



## Supplier Quality Management System Audit Checklist (ISO 9000:2000, TS 16949:2002)

Supplier: \_\_\_\_\_

Plant/Location: \_\_\_\_\_ Date: \_\_\_\_\_

Audit Team: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Scope of Audit: \_\_\_\_\_

Number of C.A.R. s: \_\_\_\_\_ Corrective Action Due: \_\_\_\_\_

Potential suppliers may be requested to conduct a self-assessment of their quality system to determine eligibility. The Mayco Sourcing Team shall determine eligibility after analysis of the self-assessment. Results of the Checklist shall be documented and communicated to the supplier by the Mayco Sourcing Team.

**NOTE: Sections in red are questions relevant to TS 16949**  
**APPENDIX H**

Q#	ISO 9001:2000 and/or ISO/TS 16949 Clause Text	Audit Question	Evidence
<b>4 Quality management system</b>			
<b>4.1 General requirements</b>			
4.1q1	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.	♦ Has Supplier established, documented, implemented and maintained a QMS and continually improved its effectiveness in accordance with ISO 9001:2000? (Questions in section 4.1 are verified throughout the audit)	
4.1q2a	The organization shall <b>a)</b> identify the processes needed for the quality management system and their application throughout the organization (see 1.2),	♦ Where has Supplier identified the processes needed for the QMS and their application throughout Supplier? (See 4.2.2)	
4.1q2b	The organization shall <b>b)</b> determine the sequence and interaction of these processes,	♦ Where has Supplier determined the sequence and interaction of QMS processes? (See 4.2.2)	
4.1q2c	The organization shall <b>c)</b> determine criteria and methods needed to ensure that both the operation and control of these processes are effective,	♦ What are the criteria and methods Supplier uses to ensure that the operation and control of QMS processes are effective?	
4.1q2d	The organization shall <b>d)</b> ensure the availability of resources and information necessary to support the operation and monitoring of these processes,	♦ Has Supplier provided resources and information needed to support the operation and monitoring of QMS processes? (See section 6)	
4.1q2e	The organization shall <b>e)</b> monitor, measure and analyze these processes, and	♦ How does Supplier monitor, measure and analyze QMS processes? (See section 8)	
4.1q2f	The organization shall <b>f)</b> implement actions necessary to achieve planned results and continual improvement of these processes.	♦ How has Supplier implemented actions necessary to achieve planned results and continual improvement of processes needed for the QMS?	
4.1q3	These processes shall be managed by the organization in accordance with the requirements of this International Standard.	♦ Are processes needed for the QMS managed by Supplier in accordance with the requirements of ISO 9001:2000?	
4.1q4	Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes.	♦ When Supplier out sources any process that affects product conformity with requirements, how is control ensured over such processes? (See 7.4)	
4.1q5	Control of such outsourced processes shall be identified within the quality management system.	♦ Where is the control of outsourced processes that affect product conformity with requirements identified within the QMS? (See 7.4)	

Q#	ISO 9001:2000 and/or ISO/TS 16949 Clause Text	Audit Question	Evidence
NOTE Processes needed for the quality management system referred to above should include processes for management activities, provision of resources, product realization and measurement.			
<b>4.1.1 General requirements — Supplemental</b>			
T4.1.1q1	Ensuring control over outsourced processes shall not absolve the organization of the responsibility of conformity to all customer requirements.	<ul style="list-style-type: none"> <li>◆ Does Supplier have adequate control over outsourced processes to ensure conformity to all customer requirements? (See 7.4)</li> </ul>	
NOTE See also 7.4.1 and 7.4.1.3.			
<b>4.2 Documentation requirements</b>			
<b>4.2.1 General</b>			
4.2.1q1a	<p>The quality management system documentation shall include</p> <ol style="list-style-type: none"> <li>a) documented statements of a quality policy and quality objectives,</li> <li>b) a quality manual,</li> <li>c) documented procedures required by this International Standard,</li> <li>d) documents needed by the organization to ensure the effective planning, operation and control of its processes, and</li> <li>e) records required by this International Standard (see 4.2.4).</li> </ol>	<ul style="list-style-type: none"> <li>◆ Does Supplier have documented statements of a quality policy and quality objectives? (See 5.3, 5.4.1)</li> <li>◆ Does Supplier have a quality manual? (See 4.2.2)</li> <li>◆ Does Supplier have the documented procedures required by ISO 9001:2000? (See 4.2.3, 4.2.4, 8.2.2, 8.3, 8.5.2, 8.5.3)</li> <li>◆ Are adequate documents in place to ensure the effective planning, operation and control of Supplier's processes?</li> <li>◆ Does documentation include the records required by ISO 9001:2000?</li> </ul>	
NOTE 1 Where the term "documented procedure" appears within this International Standard, this means that the procedure is established, documented, implemented and maintained.			
NOTE 2 The extent of the quality management system documentation can differ from one organization to another due to			
NOTE 3 The documentation can be in any form or type of medium.			
<b>4.2.2 Quality manual</b>			
4.2.2q1a	<p>The organization shall establish and maintain a quality manual that includes</p> <ol style="list-style-type: none"> <li>a) the scope of the quality management system, including details of and justification for any exclusions (see 1.2),</li> <li>b) the documented procedures established for the quality management system, or reference to them, and</li> <li>c) a description of the interaction between the processes of the quality management system.</li> </ol>	<ul style="list-style-type: none"> <li>◆ Where in the quality manual is the scope of the QMS identified, including details of and justification for exclusions?</li> <li>◆ Where does the quality manual contain or reference the documented procedures established for the QMS?</li> <li>◆ Where does the quality manual include a description of the interaction between the processes of the QMS?</li> </ul>	

