuals on measurement systems analysis. Other analytical methods and acceptance criteria may be used if approved by the customer.

In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected.

Records of the results of calibration and verification shall be maintained (see 4.2.4).

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.

NOTE Confirmation of the ability of computer software to satisfy the intended application would typically include its verification and configuration management to maintain its suitability for use.

A documented process is required for managing calibration/verification records.

This clause on calibration/verification records is expanded to cover out of
**7.6.2 CALIBRATION/VERIFICATION RECORDS**

Records of the calibration/verification activity for all gauges, measuring and test equipment, needed to provide evidence of conformity of product to determined requirements, including employee- and customer-owned equipment, shall include:

- Equipment identification, including the measurement standard against which the equipment is calibrated,
- Revisions following engineering changes,
- Any out-of-specification readings as received for calibration/verification,
- An assessment of the impact of the out-of-specification condition,
- Statements of conformity to specification after calibration/verification, and
- Notification to the customer if suspect product or material has been shipped.

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

- Revisions following engineering changes that impact measurement systems;
- Any out-of-specification readings as received 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 standard's last 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 to specification after calibration/verification;
- Verification that the software version used for product and process control is as specified;
- Records of the calibration and maintenance activities for all gauging (including employee-owned equipment, 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.

**NOTE**

A number or other identifier traceable to the device calibration record meets the intent of requirement c) above.
supplier-owned equipment); production-related software verification used for product and process control (including software installed on employee-owned equipment, customer-owned equipment, or on-site supplier-owned equipment).

7.1.5.3 Laboratory Requirements

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

b.i.a) adequacy of the laboratory technical procedures;

b.i.b) competency of the laboratory personnel;

b.i.c) testing of the product;

b.i.d) 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 available, the organization shall define and implement a methodology to verify measurement system capability;

b.i.e) customer requirements, if any;

b.i.f) review of the related records.

NOTE Third-party accreditation to ISO/IEC 17025 (or equivalent) may be used to demonstrate the organization’s in-house laboratory conformity to this requirement.

7.1.5.3.2 External laboratory
External/commercial/independent laboratory facilities used for inspection, test, or calibration services by the organization shall have a defined laboratory scope that

The internal laboratory requirements are essentially unchanged.

The external laboratory requirements are essentially unchanged.

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

- adequacy of the laboratory procedures;
- 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.), and
- review of the related records.

NOTE Accreditation to ISO/IEC 17025 may be used to demonstrate the organization’s in-house laboratory conformity to this requirement but is not mandatory.
**7.6.3.2 EXTERNAL LABORATORY**

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Description</th>
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<tbody>
<tr>
<td><strong>Required</strong></td>
<td>Includes the capability to perform the required inspection, test, or calibration, and either:</td>
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<tr>
<td></td>
<td>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 a national accreditation body; or</td>
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<tr>
<td></td>
<td>there shall be evidence that the external laboratory is acceptable to the customer.</td>
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</table>

**NOTE** Such evidence may be demonstrated by customer assessment, for example, or 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 performed by the organization assessing the laboratory using a customer-approved 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 7.1.5.3.1 have been met.

Use of calibration services, other than by qualified (or customer accepted) laboratories, may be subject to government regulatory confirmation, if required.

**NOTE 1** Such evidence may be demonstrated by customer assessment, for example, or 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 7.6.3.1 have been met.
<table>
<thead>
<tr>
<th>7.1.6 Organizational knowledge</th>
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<th>6.2 Human resources</th>
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<tbody>
<tr>
<td>The organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services. This knowledge shall be maintained and be made available to the extent necessary. When addressing changing needs and trends, the organization shall consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates. NOTE 1 Organizational knowledge is knowledge specific to the organization; it is gained by experience. It is information that is used and shared to achieve the organization’s objectives. NOTE 2 Organizational knowledge can be based on: a) internal sources (e.g. intellectual property; knowledge gained from experience; lessons learned from failures and successful projects; capturing and sharing undocumented knowledge and experience; the results of improvements in processes, products and services); b) external sources (e.g. standards; academia; conferences; gathering knowledge from customers or external providers).</td>
<td>There is no equivalent clause in ISO9001:2008.</td>
<td>Most clients do not have any process for capturing this knowledge other than external standards and specifications. Will have to consider establishing a lessons learned database to capture tribal knowledge. Clients should consider how the organization captures the knowledge gained when someone is sent to external training or external training is done internally.</td>
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<tr>
<td>7.2 Competence</td>
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<td></td>
<td>6.2.1 General</td>
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<tr>
<td>The organization shall: a) determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system;</td>
<td></td>
<td>Personnel performing work affecting conformity to product requirements shall be competent on the basis of appropriate education, training, skills and experience.</td>
<td>Awareness moved to next clause 7.3</td>
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<tr>
<td>7.2.1 Competence — supplemental</td>
<td>6.2.2 Competence, training and awareness</td>
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<tr>
<td>The organization shall establish and maintain documented process(es) for identifying training needs including awareness (see Section 7.3.1) 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.</td>
<td>The organization shall</td>
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<tr>
<td>7.2.2 Competence — on-the-job training</td>
<td>a) determine the necessary competence for personnel performing work affecting conformity to product requirements,</td>
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<tr>
<td>The organization shall provide 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 contract or agency personnel. The level of detail required for on-the-job training shall be</td>
<td>b) where applicable, provide training or take other actions to achieve the necessary competence,</td>
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<tr>
<td>NOTE 1 This applies to all employees having an effect on quality at all levels of the organization.</td>
<td>c) evaluate the effectiveness of the actions taken,</td>
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<tr>
<td>NOTE 2 An example of the customer-specific requirements is the application of</td>
<td>d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and</td>
<td></td>
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<tr>
<td>6.2.2.1 TRAINING</td>
<td>e) maintain appropriate records of education, training, skills and experience (see 4.2.4).</td>
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<tr>
<td>The organization shall establish and maintain documented procedures for identifying training needs and achieving competence of all personnel performing activities affecting conformity to product requirements. Personnel performing specific assigned tasks shall be qualified, as required, with particular attention to the satisfaction of customer requirements.</td>
<td>The clause on “Product Design Skills” was moved to clause 8.3.2.2</td>
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<tr>
<td>Additional details in the on the job training clause but no big changes</td>
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commensurate with the level of education the personnel possess and the complexity of the task(s) they are required to perform for their daily work. Persons whose work can affect quality shall be informed about the consequences of nonconformity to customer requirements.

7.2.3 Internal auditor competency
The organization shall have a documented process(es) to verify that internal auditors are competent, taking into account any customer-specific requirements. For additional guidance on auditor competencies, refer to ISO 19011. The organization shall maintain a list of qualified internal auditors. Quality management system auditors, manufacturing process auditors, and product auditors shall all be able to demonstrate the following minimum competencies:

a) understanding of the automotive process approach for auditing, including risk-based thinking;

b) understanding of applicable customer-specific requirements;

c) understanding of applicable ISO 9001 and IATF 16949 requirements related to the scope of the audit;

d) understanding of applicable core tool requirements related to the scope of the audit;

e) understanding how to plan, conduct, report, and close out audit findings.

Additionally, manufacturing process auditors shall demonstrate technical understanding of the relevant manufacturing process(es) to be audited, including process risk analysis (such as PFMEA) and control plan. Product auditors shall demonstrate competence in understanding product requirements and use of relevant measuring and test digitized mathematically based data.

6.2.2.2 TRAINING ON THE JOB
The organization shall provide 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 to the customer of nonconformity to quality requirements.

New detailed requirements for internal auditor competency including demonstration of competency.
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:

f) executing a minimum number of audits per year, as defined by the organization; and

g) maintaining knowledge of relevant requirements based on internal 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

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 and organization specific requirements;

c) applicable ISO 9001 and IATF 16949 requirements related to the scope of the audit;

d) applicable manufacturing process(es) to be audited, including PFMEA and control plan;

e) applicable core tool requirements related to the scope of the audit;

f) how to plan, conduct, prepare audit

Demonstration of the maintenance of auditor competency

New detailed requirements for second party auditor competency including demonstration of competency
reports, and close out audit findings.
<table>
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<tr>
<th>7.3 Awareness</th>
<th>5.3 d Quality policy</th>
<th>These awareness requirements were dispersed in several clauses previously</th>
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<tbody>
<tr>
<td>The organization shall ensure that persons doing work under the organization’s control are aware of:</td>
<td>5.5.2 c</td>
<td>Our clients should consider including questions related to these requirement in their internal audits to help gauge the awareness of their personnel</td>
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<tr>
<td>a) the quality policy;</td>
<td>6.2.2 d</td>
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<td>b) relevant quality objectives;</td>
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<td>c) their contribution to the effectiveness of the quality management system, including the benefits of improved performance;</td>
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<tr>
<td>d) the implications of not conforming with the quality management system requirements.</td>
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<tr>
<td>Section</td>
<td>Text</td>
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<tr>
<td>7.3.1 Awareness — supplemental</td>
<td>The organization shall maintain documented information that demonstrates that 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 nonconforming product.</td>
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<tr>
<td>7.3.2 Employee motivation and empowerment</td>
<td>The organization shall maintain a documented process(es) 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.</td>
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<tr>
<td>7.4 Communication</td>
<td>The organization shall determine the internal and external communications relevant to the quality management system, including: on what it will communicate; b) when to communicate; c) with whom to communicate; d) how to communicate; e) who communicates.</td>
<td></td>
</tr>
<tr>
<td>6.2.2.3 EMPLOYEE MOTIVATION AND EMPOWERMENT</td>
<td>The organization shall have a process to motivate employees to achieve quality objectives, to make continual improvements, and to create an environment to promote innovation. The process shall include the promotion of quality and technological awareness throughout the whole organization.</td>
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<tr>
<td>5.5.3 Internal communication</td>
<td>Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.</td>
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</table>

The clause requiring a process to measure the extent to which personnel are aware of ..... “ has been reworded to “maintain documented information that demonstrates that .....” The clause on employee motivation has been reworded; not significant changes...
### 7.5 Documented information

#### 7.5.1 General

The organization’s quality management system shall include:

- a) documented information required by this International Standard;
- b) documented information determined by the organization as being necessary for the effectiveness of the quality management system.