Q#	ISO 9001:2000 and/or ISO/TS 16949 Clause Text	Audit Question	Evidence
<b>4.2.3 Control of documents</b>			
4.2.3q1	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.	<ul style="list-style-type: none"> <li>◆ How are the documents required by the QMS controlled?</li> </ul> (Documents should be reviewed throughout the audit)	
4.2.3q2	A documented procedure shall be established to define the controls needed <ol style="list-style-type: none"> <li>a) to approve documents for adequacy prior to issue,</li> <li>b) to review and update as necessary and re-approve documents?</li> <li>c) to ensure that changes and the current revision status of documents are identified?</li> <li>d) to ensure that relevant versions of applicable documents are available at points of use?</li> <li>e) to ensure that documents remain legible and readily identifiable?</li> <li>f) to ensure that documents of external origin are identified and their distribution controlled?</li> <li>g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.</li> </ol>	Can you show a <b>documented procedure</b> that defines the controls needed for <u>each</u> of the following? <ol style="list-style-type: none"> <li>a) approve documents for adequacy prior to issue?</li> <li>b) review and update as necessary and re-approve documents?</li> <li>c) ensure that changes and the current revision status of documents are identified?</li> <li>d) ensure that relevant versions of applicable documents are available at points of use?</li> <li>e) ensure that documents remain legible and readily identifiable?</li> <li>f) ensure that documents of external origin are identified and their distribution controlled?</li> <li>g) prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.</li> </ol>	
<b>4.2.3.1 Engineering specifications</b>			
T4.2.3.1q1	The organization shall have a process to assure the timely review, distribution and implementation of all customer engineering standards/ specifications and changes based on customer-required schedule.	<ul style="list-style-type: none"> <li>◆ What process do you have to assure the timely review, distribution and implementation of customer specifications and changes?</li> <li>◆ Does it meet customer-required schedule(s)?</li> </ul>	
T4.2.3.1q2	Timely review should be as soon as possible, and shall not exceed two working weeks.	<ul style="list-style-type: none"> <li>◆ Does the review occur in two weeks or less?</li> </ul>	
T4.2.3.1q3	The organization shall maintain a record of the date on which each change is implemented in production. Implementation shall include updated documents.	<ul style="list-style-type: none"> <li>◆ What <b>records</b> do you have showing implementation dates of changes?</li> <li>◆ Is there evidence showing that documents are updated?</li> </ul>	
NOTE A change in these standards/ specifications requires an updated record of customer production part approval when these specifications are referenced on the design record or if they affect documents of production part approval process, such as control plan, FMEAs, etc.			

Q#	ISO 9001:2000 and/or ISO/TS 16949 Clause Text	Audit Question	Evidence
<b>4.2.4 Control of records</b>			
4.2.4q1	Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system.	♦ What records exist that provide evidence of conformity to requirements and of the effective operation of the QMS? (Should be reviewed throughout the audit)	
4.2.4q2	Records shall remain legible, readily identifiable and retrievable.	♦ Are records legible, readily identifiable and retrievable? (Should be reviewed throughout the audit)	
4.2.4q3	A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.	♦ Does Supplier have a <b>documented procedure</b> defining the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records?	
NOTE 1 "Disposition" above includes disposal.			
NOTE 2 "Records" also include customer-specified records.			
<b>4.2.4.1 Records retention</b>			
T4.2.4.1q1	The control of records shall satisfy regulatory and customer requirements.	♦ Have the record requirements been reviewed to ensure conformance with regulatory and customer requirements?	
<b>5 Management responsibility</b>			
<b>5.1 Management commitment</b>			
5.1q1a	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.	♦ How does top management communicate the importance of meeting customer and legal requirements throughout its organization?  ♦ Has a company quality policy been established? (See 5.3)  ♦ What are the quality objectives established by top management? (See 5.4.1)  ♦ Does top management conduct management reviews? (See 5.6)  ♦ How does top management ensure the availability of resources to support and continually improve the QMS?	
<b>5.1.1 Process efficiency</b>			
T5.1.1q1	Top management shall review the product realization processes and the support processes to assure their effectiveness and efficiency.	♦ How does top management review product realization and support processes to ensure effectiveness and efficiency? (5.6?)	

<b>5.2 Customer focus</b>		
5.2q1	Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1 & 8.2.1)	<ul style="list-style-type: none"> <li>◆ How does top management ensure that customer requirements are determined and met?</li> </ul>
<b>5.3 Quality policy</b>		
5.3q1a	<p>Top management shall ensure that the quality policy</p> <ul style="list-style-type: none"> <li>a) is appropriate to the purpose of the organization,</li> <li>b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system,</li> <li>c) provides a framework for establishing and reviewing quality objectives,</li> <li>d) is communicated and understood within the organization, and</li> <li>e) is reviewed for continuing suitability.</li> </ul>	<ul style="list-style-type: none"> <li>◆ How does top management ensure that the quality policy is appropriate to the purpose of Supplier?</li> <li>◆ Does the quality policy include a commitment to comply with requirements and continually improve QMS effectiveness?</li> <li>◆ Are the contents of the quality policy relevant to Supplier, and measurable?</li> <li>◆ Is the quality policy communicated and understood within Supplier?</li> <li>◆ Is there an established process to review the quality policy for continuing suitability?</li> </ul>
<b>5.4 Planning</b>		
<b>5.4.1 Quality objectives</b>		
5.4.1q1	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.	<ul style="list-style-type: none"> <li>◆ Has top management established quality objectives (including those needed to meet requirements for product) at relevant functions and levels within Supplier?</li> </ul>
5.4.1q2	The quality objectives shall be measurable and consistent with the quality policy.	<ul style="list-style-type: none"> <li>◆ Are the quality objectives consistent with the quality policy? What are the measurements?</li> </ul>
<b>5.4.1.1 Quality objectives – Supplemental</b>		
T5.4.1.1q1	Top management shall define quality objectives and measurements that shall be included in the business plan and used to deploy the quality policy.	<ul style="list-style-type: none"> <li>◆ Are quality objectives and metrics included in the business plan?</li> </ul>
<b>NOTE</b> Quality objectives should address customer expectations and be achievable within a defined time period.		
<b>5.4.2 Quality management system planning</b>		
5.4.2q1a	Top management shall ensure that 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	<ul style="list-style-type: none"> <li>◆ How do you ensure that the planning of the QMS is carried out in order to meet the requirements given in ISO 9001:2000 section 4.1, as well as the quality objectives?</li> </ul>

5.4.2q1b	Top management shall ensure that b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.	<ul style="list-style-type: none"> <li>◆ How do you ensure that the integrity of the QMS is maintained when changes to the QMS are planned and implemented?</li> </ul>	
<b>5.5 Responsibility, authority and communication</b>			
<b>5.5.1 Responsibility and authority</b>			
5.5.1q1	Top management shall ensure that responsibilities and authorities are defined and communicated within the organization.	<ul style="list-style-type: none"> <li>◆ How are responsibilities and authorities defined and communicated within Supplier? (Verify throughout audit)</li> </ul>	
<b>5.5.1.1 Responsibility for quality</b>			
T5.5.1.1q1	Managers with responsibility and authority for corrective action shall be promptly informed of products or processes which do not conform to requirements.	<ul style="list-style-type: none"> <li>◆ How are managers responsible for corrective action informed of nonconforming products or processes?</li> <li>◆ Are they informed in a timely manner?</li> </ul>	
T5.5.1.1q2	Personnel responsible for product quality shall have the authority to stop production to correct quality problems.	<ul style="list-style-type: none"> <li>◆ Do personnel responsible for product quality have the authority to stop production to correct quality problems?</li> </ul>	
T5.5.1.1q3	Production operations across all shifts shall be staffed with personnel in charge of, or delegated responsibility for, ensuring product quality.	<ul style="list-style-type: none"> <li>◆ What personnel on each shift have responsibility for ensuring product quality?</li> </ul>	
<b>5.5.2 Management representative</b>			
5.5.2q1a	<p>Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes</p> <ul style="list-style-type: none"> <li>a) ensuring that processes needed for the quality management system are established, implemented and maintained,</li> <li>b) reporting to top management on the performance of the quality management system and any need for improvement, and</li> <li>b) c) ensuring the promotion of awareness of customer requirements throughout the organization.</li> </ul>	<ul style="list-style-type: none"> <li>◆ Who is your ISO 9001:2000 management representative?</li> <li>◆ Does the management representative have responsibility and authority to: <ul style="list-style-type: none"> <li>a) ensure that processes needed for the QMS are established, implemented and maintained?</li> <li>b) report to top management on the performance of the QMS and any need for improvement?</li> <li>c) ensure the promotion of awareness of customer requirements throughout Supplier?</li> </ul> </li> </ul>	
NOTE The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.			

<b>5.5.2.1 Customer representative</b>		
T5.5.2.1q1	<p>Top management shall designate personnel with responsibility and authority to ensure that customer requirements are addressed.</p> <p>This includes selection of special characteristics, setting quality objectives and related training, corrective and preventive actions, product design and development.</p>	<ul style="list-style-type: none"> <li>◆ Who has top management designated to ensure that customer requirements are addressed?</li> <li>◆ Does their responsibility and authority include selection of special characteristics, setting quality objectives and related training, corrective and preventive actions, product design and development?</li> </ul>
<b>5.5.3 Internal communication</b>		
5.5.3q1	<p>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.</p>	<ul style="list-style-type: none"> <li>◆ How is information regarding the effectiveness of the QMS communicated within Supplier?</li> </ul>
<b>5.6 Management review</b>		
<b>5.6.1 General</b>		
5.6.1q1	<p>Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness.</p>	<ul style="list-style-type: none"> <li>◆ What is the frequency that top management reviews Supplier's QMS?</li> </ul>
5.6.1q2	<p>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.</p>	<ul style="list-style-type: none"> <li>◆ What kinds of information are reviewed in management reviews? (must include suitability, adequacy and effectiveness of QMS; improvement; &amp; changes to the QMS, quality policy and objectives)</li> </ul>
5.6.1q3	<p>Records from management reviews shall be maintained (see 4.2.4).</p>	<ul style="list-style-type: none"> <li>◆ Can you show me <b>records</b> from recent management reviews?</li> </ul>
<b>5.6.1.1 Quality management system performance</b>		
T5.6.1.1q1	<p>These reviews shall include all requirements of the quality management system and its performance trends as an essential part of the continual improvement process.</p>	<ul style="list-style-type: none"> <li>◆ Do management reviews include <u>all</u> requirements of the quality management system and performance trends? (Verify records)</li> </ul>
T5.6.1.1q2	<p>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).</p>	<ul style="list-style-type: none"> <li>◆ Can you show management review records including monitoring of quality objectives, and cost of poor quality metrics? (Verify records)</li> </ul>

T5.6.1.1q3	<p>These results shall be recorded to provide, as a minimum, evidence of the achievement of</p> <ul style="list-style-type: none"> <li>- the quality objectives specified in the business plan, and</li> <li>customer satisfaction with product supplied.</li> </ul>	<ul style="list-style-type: none"> <li>◆ Can you show records providing evidence of achievement of the quality objectives specified in the business plan, and customer satisfaction with product supplied?</li> </ul>	
<b>5.6.2 Review input</b>			
5.6.2q1	<p>The input to management review shall include information on</p> <ul style="list-style-type: none"> <li>a) results of audits,</li> <li>b) customer feedback,</li> <li>c) process performance and product conformity,</li> <li>d) status of preventive and corrective actions,</li> <li>e) follow-up actions from previous management reviews,</li> <li>f) changes that could affect the quality management system, and</li> <li>g) recommendations for improvement.</li> </ul>	<ul style="list-style-type: none"> <li>◆ Can you show that <u>each</u> of the following was included in review(s)?</li> <li>a) results of audits,</li> <li>b) customer feedback,</li> <li>c) process performance and product conformity,</li> <li>d) status of preventive and corrective actions,</li> <li>e) follow-up actions from previous management reviews,</li> <li>f) changes that could affect the quality management system, and</li> <li>g) recommendations for improvement</li> </ul>	
<b>5.6.2.1 Review input – Supplemental</b>			
T5.6.2.1q1	<p>Input to management review shall include an analysis of actual and potential field-failures and their impact on quality, safety or the environment.</p>	<ul style="list-style-type: none"> <li>◆ Do records show input to management review includes analysis of actual and potential field-failures and their impact? (See also 7.3.4.1)</li> </ul>	
<b>5.6.3 Review output</b>			
5.6.3q1	<p>The output from the management review shall include any decisions and actions related to</p> <ul style="list-style-type: none"> <li>a) improvement of the effectiveness of the quality management system and its processes,</li> <li>b) improvement of product related to customer requirements, and</li> <li>c) resource needs.</li> </ul>	<ul style="list-style-type: none"> <li>◆ What decisions or actions have resulted from management reviews for <u>each</u> of the following?</li> <li>a) improvement of the effectiveness of the quality management system and its processes,</li> <li>b) improvement of product related to customer requirements, and</li> <li>c) resource needs.</li> </ul>	
<b>6 Resource management</b>			
<b>6.1 Provision of resources</b>			
6.1q1	<p>The organization shall determine and provide the resources needed</p> <ul style="list-style-type: none"> <li>a) to implement and maintain the quality management system and continually improve its effectiveness, and</li> <li>b) to enhance customer satisfaction by meeting customer requirements.</li> </ul>	<ul style="list-style-type: none"> <li>◆ What resources has Supplier provided to implement and maintain the QMS and continually improve its effectiveness?</li> <li>◆ What resources has Supplier provided to ensure that customer requirements are met? (See 6.2, 6.3, 6.4)</li> </ul>	