**NOTE** The extent of documented information for a quality management system can differ from one organization to another due to:

- the size of organization and its type of activities, processes, products and services;
- the complexity of processes and their interactions;
- the competence of persons.

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#### 7.5.1.1 Quality management system documentation

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 is used, then a list shall be retained of the documents that comprise 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:**

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#### 4.2.1 General

The quality management system documentation shall include:

- a) documented statements of a quality policy and quality objectives,
- b) a quality manual,
- c) documented procedures and records required by this International Standard, and
- d) documents, including records, determined by the organization to be necessary to ensure the effective planning, operation and control of its processes.

**NOTE 1** Where the term “documented procedure” appears within this International Standard, this means that the procedure is established, documented, implemented and maintained. A single document may address the requirements for one or more procedures. A requirement for a documented procedure may be covered by more than one document.

**NOTE 2** The extent of the quality management system documentation can differ from one organization to another due to:

- a) the size of organization and type of activities,
- b) the complexity of processes and their interactions,
- c) the competence of personnel.

**NOTE 3** The documentation can be in any form or type of medium.

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#### 4.2.2 Quality manual

The organization shall establish and maintain a quality manual that includes:

- 2.2.b) the scope of the quality management system, including details of and justification for any

---

The term “documented information” is used to cover documents such as procedures and records.

There is no longer a requirement for specific procedures.

For example:

Instead of an internal audit procedure; an organization could present an internal audit schedule; and audit forms/records that demonstrate audit criteria, audit scope, audit planning; audit reporting and corrective action on NCRs.

Controls still required but may be a little more specific or descriptive.

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*IATF 16949 adds back in the requirement for a quality manual with some required content including previous content which was required.*
b) documented processes established for the quality management system, or reference to them;

c) the organization's processes and their sequence and interactions (inputs and outputs), including type and extent of control of any outsourced processes;

d) 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.

7.5.2 Creating and updating
When creating and updating documented information, the organization shall ensure appropriate:

a) identification and description (e.g. a title, date, author, or reference number);

b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic);

c) review and approval for suitability and adequacy.

Control of documented Information

7.5.3.1 Documented information required by the quality management system and by this International Standard shall be controlled to ensure:

5.3.1a) it is available and suitable for use;

exclusions (see 1.2),

2.2.c) the documented procedures established for the quality management system, or reference to them, and

2.2.d) a description of the interaction between the processes of the quality management system.

4.2.3 Control of documents
Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.
use, where and when it is needed;

5.3.1.b) it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).

7.5.3.2 For the control of documented information, the organization shall address the following activities, as applicable:

a) distribution, access, retrieval and use;

b) storage and preservation, including preservation of legibility;

c) control of changes (e.g. version control);

d) retention and disposition.

Documented information of external origin determined by the organization to be necessary for the planning and operation of the quality management system shall be identified as appropriate, and be controlled.

Documented information retained as evidence of conformity shall be protected from unintended alterations.

NOTE Access can imply a decision regarding the permission to view the documented information only, or the permission and authority to view and change the documented information.

7.5.3.2.1 Record retention

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 approvals, tooling records (including maintenance and ownership), product and process design records, purchase orders (if applicable), or.

A documented procedure shall be established to define the controls needed

a) to approve documents for adequacy prior to issue,

b) to review and update as necessary and re-approve documents,

c) to ensure that changes and the current revision status of documents are identified,

d) to ensure that relevant versions of applicable documents are available at points of use,

e) to ensure that documents remain legible and readily identifiable,

f) to ensure that documents of external origin determined by the organization to be necessary for the planning and operation of the quality management system are identified and their distribution controlled, and

g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

4.2.4 Control of records

Records established to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled.

The organization shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records.

Records shall remain legible,
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
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 ISO 9001, Section 8.3.6. When an engineering standard/specification change results in a product realization process change, refer to the requirements in Section 8.5.6.1. The organization shall retain 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.

NOTE 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. |   |   |
### 8 Operation

#### 8.1 Operational planning and control

The organization shall plan, implement and control the processes (see 4.4) needed to meet the requirements for the provision of products and services, and to implement the actions determined in Clause 6, by:

a) determining the requirements for the products and services;

b) establishing criteria for:

1) the processes;

2) the acceptance of products and services;

c) determining the resources needed to achieve conformity to the product and service requirements;

d) implementing control of the processes in accordance with the criteria;

e) determining and keeping documented information to the extent necessary:

1) to have confidence that the processes have been carried out as planned;

2) to demonstrate the conformity of products and services to their requirements.

NOTE "Keeping" implies both the maintaining and the retaining of documented information.

The output of this planning shall be suitable for the organization’s operations.

The organization shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

The organization shall ensure that outsourced processes are controlled (see 8.4).

#### 7.1 Planning of product realization

The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1).

In planning product realization, the organization shall determine the following, as appropriate:

a) quality objectives and requirements for the product;

b) the need to establish processes and documents, and to provide resources specific to the product;

c) required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance;

d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4).

The output of this planning shall be in a form suitable for the organization’s method of operations.

NOTE 1 A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract can be referred to as a quality plan.

NOTE 2 The organization may also apply the requirements given in 7.3 to the development of product realization processes

**NOTE Some customers refer to project management or advanced product quality planning as a means to achieve product realization. Advanced product quality**
8.1.1 Operational planning and control — supplemental

When planning for product realization, the following topics shall be included:

a) customer product requirements and technical specifications;

b) logistics requirements;

c) manufacturing feasibility;

d) project planning (refer to ISO 9001, Section 8.3.2);

e) acceptance criteria.

The resources identified in ISO 9001, Section 8.1 c), refer to the required verification, validation, monitoring, measurement, inspection, and test activities specific to the product and the criteria for product acceptance.

8.1.2 Confidentiality

The organization shall ensure the confidentiality of customer-contracted products and projects under development, including related product information.

7.1.1 Planning of product realization — supplemental

Customer requirements and references to its technical specifications shall be included in the planning of product realization as a component of the quality plan.

7.1.2 Acceptance criteria

Acceptance criteria shall be defined by the organization and, where required, approved by the customer.

For attribute data sampling, the acceptance level shall be zero defects.

(see 8.2.3.1).

7.1.3 Confidentiality

The organization shall ensure the confidentiality of customer-contracted products and projects under development, and related product information.

There are a few additions (logistics, project planning).

Less detail with respect to acceptance criteria.

The change control clause 7.1.4 was moved under the design and development change clause see 8.3.6.1 below.
### 8.2 Requirements for products and services

#### 8.2.1 Customer communication
Communication with customers shall include:

a) providing information relating to products and services;

b) handling enquiries, contracts or orders, including changes;

c) obtaining customer feedback relating to products and services, including customer complaints;

d) handling or controlling customer property;

e) establishing specific requirements for contingency actions, when relevant.

#### 8.2.1.1 Customer communication — supplemental

*Written or verbal communication shall be in the language agreed with the customer. The organization shall have the ability to communicate necessary information, including data in a customer-specified computer language and format (e.g., computer-aided design data, electronic data interchange).*

#### 8.2.2 Determining the requirements related to products and services
When determining the requirements for the products and services to be offered to customers, the organization shall ensure that:

a) the requirements for the products and services are defined, including:

1) any applicable statutory and

### 7.2 Determination of requirements related to the product

The organization shall determine

a) requirements specified by the customer, including the requirements for delivery and post-delivery activities,

b) requirements not stated by the customer but necessary for specified or intended

#### 7.2.1 Determination of requirements related to the product

a) requirements specified by the customer, including the requirements for delivery and post-delivery activities,

#### 7.2.3 Customer communication
The organization shall determine and implement effective arrangements for communicating with customers in relation to

a) product information,

b) enquiries, contracts or order handling, including amendments, and

c) customer feedback, including customer complaints.

#### 7.2.3.1 CUSTOMER COMMUNICATION — SUPPLEMENTAL

*The organization shall have the ability to communicate necessary information, including data, in a customer-specified language and format (e.g., computer-aided design data, electronic data exchange).*

Rearranged order of sub-clauses

Customer communication added a couple of communication topics

Some reorganization & rewording of requirements

Note on post delivery activities removed

More explicit callout concerning the communication of data
regulatory requirements;
2) those considered necessary by the organization;
b) the organization can meet the claims for the products and services it offers.