<b>6.2 Human resources</b>		
<b>6.2.1 General</b>		
6.2.1q1	Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.	(While auditing, select some personnel performing work affecting product quality) <ul style="list-style-type: none"> <li>◆ What are the education, training, skills and experience required by this job/task?</li> <li>◆ How does this person meet those qualifications?</li> </ul>
<b>6.2.2 Competence, awareness and training</b>		
6.2.2q1	The organization shall <ol style="list-style-type: none"> <li>determine the necessary competence for personnel performing work affecting product quality,</li> <li>provide training or take other actions to satisfy these needs,</li> <li>evaluate the effectiveness of the actions taken,</li> <li>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</li> <li>maintain appropriate records of education, training, skills and experience (see 4.2.4).</li> </ol>	<ul style="list-style-type: none"> <li>◆ How do you determine the necessary education, training, skills and experience for people performing work affecting product quality?</li> <li>◆ What training or other actions do you provide to satisfy the needs of personnel? (records)</li> <li>◆ When you provide training or other actions to satisfy competence needs, how do you evaluate the effectiveness of those actions? (records)</li> </ul> (Sample throughout Supplier) <ul style="list-style-type: none"> <li>◆ How do your activities contribute to the achievement of quality objectives?</li> <li>◆ Where do you maintain <b>records</b> of education, training, skills and experience?</li> </ul>
<b>6.2.2.1 Product design skills</b>		
T6.2.2.1q1	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.	<ul style="list-style-type: none"> <li>◆ What tools and techniques has the Supplier identified as necessary for product design personnel?</li> <li>◆ What records do you have showing that product design personnel are competent to design and are skilled in the identified tools and techniques?</li> </ul>
<b>6.2.2.2 Training</b>		
T6.2.2.2q1	The organization shall establish and maintain documented procedures for identifying training needs and achieving competence of all personnel performing activities affecting product quality.	<ul style="list-style-type: none"> <li>◆ Can you show <b>documented procedures</b> for identifying training needs and achieving competence of all personnel performing activities affecting product quality?</li> </ul>

T6.2.2.2q2	Personnel performing specific assigned tasks shall be qualified, as required, with particular attention to the satisfaction of customer requirements.	<ul style="list-style-type: none"> <li>◆ What records do you have that personnel performing specific assigned tasks are qualified - especially to meet customer requirements. (See 6.2.2e)</li> </ul>	
	NOTE 1 This applies to all employees having an effect on quality at all levels of the organization.		
	NOTE 2 An example of the customer specific requirements is the application of digitized mathematically based data.		
<b>6.2.2.3 Training on the job</b>			
T6.2.2.3q1	The organization shall provide on-the-job training for personnel in any new or modified job affecting product quality, including contract or agency personnel.	<ul style="list-style-type: none"> <li>◆ What kinds of on-the-job training do you provide for people in new or changed jobs?</li> <li>◆ Does this include contract and agency personnel?</li> </ul>	
T6.2.2.3q2	Personnel whose work can affect quality shall be informed about the consequences to the customer of nonconformity to quality requirements.	<ul style="list-style-type: none"> <li>◆ How do you inform personnel about the consequences to the customer of nonconformity to quality requirements? (Sample throughout Supplier)</li> </ul>	
<b>6.2.2.4 Employee motivation and empowerment</b>			
T6.2.2.4q1	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.	<ul style="list-style-type: none"> <li>◆ What process has been established to motivate employees to <ul style="list-style-type: none"> <li>- achieve quality objectives,</li> <li>- to make continual improvements, and</li> <li>- to create an environment to promote innovation?</li> </ul> </li> </ul>	
T6.2.2.4q2	The process shall include the promotion of quality and technological awareness throughout the whole organization.	<ul style="list-style-type: none"> <li>◆ Does the process include the promotion of quality and technological awareness throughout the entire Supplier?</li> </ul>	
T6.2.2.4q3	The organization shall have a process to measure the extent to which its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives [see 6.2.2 d)].	<ul style="list-style-type: none"> <li>◆ What process has been established to measure the extent to which personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives? (See 6.2.2d)</li> </ul>	

<b>6.3 Infrastructure</b>		
6.3q1	The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable a) buildings, workspace and associated utilities, b) process equipment (both hardware and software), and c) supporting services (such as transport or communication).	<ul style="list-style-type: none"> <li>◆ Are the buildings, workspace, and utilities provided appropriate to achieve conformity to product requirements? How are they maintained?</li> <li>◆ What kind of process equipment (both hardware and software) is necessary to conform to product requirements? How is the equipment maintained?</li> <li>◆ What supporting services (such as transport or communication) are needed to ensure that product meets requirements? How are they maintained?</li> </ul>
<b>6.3.1 Plant, facility and equipment planning</b>		
T6.3.1q1	The organization shall use a multidisciplinary approach (see 7.3.1.1) for developing plant, facility and equipment plans.	<ul style="list-style-type: none"> <li>◆ What groups are involved in developing plant, facility and equipment plans? (Must be multidisciplinary)</li> </ul>
T6.3.1q2	Plant layouts shall optimize material travel, handling and value-added use of floor space, and shall facilitate synchronous material flow.	<ul style="list-style-type: none"> <li>◆ Can you show that plant layouts optimize material travel, handling and floor space use, and facilitate synchronous material flow?</li> </ul>
T6.3.1q3	Methods shall be developed and implemented to evaluate and monitor the effectiveness of existing operations.	<ul style="list-style-type: none"> <li>◆ What methods are used to evaluate and monitor the effectiveness of existing operations?</li> </ul>
NOTE These requirements should focus on lean manufacturing principles and the link to the effectiveness of the quality management system.		
<b>6.3.2 Contingency plans</b>		
T6.3.2q1	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.	<ul style="list-style-type: none"> <li>◆ Can you show me contingency plans for each of the following? <ul style="list-style-type: none"> <li>- Utility interruptions</li> <li>- Labor shortages</li> <li>- Key equipment failure(s)</li> <li>- Field returns</li> </ul> </li> </ul>
<b>6.4 Work environment</b>		
6.4q1	The organization shall determine and manage the work environment needed to achieve conformity to product requirements.	<ul style="list-style-type: none"> <li>◆ What kind of work environment is required to achieve conformity to product requirements? How is this environment managed and maintained?</li> </ul>