<table>
<thead>
<tr>
<th>8.2.2.1 Determining the requirements for products and services — supplemental</th>
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<tbody>
<tr>
<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. Compliance to ISO 9001, Section 8.2.2 item a) 1), shall include but not be limited to the following: all applicable government, safety, and environmental regulations related to acquisition, storage, handling, recycling, elimination, or disposal of material.</td>
</tr>
</tbody>
</table>

use, where known,
c) statutory and regulatory requirements applicable to the product, and
d) any additional requirements considered necessary by the organization.

NOTE Post-delivery activities include, for example, actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.

NOTE 1 Post-delivery activities include any after-sales product 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).

NOTE 3 Compliance to item c) includes all applicable government, safety and environmental regulations, applied to acquisition, storage, handling, recycling, elimination or disposal of materials. |
8.2.3 Review of requirements related to products and services

8.2.3.1 The organization shall ensure that it has the ability to meet the requirements for products and services to be offered to customers. The organization shall conduct a review before committing to supply products and services to a customer, to include:
   a) requirements specified by the customer, including the requirements for delivery and post-delivery activities;
   b) requirements not stated by the customer, but necessary for the specified or intended use, when known;
   c) requirements specified by the organization;
   d) statutory and regulatory requirements applicable to the products and services;
   e) contract or order requirements differing from those previously expressed.

The organization shall ensure that contract or order requirements differing from those previously defined are resolved.

The customer’s requirements shall be confirmed by the organization before acceptance, when the customer does not provide a documented statement of their requirements.

NOTE In some situations, such as internet sales, a formal review is impractical for each order. Instead, the review can cover relevant product information, such as catalogues or advertising material.

8.2.3.1.1 Review of the requirements for products and services — supplemental

The organization shall retain documented evidence of a customer-authorized waiver for the requirements stated in ISO 9001.
8.3 Design and development of products and services

8.3.1 General
The organization shall establish, implement and maintain a design and development process that is appropriate to ensure the subsequent provision of products and services.

8.3.1.1 Design and development of products and services — supplemental
The requirements of ISO 9001, Section 8.3.1, shall apply to product and manufacturing process design and development and shall focus on error prevention rather than detection.

The organization shall document the design and development process.

8.3.2 Design and development planning
In determining the stages and controls for design and development, the organization shall consider:

a) the nature, duration and complexity of the design and development activities;

b) the required process stages, including applicable design and development reviews;

c) the required design and development verification and validation activities;

d) the responsibilities and authorities involved in the design and development process;

e) the internal and external resource needs for the design and development of products and services.

7.3 Design and development

NOTE The requirements of 7.3 include product and manufacturing process design and development, and focus on error prevention rather than detection.

7.3.1 Design and development planning
The organization shall plan and control the design and development of product. During the design and development planning, the organization shall determine

a) the design and development stages,

b) the review, verification and validation that are appropriate to each design and development stage, and

c) the responsibilities and authorities for design and development.

The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.

Planning output shall be updated, as appropriate, as the design and development progresses.

NOTE Design and development review, verification and validation have distinct purposes. They can be conducted and recorded separately or in any combination, as suitable for the product and the organization.
services;

f) the need to control interfaces between persons involved in the design and development process;

g) the need for involvement of customers and users in the design and development process;

h) the requirements for subsequent provision of products and services;

i) the level of control expected for the design and development process by customers and other relevant interested parties;

j) the documented information needed to demonstrate that design and development requirements have been met.

8.3.2.1 Design and development planning — supplemental
The organization shall ensure that design and development planning includes all affected stakeholders within the organization and, as appropriate, its supply chain. Examples of areas for using such a multidisciplinary approach include but are not limited to the following:

a) project management (for example, APQP or VDA-RGA);

b) product and manufacturing process design activities (for example, DFM and DFA), such as consideration of the use of alternative designs and manufacturing processes;

c) development and review of product design risk analysis (FMEAs), including actions to reduce potential risks;

d) development and review of manufacturing process risk analysis.

7.3.1.1 MULTIDISCIPLINARY APPROACH
The organization shall use a multidisciplinary approach to prepare for product realization, including

— development/finalization and monitoring of special characteristics,

— development and review of FMEAs, including actions to reduce potential risks, and

— development and review of control plans.

NOTE A multidisciplinary approach typically includes the organization’s design, manufacturing, engineering, quality, production and other appropriate personnel.
(for example, FMEAs, process flows, control plans, and standard work instructions).

**NOTE** A multidisciplinary approach typically includes the organization’s design, manufacturing, engineering, quality, production, purchasing, supplier, maintenance, and other appropriate functions.

### 8.3.2.2 Product design skills

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.

**NOTE** An example of product design skills is the application of digitized mathematically based data.

### 8.3.2.3 Development of products with embedded software

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).

### 6.2.2.1 PRODUCT DESIGN SKILLS

The organization shall ensure that personnel with product design responsibility are competent to achieve design requirements and are skilled in applicable tools and techniques. Applicable tools and techniques shall be identified by the organization.

**A new clause addressing software development for embedded software and quality assurance for embedded software**
8.3.3 Design and development 

Inputs: The organization shall determine the requirements essential for the specific types of products and services to be designed and developed. The organization shall consider:

3.3.a) functional and performance requirements;
3.3.b) information derived from previous similar design and development activities;
3.3.c) statutory and regulatory requirements;
3.3.d) standards or codes of practice that the organization has committed to implement;
3.3.e) potential consequences of failure due to the nature of the products and services.

Inputs shall be adequate for design and development purposes, complete and unambiguous. Conflicting design and development inputs shall be resolved. The organization shall retain documented information on design and development inputs.

7.3.2 Design and development inputs

Inputs relating to product requirements shall be determined and records maintained (see 4.2.4). These inputs shall include:

- functional and performance requirements,
- applicable statutory and regulatory requirements,
- where applicable, information derived from previous similar designs, and
- other requirements essential for design and development.

The inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.

**NOTE** Special characteristics (see 7.2.1.1) are included in this requirement.

7.3.2.1 PRODUCT DESIGN INPUT

The organization shall identify, document and review the product design input requirements, including the following:

- customer requirements (contract review) such as special characteristics (see 7.3.2.3), identification, traceability and packaging;
- use of information: the organization shall have a process to deploy information gained from previous design projects, competitor analysis, supplier feedback.

The design input clause now includes a tie to the feasibility analysis and requires a process for deploying information from previous projects; benchmarking; supplier feedback.
a) **product specifications including but not limited to special characteristics** (see Section 8.3.3.3);
b) **boundary and interface requirements**;
c) identification, traceability, and packaging;
d) **consideration of design alternatives**;
e) **assessment of risks with the input requirements and the organization's ability to mitigate/manage the risks**, including from the feasibility analysis;
f) **targets for conformity to product requirements including preservation, reliability, durability, serviceability, health, safety, environmental, development timing, and cost**;
g) **applicable statutory and regulatory requirements of the customer-identified country of destination, if provided**;
h) **embedded software requirements**.

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.

7.3.2.2 **MANUFACTURING PROCESS DESIGN INPUT**

The organization shall identify, document and review the manufacturing process design input requirements, including:

- product design output data,
- **targets for productivity, process capability and cost**, and
- customers requirements, if any, and experience from previous developments.

**NOTE** The manufacturing process design input requirements include:

- feedback, internal input, field data, and other relevant sources, for current and future projects of a similar nature:
- targets for conformity to product requirements, life, reliability, durability, maintainability, timing and cost.

A few new inputs listed including technological alternatives, new materials; product handling and ergonomics.
<table>
<thead>
<tr>
<th>Capability, timing, and cost:</th>
<th>includes the use of error-proofing methods to a degree appropriate to the magnitude of the problems and commensurate with the risks encountered.</th>
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<tr>
<td>d) Customer requirements, if any:</td>
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<tr>
<td>e) Experience from previous developments:</td>
<td></td>
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<tr>
<td>f) New materials:</td>
<td></td>
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<tr>
<td>g) Product handling and ergonomic requirements: and</td>
<td></td>
</tr>
<tr>
<td>h) Design for manufacturing and design for assembly.</td>
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</tbody>
</table>

The manufacturing process design shall include the use of error-proofing methods to a degree appropriate to the magnitude of the problem(s) and commensurate with the risks encountered.

### 8.3.2.3 Special characteristics

The organization shall identify special characteristics [see 7.3.3 d)] and include all special characteristics in the control plan.
- Comply with customer-specified definitions and symbols, 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.

**7.3.2.3 SPECIAL CHARACTERISTICS**

The organization shall identify special characteristics, including those determined by the customer and the risk analysis performed by the organization, and shall include the following:

- **h.a)** Documentation of all special characteristics in the drawings (as required), risk analysis (such as FMEA), control plans, and standard work/operator instructions; special characteristics are identified with specific markings and are cascaded through each of these documents;
- **h.b)** Development of control and monitoring strategies for special characteristics of products and production processes;
- **h.c)** Customer-specified approvals, when required;
- **h.d)** Compliance with customer-specified definitions and symbols or the
8.3.4 Design and development controls

The organization shall apply controls to the design and development process to ensure that:

a) the results to be achieved are defined;
b) reviews are conducted to evaluate the ability of the results of design and development to meet requirements;
c) verification activities are conducted to ensure that the design and development outputs meet the input requirements;
d) validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use;
e) any necessary actions are taken on problems determined during the reviews, or verification and validation activities;
f) documented information of these activities is retained.