<b>6.4.1 Personnel safety to achieve product quality</b>		
T6.4.1q1	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.	<ul style="list-style-type: none"> <li>◆ How are product safety and potential risks to employees addressed by Supplier?</li> </ul>
<b>6.4.2 Cleanliness of premises</b>		
T6.4.2q1	The organization shall maintain its premises in a state of order, cleanliness and repair consistent with the product and manufacturing process needs.	<ul style="list-style-type: none"> <li>◆ Does Supplier maintain the state of order, cleanliness and repair needed for products and manufacturing processes? (Verify throughout audit)</li> </ul>
<b>7 Product realization</b>		
<b>7.1 Planning of product realization</b>		
7.1q1	The organization shall plan and develop the processes needed for product realization.	<ul style="list-style-type: none"> <li>◆ Where are the processes needed for product realization identified?</li> </ul>
7.1q2	Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1).	<ul style="list-style-type: none"> <li>◆ Is the planning of product realization consistent with the requirements of the other processes of the QMS? (Verify there are no inconsistencies or conflicts between quality system procedures)</li> </ul>
7.1q3	In planning product realization, the organization shall determine the following, as appropriate: <ul style="list-style-type: none"> <li>a) quality objectives and requirements for the product;</li> <li>b) the need to establish processes, documents, and provide resources specific to the product;</li> <li>c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance;</li> <li>d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4).</li> </ul>	<ul style="list-style-type: none"> <li>◆ Where in the product realization process do you determine the quality objectives and requirements for products?</li> <li>◆ When planning for product realization, how do you establish processes, documents, and provide resources specific to the product</li> <li>◆ How do you determine verification, validation, monitoring, inspection and test activities specific to the product, and the criteria for product acceptance?</li> <li>◆ What <b>records</b> exist showing that both the realization processes and the product meet requirements?</li> </ul>
7.1q4	The output of this planning shall be in a form suitable for the organization's method of operations.	<ul style="list-style-type: none"> <li>◆ What are the outputs of product realization planning? Are they in a form suitable for Supplier?</li> </ul>
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 planning embodies the concepts of error prevention and continual improvement as contrasted with error detection, and is based on a multidisciplinary approach.	
	<b>7.1.1 Planning of product realization – Supplemental</b>	
T7.1.1q1	Customer requirements and references to its technical specifications shall be included in the planning of product realization as a component of the quality plan.	◆ Does the quality plan include customer requirements and reference to technical specifications?
	<b>7.1.2 Acceptance Criteria</b>	
T7.1.2q1	Acceptance criteria shall be defined by the organization and, where required, approved by the customer.	◆ Where are acceptance criteria defined? When required, does the customer approve them?
T7.1.2q2	For attribute data sampling, the acceptance level shall be zero defects (see 8.2.3.1).	◆ When attribute data sampling, is the acceptance level zero defects?
	<b>7.1.3 Confidentiality</b>	
T7.1.3q1	The organization shall ensure the confidentiality of customer-contracted products and projects under development, and related product information.	◆ How does Supplier ensure the confidentiality of customer-contracted products, projects under development, and related product information?
	<b>7.1.4 Change control</b>	
T7.1.4q1	The organization shall have a process to control and react to changes that impact product realization.	◆ What process is there to control and react to changes that impact product realization?
T7.1.4q2	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.	◆ How are the effects of changes assessed, including changes caused by suppliers? , and verification and validation activities shall be defined, to ensure compliance with customer requirements.
T7.1.4q3	Changes shall be validated before implementation.	◆ Are changes validated before implementation?
T7.1.4q4	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.	◆ Is impact on form, fit and function (including performance and/or durability) reviewed with the customer for proprietary designs so that all effects can be properly evaluated?
T7.1.4q5	When required by the customer, additional verification/identification requirements, such as those required for new product introduction, shall be met.	◆ Do you have evidence that any additional verification/identification requirements required by the customer are met?

	NOTE 1 Any product realization change affecting customer requirements requires notification to, and agreement from, the customer.	
	NOTE 2 The above requirement applies to product and manufacturing process changes.	
	<b>7.2 Customer-related processes</b>	
	<b>7.2.1 Determination of requirements related to the product</b>	
7.2.1q1a	<p>The organization shall determine</p> <ul style="list-style-type: none"> <li>a) requirements specified by the customer, including the requirements for delivery and post-delivery activities,</li> <li>b) requirements not stated by the customer but necessary for specified or intended use, where known,</li> <li>c) statutory and regulatory requirements related to the product, and</li> <li>d) any additional requirements determined by the organization.</li> </ul>	<ul style="list-style-type: none"> <li>◆ How does Supplier determine <u>each</u> of the following requirements? <ul style="list-style-type: none"> <li>a) requirements specified by the customer, including the requirements for delivery and post-delivery activities,</li> <li>b) requirements not stated by the customer but necessary for specified or intended use, where known,</li> <li>c) statutory and regulatory requirements related to the product, and</li> <li>d) any additional requirements determined by Supplier.</li> </ul> </li> </ul>
	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.	
	<b>7.2.1.1 Customer-designated special characteristics</b>	
T7.2.1.1q1	<p>The organization shall demonstrate conformity to customer requirements for designation, documentation and control of special characteristics.</p>	<ul style="list-style-type: none"> <li>◆ How do you meet customer requirements for designation, documentation and control of special characteristics?</li> </ul>
	<b>7.2.2 Review of requirements related to the product</b>	
7.2.2q1	<p>The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that</p> <ul style="list-style-type: none"> <li>a) product requirements are defined,</li> <li>b) contract or order requirements</li> <li>c) the organization has the ability to meet the defined requirements.</li> </ul>	<ul style="list-style-type: none"> <li>◆ What kind of review is done to ensure that Supplier has the ability to meet requirements before committing to supply product?</li> <li>◆ How do you ensure that product requirements are defined and reviewed before committing to supply product?</li> <li>◆ How do you ensure that contract or order requirements differing from those previously expressed are resolved before committing to supply product?</li> </ul>