NOTE Design and development reviews, verification and validation have distinct purposes. They can be conducted separately or in any combination, as is suitable for the products and services of the organization.

7.3.4.1 Monitoring

Measurements at specified stages during the design and development shall be defined, analysed and reported with summary results as an input to management review.

NOTE These measurements include quality, risks, costs, lead-times, critical paths and others, as appropriate.

Design and development review

At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1)

3.4.a) to evaluate the ability of the results of design and development to meet requirements, and
3.4.b) to identify any problems and propose necessary actions.

Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained (see 4.2.4).

NOTE These reviews are normally coordinated with the design phases and include manufacturing process design and development.

7.3.5 Design and

controls

Now includes activity reporting to the customer as required
**design and development of products and processes shall be defined, analysed, 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.

**NOTE** When appropriate, these measurements may include quality risks, costs, lead times, critical paths, and other measurements.

8.3.4.2 **Design and development validation**

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

Where contractually agreed with the customer, this shall include evaluation of the interaction of the organization's product, including embedded software, within the system of the final customer's product.

7.3.6 **Design and development validation**

Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained (see 4.2.4).

**NOTE 1** The validation process normally includes an analysis of field reports for similar products.

**NOTE 2** The requirements of 7.3.5 and 7.3.6 above apply to both product and manufacturing processes.

7.3.6.1 **DESIGN AND DEVELOPMENT VALIDATION — SUPPLEMENTAL**

Design and development validation shall be performed in accordance with customer requirements, including programme timing.

7.3.6.2 **PROTOTYPE PROGRAMME**
### 8.3.4.3 Prototype programme

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.

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, Section 8.4).

### 8.3.4.4 Product approval process

The organization shall establish, implement, and maintain a product and manufacturing approval process conforming to requirements defined by the customer(s).

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

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

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### 7.3.6.3 PRODUCT APPROVAL PROCESS

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. This product and manufacturing process approval procedure shall also be applied to suppliers.
NOTE Product approval should be subsequent to the verification of the manufacturing process.
### 8.3.5 Design and development outputs

The organization shall ensure that design and development outputs:

- a) meet the input requirements;
- b) are adequate for the subsequent processes for the provision of products and services;
- c) include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria;
- d) specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision.

The organization shall retain documented information on design and development outputs.

#### 8.3.5.1 Design and development outputs — 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:

- a) **design risk analysis (FMEA)**;
- b) **reliability study results**;
- c) **product special characteristics**;
- d) **results of product design error-proofing, such as DFSS, DFMA, and FTA**;
- e) **product definition including 3D models, technical data packages, product manufacturing information, and geometric dimensioning & tolerancing (GD&T)**;
- f) **2D drawings, product manufacturing information, and geometric**

### 7.3.3 Design and development outputs

The outputs of design and development shall be in a form suitable for verification against the design and development input and shall be approved prior to release.

Design and development outputs shall:

- a) meet the input requirements for design and development,
- b) provide appropriate information for purchasing, production and service provision,
- c) contain or reference product acceptance criteria, and
- d) specify the characteristics of the product that are essential for its safe and proper use.

**NOTE** Information for production and service provision can include details for the preservation of product.

#### 7.3.3.1 PRODUCT DESIGN OUTPUTS — 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.
| dimensioning & tolerancing (GD&T): | — product design reviews results, and |
| g) product design review results: | — diagnostic guidelines, where applicable. |
| h) service diagnostic guidelines and | |
| repair and serviceability instructions: | |
| i) service part requirements; | |
| j) packaging and labeling requirements | |
| for shipping. | |

NOTE Interim design outputs should include any engineering problems being resolved through a tradeoff process.

8.3.5.2 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:

| a) specifications and drawings; | |
| b) special characteristics for product and manufacturing process; | |
| c) identification of process input variables that impact characteristics; | |
| d) tooling and equipment for production and control, including capability studies of equipment and process(es); | |
| e) manufacturing process flow charts/layout, including linkage of product, process, and tooling; | |
| f) capacity analysis; | |
| g) manufacturing process FMEA; | |
| h) maintenance plans and instructions; | |
| i) control plan (see Annex A); | |
| j) standard work and work instructions; | |
| k) process approval acceptance criteria; | |
| l) data for quality, reliability, maintainability, and measurability; | |
| m) results of error-proofing identification and verification, as appropriate; | |
n) methods of rapid detection, feedback, and correction of product/manufacturing process nonconformities.
8.3.6 Design and development changes
The organization shall identify, review and control changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements.

The organization shall retain documented information on:

a) design and development changes;
b) the results of reviews;
c) the authorization of the changes;
d) the actions taken to prevent adverse impacts.

8.3.6.1 Design and development changes — supplemental
The organization shall evaluate all design changes after initial product approval, including those proposed by the organization or its suppliers, for potential impact on fit, form, function, performance, and/or durability. These changes shall be validated against customer requirements and approved internally, prior to production implementation.

If required by the customer, the organization shall obtain documented approval, or a documented waiver, from the customer prior to production implementation.

For products with embedded software, the

7.3.7 Control of design and development changes
Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered. Records of the results of the review of changes and any necessary actions shall be maintained (see 4.2.4).

NOTE Design and development changes include all changes during the product programme life (see 7.1.4).

7.1.4 CHANGE CONTROL
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.
**8.4 Control of external provision of goods and services**

8.4.1 General

The organization shall ensure that externally provided processes, products and services conform to requirements.

The organization shall determine the controls to be applied to externally provided processes, products and services when:

a) products and services from external providers are intended for incorporation into the organization’s own products and services;

b) products and services are provided directly to the customer(s) by external providers on behalf of the organization;

c) a process, or part of a process, is provided by an external provider as a

**7.4 Purchasing**

7.4.1 Purchasing process

The organization shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.

The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization’s requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall

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**NOTE 2** The above requirement applies to product and manufacturing process changes.
result of a decision by the organization. The organization shall determine and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. The organization shall retain documented information of these activities and any necessary actions arising from the evaluations.

8.4.1.1 General — supplemental
The organization shall include all products and services that affect customer requirements such as subassembly, sequencing, sorting, rework, and calibration services in the scope of their definition of externally provided products, processes, and services.

8.4.1.2 Supplier selection process
The organization shall have a documented supplier selection process. The selection process shall include:

a) an assessment of the selected supplier's risk to product conformity and uninterrupted supply of the organization's product to their customers;

b) relevant quality and delivery performance;

c) an evaluation of the supplier's quality management system;

d) multidisciplinary decision making; and

e) an assessment of software development capabilities, if applicable.

Other supplier selection criteria that should be maintained (see 4.2.4).

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

NOTE 2 When there are mergers, acquisitions or affiliations associated with suppliers, the organization should verify the continuity of the supplier's quality management system and its effectiveness.

Note 1 is now in the supplemental requirements clause 8.4.1.1

Note 2 is now in the supplemental requirements clause 8.4.1.2

Requires a documented supplier selection process including more details concerning topics considered.
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**.

### 8.4.1.3 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 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.

### 7.4.1.3 CUSTOMER-APPROVED SOURCES

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.

Note that the requirements in 8.4.1.2 with respect to supplier selection do not apply to directed buy sources.
8.4.2 Type and extent of control
The organization shall ensure that externally provided processes, products and services do not adversely affect the organization’s ability to consistently deliver conforming products and services to its customers. The organization shall:

a) ensure that externally provided processes remain within the control of its quality management system;

b) define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;

c) take into consideration:

1) the potential impact of the externally provided processes, products and services on the organization’s ability to consistently meet customer and applicable statutory and regulatory requirements;

2) the effectiveness of the controls applied by the external provider;

d) determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.

7.4.3 Verification of purchased product
The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

Where the organization or its customer intends to perform verification at the supplier’s premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.

Type & extent of control separated into new clause and verification of purchased product incorporated into this clause

New requirements “to ensure that externally provided processes remain within the control of its QMS” – we do not interpret this to mean that an organization having an outsource Process cannot drop ship to the customer

8.4.2.1 Type and extent of control — supplemental
The organization shall have a documented process to identify outsourced processes and to select the types and extent of controls used to

Need a documented process to select and control outsourced processes

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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 risks.

8.4.2.2 Statutory and regulatory requirements
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 the customer-identified country of destination, if provided.

If 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 at suppliers.

8.4.2.3 Supplier quality management system development
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 [e.g., 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:

<table>
<thead>
<tr>
<th>7.4.1.1 STATUTORY AND REGULATORY CONFORMITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>All purchased products or materials used in product shall conform to applicable statutory and regulatory requirements.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>7.4.1.2 SUPPLIER QUALITY MANAGEMENT SYSTEM DEVELOPMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>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 in achieving this goal.</td>
</tr>
</tbody>
</table>

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

Expanded supplemental clause requiring a documented process for ensuring regulatory compliance and associated customer compliance by the supply chain

The supplier QMS development has been clarified; now includes second party audits; ISO9001 certification by accredited CB; the process sequence leads to certification to IATF 16949

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a) **compliance to ISO 9001 through second-party audits;**
b) **certification to ISO 9001 through third-party audits:** unless otherwise specified by the customer, suppliers to the organization shall demonstrate conformity to ISO 9001 by maintaining a third-party certification issued by a certification body bearing the accreditation mark of a recognized IAF MLA (International Accreditation Forum Multilateral Recognition Arrangement) member and where the accreditation body’s main scope includes management system certification to ISO/IEC 17021;
c) **certification to ISO 9001 with compliance to other customer-defined QMS requirements (such as Minimum Automotive Quality Management System Requirements for Sub-Tier Suppliers [MAQMSR] or equivalent) through second-party audits;**
d) **certification to ISO9001 with compliance to IATF 16949 through second-party audits;**
e) **certification to 16949 through third-party audits (valid third-party certification of the supplier to IATF 16949 by an IATF-recognized certification body).**

8.4.2.3.1 **Automotive product-related software or automotive products with embedded software**
The organization shall require their suppliers of automotive product-related software, or automotive products with embedded software, to implement and maintain a process for software quality assurance for their products.

A software development assessment methodology shall be utilized to assess...
the supplier's software development process. Using prioritization based on risk and potential impact to the customer, the organization shall require the supplier to retain documented information of a software development capability self-assessment.

8.4.2.4 Supplier monitoring
The organization shall have a documented process and criteria to evaluate supplier 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:

- e.a) delivered product conformity to requirements;
- e.b) customer disruptions at the receiving plant, including yard holds and stop ships;
- e.c) delivery schedule performance;
- e.d) number of occurrences of premium freight.

If provided by the customer, the organization shall also include the following, as appropriate, in their supplier performance monitoring:

- e.e) special status customer notifications related to quality or delivery issues;
- e.f) dealer returns, warranty, field actions, and recalls.

8.4.2.4.1 Second-party audits
The organization shall include a second-party audit process in their supplier management approach. Second-party audits may be used for the following:

- e.f.a) supplier risk assessment;
- e.f.b) supplier monitoring;
- e.f.c) supplier QMS development;

7.4.3.2 SUPPLIER MONITORING
Supplier performance shall be monitored through the following indicators:

- delivered product conformity to requirements;
- customer disruptions, including field returns;
- delivery schedule performance (including incidents of premium freight);
- special status customer notifications related to quality or delivery issues.

The organization shall promote supplier monitoring of the performance of their manufacturing processes.

This new clause requires a second party audit process of suppliers.
Based on a risk analysis, including product safety/regulatory requirements, performance of the supplier, and QMS certification level, at a minimum, the organization shall document the criteria for determining the need, type, frequency, and scope of second-party audits. The organization shall retain records of the second-party audit reports. If the scope of the second-party audit is to assess the supplier’s quality management system, then the approach shall be consistent with the automotive process approach. NOTE Guidance may be found in the IATF Auditor Guide and ISO 19011.

8.4.2.5 Supplier development
The organization shall determine the priority, type, extent, and timing of required supplier development actions for its active suppliers. Determination inputs shall include but are not limited to the following:

- performance issues identified through supplier monitoring (see Section 8.4.2.4);
- second-party audit findings (see Section 8.4.2.4.1);
- 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.

Supplier development has to include performance monitoring, second party audits and risk analysis with issues identified and followed to effective completion.
### 8.4.3 Information for external providers

The organization shall ensure the adequacy of requirements prior to their communication to the external provider.

The organization shall communicate to external providers its requirements for:

- a) the processes, products and services to be provided;
- b) the approval of:
  - 1) products and services;
  - 2) methods, processes and equipment;
  - 3) the release of products and services;
- c) competence, including any required qualification of persons;
- d) the external providers’ interactions with the organization;
- e) control and monitoring of the external providers’ performance to be applied by the organization;
- f) verification or validation activities that the organization, or its customer, intends to perform at the external providers’ premises.

### 8.4.3.1 Information for external providers — supplemental

*The organization shall pass down all applicable statutory and regulatory requirements and special product and*

### 7.4.2 Purchasing information

Purchasing information shall describe the product to be purchased, including, where appropriate,

- a) requirements for approval of product, procedures, processes and equipment,
- b) requirements for qualification of personnel, and
- c) quality management system requirements.

The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.

Wording change: ISO 9001:2008 required that purchasing information (POs) describe requirements “where appropriate”

Those words are not in the revised standard; however, the words are now “communicate to external providers its requirements” So if they do not have such requirements there is nothing to communicate. Our interpretation is that there was no essential change

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**Clause requiring flowdown of regulatory and special characteristics to suppliers and to supply chain**
process characteristics to their suppliers and require the suppliers to cascade all applicable requirements down the supply chain to the point of manufacture.
### 8.5 Production and service provision

#### 8.5.1 Control of production and service provision

The organization shall implement production and service provision under controlled conditions. Controlled conditions shall include, as applicable:

- a) the availability of documented information that defines:
  
- 1) the characteristics of the products to be produced, the services to be provided, or the activities to be performed;

- 2) the results to be achieved;

- b) the availability and use of suitable monitoring and measuring resources;

- c) the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met;

- d) the use of suitable infrastructure and environment for the operation of processes;

- e) the appointment of competent persons, including any required qualification;

- f) the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;

- g) the implementation of actions to prevent

### 7.5.1 Control of production and service provision

The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable,

- a) the availability of information that describes the characteristics of the product,

- b) the availability of work instructions, as necessary,

- c) the use of suitable equipment,

- d) the availability and use of monitoring and measuring equipment,

- e) the implementation of monitoring and measurement, and

- f) the implementation of product release, delivery and post-delivery activities.

### 7.5.2 Validation of processes for production and service provision

The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered.

Validation shall demonstrate the ability of these processes to achieve planned
human error;
h) the implementation of release, delivery and post-delivery activities.

**NOTE** Suitable infrastructure includes appropriate manufacturing equipment required to ensure product compliance. Monitoring and measuring resources include appropriate monitoring and measuring equipment required to ensure effective control of manufacturing processes.

### 8.5.1.1 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. Family 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 process 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 plan:

- **a)** controls used for the manufacturing process control, including results.
- **b)** approval of equipment and qualification of personnel,
- **c)** use of specific methods and procedures,
- **d)** requirements for records (see 4.2.4), and
- **e)** revalidation.

### 7.5.2.1 VALIDATION OF PROCESSES FOR PRODUCTION AND SERVICE PROVISION — SUPPLEMENTAL

The requirements of 7.5.2 shall apply to all processes for production and service provision.

**CONTROL PLAN**

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, and
- have a control plan for pre-launch and production that takes into account the design FMEA and manufacturing process FMEA outputs.

The control plan shall

- list the controls used for the manufacturing process control,
- include methods for monitoring of control exercised over special characteristics (see 7.3.2.3) defined by both the customer and the organization,
- include the customer-required

The separate clause requiring validation of all production & service provision processes is no longer in the standard

The requirements now specifically recognize that family control plans are OK

The requirements now specifically include verification of job set-ups and 1st piece inspections.
verification of job set-ups;
e.f.e.d.b) first-off/last-off part validation, as applicable;
e.f.e.d.c) methods for monitoring of control exercised over special characteristics (see Annex A) defined by both the customer and the organization;
e.f.e.d.d) the customer-required information, if any;
e.f.e.d.e) specified reaction plan (see Annex A); when nonconforming product is detected, the process becomes statistically unstable or not statistically capable.

The organization shall review control plans and update as required, for any of the following:
e.f.e.d.f) the organization determines it has shipped nonconforming product to the customer;
e.f.e.d.g) when any change occurs affecting product, manufacturing process, measurement, logistics, supply sources, production volume changes, or risk analysis (FMEA) (see Annex A);
e.f.e.d.h) after a customer complaint and implementation of the associated corrective action, when applicable;
e.f.e.d.i) at a set frequency based on a risk analysis.

If required by the customer, the organization shall obtain customer approval after review or revision of the control plan.

8.5.1.2 Standardised work — operator instructions and visual standards
The organization shall ensure that standardised work documents are:
e.f.e.d.i.a) communicated to and understood by the employees who are responsible for performing the work;

information, if any, and initiate the specified reaction plan (see 8.2.3.1) when the process becomes unstable or not statistically capable.

Control plans 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.

7.5.1.2 WORK INSTRUCTIONS
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.

Work instructions now also should include rules for operator safety.
8.5.1.3 Verification of job set-ups
The organization shall:

e.f.e.d.a) 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;

e.f.e.d.b) maintain documented information for set-up personnel;

e.f.e.d.c) use statistical methods of verification, where applicable;

e.f.e.d.d) 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;

e.f.e.d.e) retain records of process and product approval following set-up and first-off/last-off part validations.

8.5.1.4 Verification after shutdown
The organization shall define and implement the necessary actions to ensure product compliance with requirements after a planned or unplanned production shutdown period.

7.5.1.4 PREVENTIVE AND PREDICTIVE MAINTENANCE
The organization shall identify key process equipment and provide resources for machine/equipment maintenance and develop an effective planned total maintenance system.

NOTE Last-off-part comparisons are recommended.

Verification after shutdown is a new sub-clause.
8.5.1.6 Management of production tooling 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, as applicable.