7.2.2q2	Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4).	◆ Can you show me records of the product requirement review results and actions resulting from them?	
7.2.2q3	Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance.	◆ When customers don't have documented requirements, how do you confirm their requirements before accepting orders?	
7.2.2q4	Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.	◆ When product requirements are changed, how do you ensure that relevant documents are changed and that relevant personnel are made aware of the changes?	
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.			
<b>7.2.2.1 Review of requirements related to the product — Supplemental</b>			
T7.2.2.1q1	Waiving the requirement stated in 7.2.2 for a formal review (see note) shall require customer authorization.	◆ If you have waived the requirement for a formal review above, have you obtained customer authorization?	
<b>7.2.2.2 Organization manufacturing feasibility</b>			
T7.2.2.2q1	The organization shall investigate, confirm and document the manufacturing feasibility of the proposed products in the contract review process, including risk analysis.	◆ What documents do you have that show investigation and confirmation of manufacturing feasibility in the contract review process for proposed products, including risk analysis?	
<b>7.2.3 Customer communication</b>			
7.2.3q1	The organization shall determine and implement effective arrangements for communicating with customers in relation to a) product information, b) enquiries, contracts or order c) customer feedback, including customer complaints.	◆ What method(s) are used to communicate with customers regarding - product information? - enquiries, contracts, or order handling, including amendments? - feedback, including customer complaints?	
X	<b>7.2.3.1 Customer communication – Supplemental</b>		
X	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).	◆ Do your customers require information to be communicated in specific languages and/or formats?  ◆ If so, how do you meet those requirements?	
<b>7.3 Design and development</b>			
NOTE The requirements of 7.3 include product and manufacturing process design and development, and focus on error prevention rather than detection.			
<b>7.3.1 Design and development planning</b>			
7.3.1q1	The organization shall plan and control the design and development of product.	◆ Can you explain to me the process used by Supplier to plan and control the design and development of product?	

7.3.1q2	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.	<ul style="list-style-type: none"> <li>◆ What are the stages in the design and development process?</li> <li>◆ How do you determine the review, verification and validation activities appropriate to each design and development stage?</li> <li>◆ How /where are design and development responsibilities and authorities defined?</li> </ul>	
7.3.1q3	The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.	<ul style="list-style-type: none"> <li>◆ How does Supplier ensure effective communication and clear assignment of responsibility between different groups involved in design and development?</li> </ul>	
7.3.1q4	Planning output shall be updated, as appropriate, as the design and development progresses.	<ul style="list-style-type: none"> <li>◆ As product design and development progresses, how are the planning outputs updated?</li> </ul>	
<b>7.3.1.1 Multidisciplinary approach</b>			
7.3.1.1q1	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.	<ul style="list-style-type: none"> <li>◆ Do you use a multidisciplinary approach to prepare for product realization? Does it include: <ul style="list-style-type: none"> <li>- development/finalization and monitoring of special characteristics</li> <li>- development and review of FMEAs, including actions to reduce potential risks,</li> <li>- development and review of control plans.</li> </ul> </li> </ul>	
NOTE A multidisciplinary approach typically includes the organization's design, manufacturing, engineering, quality, production and other appropriate personnel.			
<b>7.3.2 Design and development inputs</b>			
7.3.2q1a	Inputs relating to product requirements shall be determined and records maintained (see 4.2.4). These inputs shall include  a) functional and performance requirements, b) applicable statutory and regulatory requirements, c) where applicable, information derived from previous similar designs, and d) other requirements essential for design and development.	<ul style="list-style-type: none"> <li>◆ What are the design inputs relating to <u>each</u> of the following product requirements? <ul style="list-style-type: none"> <li>a) functional and performance requirements,</li> <li>b) applicable statutory and regulatory requirements,</li> <li>c) where applicable, information derived from previous similar designs, and</li> <li>d) other requirements essential for design and development.</li> </ul> </li> <li>◆ Where are they <b>recorded</b>?</li> </ul>	
7.3.2q2	These inputs shall be reviewed for adequacy.	<ul style="list-style-type: none"> <li>◆ How &amp; when are the design and development inputs reviewed for adequacy?</li> </ul>	

7.3.2q3	Requirements shall be complete, unambiguous and not in conflict with each other.	<ul style="list-style-type: none"> <li>◆ How does Supplier ensure that requirements are complete, unambiguous and don't conflict with each other?</li> </ul>	
NOTE Special characteristics (see 7.2.1.1) are included in this requirement.			
<b>7.3.2.1 Product design input</b>			
T7.3.2.1q1	<p>The organization shall identify, document and review the product design inputs requirements, including the following:</p> <ul style="list-style-type: none"> <li>- customer requirements (contract review) such as special characteristics (see 7.3.2.3), identification, traceability and packaging;</li> <li>- use of information: the organization shall have a process to deploy information gained from previous design projects, competitor analysis, supplier feedback, internal input, field data, and other relevant sources, for current and future projects of a similar nature;</li> <li>- targets for product quality, life, reliability, durability, maintainability, timing and cost.</li> </ul>	<ul style="list-style-type: none"> <li>◆ Where is product design input requirements documented? (including the following: <ul style="list-style-type: none"> <li>- contract reviews of requirements such as special characteristics, identification, traceability and packaging;</li> <li>- a process to deploy information gained from previous design projects, competitor analysis, supplier feedback, internal input, field data, and other relevant sources, for current and future projects of a similar nature;</li> <li>- targets for product quality, life, reliability, durability, maintainability, timing and cost.)</li> </ul> </li> <li>◆ Can you show me they are reviewed?</li> </ul>	
<b>7.3.2.2 Manufacturing process design input</b>			
T7.3.2.2q1	<p>The organization shall identify, document and review the manufacturing process design input requirements, including</p> <ul style="list-style-type: none"> <li>- product design output data</li> <li>- targets for productivity, process capability and cost,</li> <li>- customers requirements, if any, and</li> <li>- experience from previous developments.</li> </ul>	<ul style="list-style-type: none"> <li>◆ Where are manufacturing process design input requirements documented? (including the following: <ul style="list-style-type: none"> <li>- product design output data</li> <li>- targets for productivity, process capability and cost,</li> <li>- customers requirements, if any, and</li> <li>- experience from previous developments.)</li> </ul> </li> <li>◆ Can you show me they are reviewed?</li> </ul>	
NOTE The manufacturing process design includes the use of error-proofing methods to a degree appropriate to the magnitude of the problems and commensurate with the risks encountered.			
<b>7.3.2.3 Special characteristics</b>			
T7.3.2.3q1	<p>The organization shall identify special characteristics [see 7.3.3 d)] and</p> <ul style="list-style-type: none"> <li>- include all special characteristics in the control plan,</li> <li>- comply with customer-specified definitions and symbols, and</li> <li>- identify process control documents including drawings, FMEAs, control plans, and operator instructions with the customer's SC symbol or equivalent symbol to include those process steps that affect special characteristics.</li> </ul>	<ul style="list-style-type: none"> <li>◆ Can you show me that all special characteristics are identified and included in drawings, FMEAs, control plans, and operator instructions?</li> <li>◆ Are the customer-specified (or equivalent) symbols used?</li> <li>◆ Do they meet customer-specified definitions?</li> <li>◆ Do they include process steps that affect special characteristics?</li> </ul>	
NOTE Special characteristics can include product characteristics and process parameters.			

<b>7.3.3 Design and development outputs</b>		
7.3.3q1	The outputs of design and development shall be provided in a form that enables verification against the design and development input and shall be approved prior to release.	<ul style="list-style-type: none"> <li>◆ How can design and development outputs be verified against the inputs? (see 7.3.5q1) Are these outputs approved prior to release?</li> </ul>
7.3.3q2	Design and development outputs shall <ol style="list-style-type: none"> <li>a) meet the input requirements for design and development,</li> <li>b) provide appropriate information for purchasing, production and for service provision,</li> <li>c) contain or reference product acceptance criteria, and</li> <li>d) specify the characteristics of the product that are essential for its safe and proper use.</li> </ol>	<ul style="list-style-type: none"> <li>◆ Can you show me examples of design and development outputs and how they meet the input requirements?</li> <li>◆ What outputs include information for purchasing, production and service?</li> <li>◆ Where are product acceptance criteria specified?</li> <li>◆ Where are product characteristics needed for safe and proper use specified?</li> </ul>
<b>7.3.3.1 Product design outputs – Supplemental</b>		
T7.3.3.1q1	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 <ul style="list-style-type: none"> <li>- design FMEA, reliability results</li> <li>- product special characteristics, specifications,</li> <li>- product error-proofing, as appropriate,</li> <li>- product definition including drawings or mathematically based data,</li> <li>- product design reviews results, and</li> <li>- diagnostic guidelines where applicable</li> </ul>	<ul style="list-style-type: none"> <li>◆ Can you show that the product design outputs include               <ul style="list-style-type: none"> <li>- design FMEA, reliability results</li> <li>- product special characteristics, specifications,</li> <li>- product error-proofing, as appropriate,</li> <li>- product definition including drawings or mathematically based data,</li> <li>- product design reviews results, and</li> <li>- diagnostic guidelines where applicable</li> </ul> </li> <li>◆ Are the outputs expressed in terms that can be verified and validated against product design input requirements?</li> </ul>
<b>7.3.3.2 Manufacturing process design output</b>		
T7.3.3.1q1	The manufacturing process design output shall be expressed in terms that can be verified against manufacturing process design input requirements and validated. The manufacturing process design output shall include <ul style="list-style-type: none"> <li>- specifications and drawings.</li> <li>- manufacturing process flow chart/ layout,</li> <li>- manufacturing process FMEAs,</li> <li>- control plan (see 7.5.1.1),</li> <li>- work instructions,</li> <li>- process approval acceptance criteria,</li> <li>- data for quality, reliability, maintainability and measurability</li> <li>- results of error-proofing activities, as appropriate, and</li> <li>- methods of rapid detection and feedback of product/manufacturing process nonconformities.</li> </ul>	<ul style="list-style-type: none"> <li>◆ Can you show that the manufacturing process design outputs include               <ul style="list-style-type: none"> <li>- specifications and drawings,</li> <li>- manufacturing process flow chart/ layout,</li> <li>- manufacturing process FMEAs,</li> <li>- control plans,</li> <li>- work instructions,</li> <li>- process approval acceptance criteria,</li> <li>- data for quality, reliability, maintainability and measurability</li> <li>- results of error-proofing activities, as appropriate, and</li> <li>- methods of rapid detection and feedback of product/manufacturing process nonconformities.</li> </ul> </li> </ul> <p>The manufacturing process design output shall be expressed in terms that can be verified against manufacturing process design input requirements and validated.</p>