The organization shall utilize predictive maintenance methods to continually improve the effectiveness and the efficiency of production equipment.
including:
a) **maintenance and repair facilities and personnel:**
b) **storage and recovery:**
c) **set-up:**
d) **tool-change programmes for perishable tools:**
e) **tool design modification documentation, including engineering change level:**
f) **tool modification and revision to documentation:**
g) **tool identification, such as serial or asset number; the status, such as production, repair or disposal; ownership; and 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.

7.5.1.6 **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.

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

**NOTE** This requirement also applies to the availability of tools for vehicle service parts.

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

Tools:
- **tool design modification documentation,** including engineering change level:
- **tool modification and revision to documentation:**
- **tool identification, defining the status, such as production, repair or disposal.**

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

The organization shall use suitable means to identify outputs when it is necessary to ensure the conformity of products and services.

The organization shall identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision.

The organization shall control the unique identification of the outputs when traceability is a requirement, and shall retain the documented information necessary to enable traceability.

NOTE Inspection and test status is not indicated by the location of product in the production flow unless inherently obvious, such as material in an automated production transfer process. Alternatives are permitted if the status is clearly identified, documented, and achieves the designated purpose.

8.5.2.1 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

7.5.3 Identification and traceability

Where appropriate, the organization shall identify the product by suitable means throughout product realization.

The organization shall identify the product status with respect to monitoring and measurement requirements throughout product realization.

Where traceability is a requirement, the organization shall control the unique identification of the product and maintain records (see 4.2.4).

NOTE In some industry sectors, configuration management is a means by which identification and traceability are maintained.

7.5.3.1 IDENTIFICATION AND TRACEABILITY — SUPPLEMENTAL

The words “Where appropriate” in 7.5.3 shall not apply.

The revised requirements expect the traceability of product so that nonconforming product can be clearly traced to allow customer to contain nonconforming product escapes.

The requirements expect a study of customer and regulatory traceability requirements and the definition of appropriate systems.
appropriate traceability systems, processes, and methods by product, process, and manufacturing location that:

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

8.5.3 Property belonging to customers or external providers
The organization shall exercise care with property belonging to customers or external providers while it is under the organization’s control or being used by the organization. The organization shall identify, verify, protect and safeguard customers’ or external providers’ property provided for use or incorporation into the products and services. When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer or external provider and retain documented information on what has occurred.

NOTE A customer’s or external provider’s property can include material, components, tools and equipment, premises, intellectual property and

7.5.4 Customer property
The organization shall exercise care with customer property while it is under the organization’s control or being used by the organization. The organization shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer and maintain records (see 4.2.4).

NOTE Customer property can include intellectual property and personal data.

Note broadens the description of the applicability of customer owned property
personal data.
### 8.5.4 Preservation
The organization shall preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements.

**NOTE** Preservation can include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection.

### 8.5.4.1 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 shipment and until delivery to/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 similar manner to nonconforming product.

### 7.5.5 Preservation of product
The organization shall preserve the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, preservation shall include identification, handling, packaging, storage, and protection. Preservation shall also apply to the constituent parts of a product.

**NOTE** Preservation can include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection.

### 7.5.5.1 STORAGE AND INVENTORY
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 similar manner to nonconforming product.

The examples of preservation were moved to a note.
8.5.5 Post-delivery activities
The organization shall meet requirements for post-delivery activities associated with the products and services.

In determining the extent of post-delivery activities that are required, the organization shall consider:

a) statutory and regulatory requirements;

b) the potential undesired consequences associated with its products and services;

c) the nature, use and intended lifetime of its products and services;

d) customer requirements;

e) customer feedback.

NOTE Post-delivery activities can include actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.

8.5.5.1 Feedback of information from service
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

7.5.1.7 FEEDBACK OF INFORMATION FROM SERVICE
A process for communication of information on service concerns to manufacturing, engineering and design activities shall be established and maintained.

NOTE  The intent of the addition of “service concerns” to this subclause is to ensure that the organization is aware of nonconformities that occur outside of its organization.

In ISO 9001:2008 post-delivery activities were very briefly mentioned in “contract review” and “production & service provision” This has been expanded to this sub-clause

For most of our clients this sub-clause will not apply – they probably need to have a discussion that will lead to exclusion. If they do have post delivery activities, other than customer rejected product which is covered under nonconforming product and customer complaints; then they need to address this sub-clause
customer location or in the field.

NOTE 2 "Service concerns" should include the results of field failure test analysis (see Section 10.2.6) where applicable.

8.5.5.2 Service agreement with customer
When there is a service agreement with the customer, the organization shall:
   a) verify that the relevant service centres comply with applicable requirements;
   b) verify the effectiveness of any special purpose tools or measurement equipment;
   c) ensure that all service personnel are trained in applicable requirements.

8.5.6 Control of changes
The organization shall review and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements.

The organization shall retain documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.

8.5.6.1 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:
   c.a) define verification and validation
activities to ensure compliance with customer requirements:

c.b) validate changes before implementation;

c.c) document the evidence of related risk analysis;

c.d) 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:

c.e) notify the customer of any planned product realization changes after the most recent product approval;

c.f) obtain documented approval, prior to implementation of the change;

c.g) complete additional verification or identification requirements, such as production trial run and new product validation.

8.5.6.1.1 Temporary change of process controls

The organization shall identify, document, and maintain a list of the process controls, including inspection, measuring, test, 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 analysis (such as FMEA), severity, and the internal approvals to be obtained prior to production implementation of the alternate control method.

This clause requires a documented process to control temporary changes including the alternate control methods; a risk analysis and customer approvals.
Before shipping 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:
- c.g.a) daily quality focused audits (e.g., layered process audits, as applicable);
- c.g.b) daily leadership meetings.

Restart verification is documented for a defined period based 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).

WIs are required for the alternate control methods.

A daily review of the alternate process controls is required.

Required traceability of the product produced while the alternate process is used.
### 8.6 Release of products and services

The organization shall implement planned arrangements, at appropriate stages, to verify that the product and service requirements have been met.

The release of products and services to the customer shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer.

The organization shall retain documented information on the release of products and services. The documented information shall include:

- Evidence of conformity with the acceptance criteria;
- Traceability to the person(s) authorizing the release.

#### 8.6.1 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.

### 8.2.4 Monitoring and measurement of product

The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1). Evidence of conformity with the acceptance criteria shall be maintained.

Records shall indicate the person(s) authorizing release of product for delivery to the customer (see 4.2.4).

The release of product and delivery of service to the customer shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

**NOTE** When selecting product parameters to monitor compliance to specified internal and external requirements, the organization determines the types of product characteristics, leading to:

- The types of measurement,
- Suitable measurement means, and
- The capability and skills required.
according to ISO 9001, Section 8.5.6.

8.6.2 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 plans. 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.

8.6.3 Appearance items

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

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

8.6.4 Verification and acceptance of conformity of externally provided products and services

The organization shall have a process to assure the quality of purchased product.
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:

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

8.6.5 Statutory and regulatory conformity
Prior to release of externally provided products into its 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-identified countries of destination, if provided.

8.6.6 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 9.1.1.1).
### 8.7 Control of nonconforming outputs

8.7.1 The organization shall ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

The organization shall take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This shall also apply to nonconforming products and services detected after delivery of products, during or after the provision of services.

The organization shall deal with nonconforming outputs in one or more of the following ways:

- a) correction;
- b) segregation, containment, return or suspension of provision of products and services;
- c) informing the customer;
- d) obtaining authorization for acceptance under concession.

Conformity to the requirements shall be verified when nonconforming outputs are corrected.

**8.7.1.1 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.

### 8.3 Control of nonconforming product

The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. A documented procedure shall be established to define the controls and related responsibilities and authorities for dealing with nonconforming product.

Where applicable, the organization shall deal with nonconforming product by one or more of the following ways:

- a) by taking action to eliminate the detected nonconformity;
- b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer;
- c) by taking action to preclude its original intended use or application;
- d) by taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started.

When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be

---

ASR interpretation – correction includes not only correcting the nonconforming product but also includes regrading or approving the product for an alternate use.

Informing the customer (bullet c) applies to nonconforming product that has already shipped.
The organization shall obtain customer authorization prior to further processing for "use as is" and rework dispositions of nonconforming product. If subcomponents are reused in the manufacturing process, that subcomponent reuse shall be clearly communicated to the customer in the concession or deviation permit.

The organization shall maintain a record of the expiration date or quantity authorized 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 product). The organization shall approve any requests from suppliers before submission to the customer.

8.7.1.2 Control of nonconforming product — customer-specified process
The organization shall comply with applicable customer-specified controls for nonconforming product(s).

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

8.7.1.4 Control of reworked product
Instructions for rework, including reinspection requirements, shall be accessible to and utilized by the appropriate personnel.

8.7.1.5 Control of reworked product — supplemental
Product with unidentified or suspect status shall be classified as nonconforming product (see 7.5.3).

8.3.1 CONTROL OF NONCONFORMING PRODUCT — SUPPLEMENTAL
Product with unidentified or suspect status shall be classified as nonconforming product (see 7.5.3).

8.3.2 CONTROL OF REWORKED PRODUCT

8.3.3 CUSTOMER INFORMATION
Customers shall be informed promptly in the event that nonconforming product has been shipped.

8.3.4 CUSTOMER WAIVER
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 maintain a record of the expiration date or quantity authorized. The organization shall also ensure compliance with the original or superseding specifications and requirements when the authorization expires. Material shipped on an authorization shall be properly identified on each shipping container.

This applies equally to purchased product. The organization shall approve any
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 disposition of reworked product including quantity, disposition, disposition date, and applicable traceability information.

8.7.1.5 Control of repaired product
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 before 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.

requests from suppliers before submission to the customer.

New requirement to use risk analysis (FMEA) to assess risks in the rework process.

New clause on repair of product
Rework is defined (ISO 9000 definition) as action to ensure the product meets requirements
Repair is defined (ISO 9000 definition) as action to ensure the product meets intended use

Documented repair process and repair instructions
Documented customer authorization for concession
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.

8.7.1.6 Customer notification
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.

8.7.1.7 Nonconforming product disposition
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.

The organization shall not divert nonconforming product to service or other use without prior customer approval.

The organization shall retain documented information that:

a) describes the nonconformity;
b) describes the actions taken;
c) describes any concessions obtained;
d) identifies the authority deciding the action.

New requirements to render scrap unusable and controls on diverting nonconforming product to other uses.

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9 Performance evaluation

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General
The organization shall determine:
   a) what needs to be monitored and measured;
   b) the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;
   c) when the monitoring and measuring shall be performed;
   d) when the results from monitoring and measurement shall be analysed and evaluated.

The organization shall evaluate the performance and the effectiveness of the quality management system. The organization shall retain appropriate documented information as evidence of the results.

8 Measurement, analysis and improvement

8.1 General
The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed to demonstrate conformity to product requirements, to ensure conformity of the quality management system, and to continually improve the effectiveness of the quality management system.
This shall include determination of applicable methods, including statistical techniques, and the extent of their use.
<table>
<thead>
<tr>
<th>8.2.3 Monitoring and measurement of processes</th>
</tr>
</thead>
<tbody>
<tr>
<td>The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate.</td>
</tr>
</tbody>
</table>

**NOTE** When determining suitable methods, it is advisable that the organization consider the type and extent of monitoring or measurement appropriate to each of its processes in relation to their impact on the conformity to product requirements and on the effectiveness of the quality management system. |

<table>
<thead>
<tr>
<th>9.1.1.1 Monitoring and measurement of manufacturing processes</th>
</tr>
</thead>
<tbody>
<tr>
<td>The organization shall perform process studies on all new manufacturing (including assembly or sequencing) processes to verify process capability and to provide additional input for process control, including those for special characteristics.</td>
</tr>
</tbody>
</table>

**NOTE** For some manufacturing processes, it may not be possible to demonstrate product compliance through process capability. For those processes, alternate methods such as batch conformance to specification may be used. |

The organization shall maintain manufacturing process capability or performance results as specified by the customer's part approval process. |

<table>
<thead>
<tr>
<th>8.2.3.1 MONITORING AND MEASUREMENT OF MANUFACTURING PROCESSES</th>
</tr>
</thead>
<tbody>
<tr>
<td>The organization shall perform process studies on all new manufacturing (including assembly or sequencing) processes to verify process capability and to provide additional input for process control. The results of process studies shall be documented with specifications, where applicable, for means of production, measurement and test, and maintenance instructions. These documents shall include objectives for manufacturing process capability, reliability, maintainability and availability, as well as acceptance criteria.</td>
</tr>
</tbody>
</table>
The organization shall maintain manufacturing process capability or performance as specified by the customer part approval process requirements. The organization shall ensure that the control plan and process flow diagram are implemented, including adherence to the specified:

- measurement techniques,
- sampling plans,
- acceptance criteria, and
- reaction plans when acceptance criteria are not met.

Significant process events, such as tool change or machine repair, shall be recorded and retained as documented information.

The organization shall initiate a reaction plan indicated on the control plan and evaluated for impact on compliance to specifications for characteristics that are either not statistically capable or are unstable. These reaction plans shall include containment of product and 100 percent 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 statistically 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.

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### 9.1.2 Identification of statistical tools

The organization shall determine the appropriate use of statistical tools. The organization shall verify that appropriate statistical tools are included as part of the advanced product quality planning (or equivalent) process and included in the design risk analysis (such as DFMEA) (where applicable), the process risk analysis (such as PFMEA), and the control plan.

### 9.1.1.3 Application of statistical concepts

Statistical concepts, such as variation, control (stability), process capability, and the consequences of over-adjustment, shall be understood and used by employees involved in the collection, analysis, and management of statistical data.

### 8.2.1 Customer satisfaction

As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined.

**NOTE**

Examples of monitoring customer perceptions can include customer surveys, customer feedback on delivered products and services, meetings with customers, market-share analysis, compliments, warranty claims.

**NOTE**

Monitoring customer perception can include obtaining input from sources such as customer satisfaction surveys, customer data.
9.1.2.1 Customer satisfaction — supplemental
Customer satisfaction with the organization shall be monitored through continual evaluation of internal and external performance indicators to ensure compliance to the product and process specifications and other customer requirements.

Performance indicators shall be based on objective evidence and include but not be limited to the following:

- delivered part quality performance;
- customer disruptions;
- field returns, recalls, and warranty (where applicable);
- delivery schedule performance (including incidents of premium freight);
- customer notifications related to quality or delivery issues, including special status.

The organization shall monitor the performance of manufacturing processes to demonstrate compliance with customer requirements for product quality and process efficiency. The monitoring shall include the review of customer performance data, including online customer portals and customer scorecards, where provided.

9.1.3 Analysis and evaluation of data

Customer satisfaction now includes a specific reference to online customer scorecards and customer portals

8.2.1.1 CUSTOMER SATISFACTION — SUPPLEMENTAL
Customer satisfaction with the organization shall be monitored through continual evaluation of performance of the realization processes. Performance indicators shall be based on objective data and include, but not be limited to:

- delivered part quality performance,
- 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.

8.4 Analysis of data

The organization shall determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the
The organization shall analyse and evaluate appropriate data and information arising from monitoring and measurement. The results of analysis shall be used to evaluate:

a) conformity of products and services;
b) the degree of customer satisfaction;
c) the performance and effectiveness of the quality management system;
d) if planning has been implemented effectively;
e) the effectiveness of actions taken to address risks and opportunities;
f) the performance of external providers;
g) the need for improvements to the quality management system.

NOTE Methods to analyse data can include statistical techniques.

9.1.3.1 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.

8.4.1 ANALYSIS AND USE OF DATA

Trends in quality and operational performance shall be compared with progress toward objectives and lead to action to support the following:

- development of priorities for prompt solutions to customer-related problems;
- determination of key customer-related trends and correlation for status review, decision-making and longer term planning;
- an information system for the timely reporting of product information arising from usage.

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

quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data shall provide information relating to

a) customer satisfaction (see 8.2.1),
b) conformity to product requirements (see 8.2.4),
c) characteristics and trends of processes and products, including opportunities for preventive action (see 8.2.3 and 8.2.4), and suppliers (see 7.4).
<table>
<thead>
<tr>
<th>9.2 Internal Audit</th>
<th>8.2.2 Internal audit</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>9.2.1</strong> The organization shall conduct internal audits at planned intervals to provide information on whether the quality management system:</td>
<td><strong>8.2.2 Internal audit</strong> The organization shall conduct internal audits at planned intervals to determine whether the quality management system</td>
<td></td>
</tr>
<tr>
<td>a) conforms to:</td>
<td>a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization, and</td>
<td></td>
</tr>
<tr>
<td>1) the organization’s own requirements for its quality management system;</td>
<td>b) is effectively implemented and maintained. An audit programme shall be planned,</td>
<td></td>
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<tr>
<td>2) the requirements of this International Standard;</td>
<td>taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.</td>
<td></td>
</tr>
<tr>
<td>b) is effectively implemented and maintained.</td>
<td>A documented procedure shall be</td>
<td></td>
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</tbody>
</table>

A procedure is no longer required, but you do need to have documented evidence of the implementation of the internal audit programme (for example: schedule; audit scopes, audit criteria, checklists) and of the audit results.
the results of previous audits;
b) define the audit criteria and scope for each audit;
c) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;
d) ensure that the results of the audits are reported to relevant management;
e) take appropriate correction and corrective actions without undue delay;
f) retain documented information as evidence of the implementation of the audit programme and the audit results.

**NOTE** See ISO 19011 for guidance.

<table>
<thead>
<tr>
<th>9.2.2.1 Internal audit programme</th>
<th>8.2.2.1 QUALITY MANAGEMENT SYSTEM AUDIT</th>
</tr>
</thead>
<tbody>
<tr>
<td>The organization shall have a documented internal audit process. The process shall include the development and implementation of an internal audit programme that covers the entire quality management system including quality management system audits, manufacturing process audits, and product audits.</td>
<td>The organization shall audit its quality management system to verify compliance with this Technical Specification and any additional quality management system requirements.</td>
</tr>
<tr>
<td>The audit programme shall be prioritized based upon risk, internal and external performance trends, and criticality of the process(es).</td>
<td>8.2.2.2 MANUFACTURING PROCESS AUDIT</td>
</tr>
<tr>
<td>Where the organization is responsible for software development, the organization shall include software development capability assessments in their internal audit programme.</td>
<td>The organization shall audit each manufacturing process to determine its effectiveness.</td>
</tr>
<tr>
<td>IATF requires a documented process</td>
<td>8.2.2.3 PRODUCT AUDIT</td>
</tr>
<tr>
<td>Formally requires basing the programme on priorities from risk analysis</td>
<td>The organization shall audit products at</td>
</tr>
</tbody>
</table>
The frequency of audits shall be reviewed and, where appropriate, adjusted based on occurrence of process changes, internal and external nonconformities, and/or customer complaints. The effectiveness of the audit programme shall be reviewed as part of management review.

9.2.2.2 Quality management system audit
The organization shall audit all quality management system processes over each three-year calendar period, according to an annual programme, using the process approach to verify compliance with this Automotive QMS Standard. Integrated with these audits, the organization shall sample customer-specific quality management system requirements for effective implementation.

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

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 PFMEA), control plan, and associated documents.

9.2.2.4 Product audit
The organization shall audit products using customer-specific required 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.

8.2.2.4 INTERNAL AUDIT PLANS
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.

NOTE Specific checklists should be used for each audit.

8.2.2.5 INTERNAL AUDITOR QUALIFICATION
The organization shall have internal auditors who are qualified to audit the requirements of this Technical Specification (see 6.2.2.2).

QMS audits specifies an annual programme and so that all QMS processes are audited over a three year calendar period. Also requires sampling of customer specific QMS requirements for effectiveness

Manufacturing process audits – audit all of them over the three year period; determine effectiveness and efficiency using customer specified approaches Include audit of the process risk analysis PFMEA and Control Plan

Product audits using customer specific approaches
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.

<table>
<thead>
<tr>
<th>9.3 Management review</th>
<th>Management review</th>
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<tbody>
<tr>
<td><strong>9.3.1 General</strong></td>
<td><strong>5.6.1 General</strong></td>
</tr>
<tr>
<td>Top management shall review the organization’s quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organization.</td>
<td>Top management shall review the organization’s quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.</td>
</tr>
<tr>
<td><strong>9.3.1.1 Management review — supplemental</strong></td>
<td><strong>5.6.1.1 QUALITY MANAGEMENT SYSTEM PERFORMANCE</strong></td>
</tr>
<tr>
<td><em>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.</em></td>
<td><em>These reviews shall include all requirements of the quality management system and its performance trends as an</em></td>
</tr>
<tr>
<td><strong>9.3.2 Management Review Inputs</strong></td>
<td><strong>Annual management reviews required with frequency increased based on risk to compliance to customer requirements resulting from changes and performance issues</strong></td>
</tr>
<tr>
<td>The management review shall be planned and carried out taking into consideration: a) the status of actions from previous</td>
<td></td>
</tr>
<tr>
<td>management reviews shall be maintained (see 4.2.4).</td>
<td>Management review now needs to align with the strategic direction of the organization</td>
</tr>
<tr>
<td>Management review inputs now include supplier performance; effectiveness of actions to address risks adequacy of resources changes in internal and external issues</td>
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management reviews;
b) changes in external and internal issues that are relevant to the quality management system;
c) information on the performance and effectiveness of the quality management system, including trends in:

1) customer satisfaction and feedback from relevant interested parties;
2) the extent to which quality objectives have been met;
3) process performance and conformity of products and services;
4) nonconformities and corrective actions;
5) monitoring and measurement results;
6) audit results;
7) the performance of external providers;
d) the adequacy of resources;
e) the effectiveness of actions taken to address risks and opportunities (see 6.1);
f) opportunities for improvement.

| 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 |

5.6.2 Review input
The input to management review shall include information on

a) results of audits,
b) customer feedback,
c) process performance and product conformity,
9.3.2.1 *Management review inputs — supplemental*

Input to management review shall include:

a) cost of poor quality (cost of internal and external nonconformance);
b) measures of process effectiveness;
c) measures of process efficiency;
d) product conformance;
e) assessments of manufacturing feasibility made for changes to existing operations and for new facilities or new product (see Section 7.1.3.1);
f) customer satisfaction (see ISO 9001, 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 FMEA);
k) actual field failures and their impact on safety or the environment.

9.3.3 Management Review Outputs

The outputs of the management review shall include decisions and actions related to:

a) opportunities for improvement;
b) any need for changes to the quality management system and its effectiveness;
c) status of preventive and corrective actions;
d) follow-up actions from previous management reviews;
e) changes that could affect the quality management system, and
f) recommendations for improvement.

5.6.2.1 *REVIEW INPUT — SUPPLEMENTAL*

Input to management review shall include an analysis of actual and potential field-failures and their impact on quality, safety or the environment.

There is now a list of additional management review inputs.

Review output

The output from the management review shall include any decisions and actions related to:

6.3.a) improvement of the effectiveness of the quality management system and its
<table>
<thead>
<tr>
<th>9.3.3.1 <strong>Management review outputs — supplemental</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Top management shall document and implement an action plan when customer performance targets are not met.</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>10 Improvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.5.1 <strong>Continual improvement</strong></td>
</tr>
<tr>
<td>The organization shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.</td>
</tr>
</tbody>
</table>

**NOTE** Examples of improvement can include correction, corrective action, continual improvement, breakthrough change, innovation and re-organization.
### 10.2 Nonconformity and corrective action

#### 10.2.1 When a nonconformity occurs, including any arising from complaints, the organization shall:

- **a)** react to the nonconformity and, as applicable:
  - 1) take action to control and correct it;
  - 2) deal with the consequences;
- **b)** evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:
  - 1) reviewing and analyzing the nonconformity;
  - 2) determining the causes of the nonconformity;
  - 3) determining if similar nonconformities exist, or could potentially occur;
- **c)** implement any action needed;
- **d)** review the effectiveness of any corrective action taken;
- **e)** update risks and opportunities determined during planning, if necessary;
- **f)** make changes to the quality management system, if necessary.

### 8.5.2 Corrective action

The organization shall take action to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.

A documented procedure shall be established to define requirements for:

- **a)** reviewing nonconformities (including customer complaints),
- **b)** determining the causes of nonconformities,
- **c)** evaluating the need for action to ensure that nonconformities do not recur,
- **d)** determining and implementing action needed,
- **e)** records of the results of action taken (see 4.2.4), and
- **f)** reviewing the effectiveness of the corrective action taken.

A procedure is no longer required; do need documented evidence.
| 10.2.2 | The organization shall retain documented information as evidence of:  
|  | a) the nature of the nonconformities and any subsequent actions taken;  
|  | b) the results of any corrective action.  

10.2.3 Problem solving  
The organization shall have a documented process(es) for problem solving including:  

| a) | defined approaches for various types and scale of problems (e.g., new product development, current manufacturing issues, field failures, audit findings);  
| b) | containment, interim actions, and related activities necessary for control of nonconforming outputs (see ISO 9001, Section 8.7);  
| c) | root cause analysis, methodology used, analysis, and results;  
| d) | implementation of systemic corrective actions, including consideration of the impact on similar processes and products;  
| e) | verification of the effectiveness of implemented corrective actions;  
| f) | reviewing and, where necessary, updating 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.  

10.2.4 Error-proofing  
The organization shall have a documented process to determine the use of appropriate error-proofing methodologies. Details of the method used shall be documented in the process.  

8.5.2.1 PROBLEM SOLVING  
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.  

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

8.5.2.3 CORRECTIVE ACTION IMPACT  
The organization shall apply to other similar processes and products the corrective action, and controls implemented, in order to eliminate the cause of a nonconformity.  

Corrective action impact is now included in the Problem Solving clause.  

Error-Proofing is in the clause below (10.2.4). A documented process is required. Methodologies to be documented in the PFMEA. The testing of error-proofing devices is required and records of the testing are required.
risk analysis (such as PFMEA) and test frequencies shall be documented in the control plan.

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

10.2.5 Warranty management systems
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.

10.2.6 Customer complaints and field failure test analysis
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.

<table>
<thead>
<tr>
<th>8.5.2.4</th>
<th>REJECTED PRODUCT TEST/ANALYSIS</th>
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<tr>
<td>The organization shall analyse 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.</td>
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NOTE Cycle time related to rejected product analysis should be consistent with the determination of root cause, corrective action and monitoring the.

This warranty management system is a new clause and applies when the organization is required to provide warranty for their products.
10.3 Continual improvement
The organization shall continually improve the suitability, adequacy and effectiveness of the quality management system.

The organization shall consider the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities that shall be addressed as part of continual improvement.

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

a) identification of the methodology used, objectives, measurement, effectiveness, and documented information;

b) a manufacturing process improvement action plan with emphasis on the reduction of process variation and waste; risk analysis (such as FMEA).

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

8.5.1.1 CONTINUAL IMPROVEMENT OF THE ORGANIZATION
The organization shall define a process for continual improvement.

3.5.1.2 MANUFACTURING PROCESS IMPROVEMENT
Manufacturing process improvement shall continually focus upon control and reduction of variation in product characteristics and manufacturing process parameters.

NOTE 1 Controlled characteristics are documented in the control plan.

NOTE 2 Continual improvement is implemented once manufacturing processes are capable and stable, or product characteristics are predictable and meet customer requirements.

Requires a documented CI process including methodology; objectives; effectiveness; manufacturing process improvement plan.