7.3.4 Design and development review		
7.3.4q1a	At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1) a) to evaluate the ability of the results of design and development to meet requirements, and b) to identify any problems and propose necessary actions.	<ul style="list-style-type: none"> <li>◆ At what stages of design and development do you perform reviews to evaluate if the results meet requirements? (See 7.3.1q2b)</li> <li>◆ Can you show me some problems that have been identified and actions proposed at these reviews?</li> </ul>
7.3.4q2	Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed	<ul style="list-style-type: none"> <li>◆ What functions are represented at these reviews?</li> <li>◆ At each stage, are all functions concerned with that stage represented?</li> </ul>
7.3.4q3	Records of the results of the reviews and any necessary actions shall be maintained (see 4.2.4).	<ul style="list-style-type: none"> <li>◆ Can you show me records of the results of the reviews and any necessary actions taken?</li> </ul>
NOTE These reviews are normally coordinated with the design phases and include manufacturing process design and development.		
7.3.4.1 Monitoring		
T7.3.4.1q1	Measurements at specified stages of design and development shall be defined, analyzed and reported with summary results as an input to management review.	<ul style="list-style-type: none"> <li>◆ Can you show me reports of analysis of measurements at specified design and development stages?</li> <li>◆ Are summary results included in management reviews? (See 5.6.2)</li> </ul>
NOTE These measurements include quality risks, costs, lead-times, critical paths and others, as appropriate.		
7.3.5 Design and development verification		
7.3.5q1	Verification 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.	<ul style="list-style-type: none"> <li>◆ What verification activities are performed to ensure that the design and development outputs have met the input requirements? (See 7.3.3q1)</li> </ul>
7.3.5q2	Records of the results of the verification and any necessary actions shall be maintained (see 4.2.4).	<ul style="list-style-type: none"> <li>◆ Can you show me <b>records</b> of the results of the verification activities <u>and</u> resulting actions?</li> </ul>
7.3.6 Design and development validation		
7.3.6q1	Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known.	<ul style="list-style-type: none"> <li>◆ What design and development validation activities are performed to ensure that the product is capable of meeting the requirements for the intended use?</li> </ul>
7.3.6q2	Wherever practicable, validation shall be completed prior to the delivery or implementation of the product.	<ul style="list-style-type: none"> <li>◆ Do records show that validation is done before product shipment? If not, is the justification recorded?</li> </ul>
7.3.6q3	Records of the results of validation and any necessary actions shall be maintained (see 4.2.4).	<ul style="list-style-type: none"> <li>◆ Can you show me <b>records</b> of the validation activity results <u>and</u> any follow-up actions?</li> </ul>
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.	
<b>7.3.6.1 Design and development validation – Supplemental</b>		
T7.3.6.1q1	Design and development validation shall be performed in accordance with customer requirements including programme timing.	<ul style="list-style-type: none"> <li>◆ Is design and development validation performed in accordance with customer requirements, including program timing?</li> </ul>
<b>7.3.6.2 Prototype program</b>		
T7.3.6.2q1	When required by the customer, the organization shall have a prototype program and control plan.	<ul style="list-style-type: none"> <li>◆ Do your customer(s) require a prototype program and control plan?</li> <li>◆ If so, can you describe the program?</li> <li>◆ Can you show me the control plan(s)?</li> </ul>
T7.3.6.2q2	The organization shall use, whenever possible, the same suppliers, tooling and manufacturing processes as will be used in production.	<ul style="list-style-type: none"> <li>◆ Does Supplier's prototype program use the same suppliers, tooling and manufacturing processes as will be used in production? If not, what is the justification?</li> </ul>
T7.3.6.2q3	All performance testing activities shall be monitored for timely completion and conformance to requirements.	<ul style="list-style-type: none"> <li>◆ What records show that performance-testing activities are monitored for timely completion and conformance to requirements?</li> </ul>
T7.3.6.2q4	While services may be outsourced, the organization shall be responsible for the outsourced services, including technical leadership.	<ul style="list-style-type: none"> <li>◆ Are any prototyping services outsourced?</li> <li>◆ If so, who is responsible for the outsourced services, including technical leadership?</li> </ul>
<b>7.3.6.3 Product approval process</b>		
T7.3.6.3q1	The organization shall conform to a product and process approval procedure recognized by the customer.	<ul style="list-style-type: none"> <li>◆ What product and/or process approval procedure(s) do your customer(s) require?</li> <li>◆ Can you show me records of both process and product approvals?</li> </ul>
NOTE Product approval should be subsequent to the verification of the manufacturing process.		
T7.3.6.3q2	This product and manufacturing process approval procedure shall also be applied to suppliers.	<ul style="list-style-type: none"> <li>◆ Do you have evidence that the product and manufacturing process approval procedures are applied to suppliers? (See 7.4.2)</li> </ul>
<b>7.3.7 Control of design and development changes</b>		
7.3.7q1	Design and development changes shall be identified and records maintained.	<ul style="list-style-type: none"> <li>◆ How are design and development changes identified? Where are the <b>records</b> kept?</li> </ul>

7.3.7q2	The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation.	◆ Are changes reviewed, verified, validated, and approved before implementation?	
7.3.7q3	The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered.	◆ Can you show me evidence that the review of design and development changes includes evaluation of the effect on component parts and products in the field?	
7.3.7q4	Records of the results of the review of changes and any necessary actions shall be maintained (see 4.2.4).	◆ Can you show me <b>records</b> of the results of change reviews and any necessary actions?	
NOTE 1 Design and development changes include all changes during the product program life (see 7.1.4).			
<b>7.4 Purchasing</b>			
<b>7.4.1 Purchasing process</b>			
7.4.1q1	The organization shall ensure that purchased product conforms to specified purchase requirements.	◆ How do you ensure that purchased product conforms to specified purchase requirements?	
7.4.1q2	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.	◆ How do you determine the type and extent of control applied to the supplier and the purchased product?	
7.4.1q3	The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements.	◆ How do you evaluate and select suppliers? (based on their ability to supply product in accordance with Supplier's requirements)	
7.4.1q4	Criteria for selection, evaluation and re-evaluation shall be established.	◆ Can you show me the criteria for selection, evaluation and re-evaluation of suppliers?	
7.4.1q5	Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see 4.2.4).	◆ Can you show me <b>records</b> of the results of supplier evaluations and any necessary actions? (verify that criteria have been met)	
NOTE 1 Purchased products above includes 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 system and its effectiveness.			
<b>7.4.1.1 Regulatory conformity</b>			
7.4.1.1q1	All purchased products or materials used in product shall conform to applicable regulatory requirements.	◆ What evidence is there that all purchased products or materials used in product conform to regulatory requirements?	

7.4.1.2 Supplier quality management system development		
T7.4.1.2q1	The organization shall perform supplier quality management system development with the goal of supplier conformity with this Technical Specification. Conformity with ISO 9001:2000 is the first step in achieving this goal.	<ul style="list-style-type: none"> <li>◆ What supplier development actions are being taken toward the goal of supplier conformity with TS 16949?</li> <li>◆ Do your suppliers' quality management systems conform with ISO 9001:2000? (see below)</li> </ul>
NOTE The prioritization of suppliers for development depends upon, for example, the supplier's quality performance and the importance of the product supplied.		
T7.4.1.2q2	Unless otherwise specified by the customer, suppliers to the organization shall be third party registered to ISO 9001:2000 by an accredited third-party certification body.	<ul style="list-style-type: none"> <li>◆ Are all of your suppliers registered to ISO 9001:2000?</li> <li>◆ If not, do you have written waivers from applicable customer(s)?</li> </ul>
7.4.1.3 Customer-approved sources		
T7.4.1.3q1	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.	<ul style="list-style-type: none"> <li>◆ Do your customer(s) specify supplier(s) in contracts/ purchase orders?  (This includes products, materials, services, tooling, &amp; gages, )</li> <li>◆ If so, can you show that the customer-designated sources are being used as required?</li> </ul>
7.4.2 Purchasing information		
7.4.2q1	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.	<ul style="list-style-type: none"> <li>◆ Do orders/contracts include requirements for approval of product, procedures, processes and equipment?</li> <li>◆ Do require any qualification of supplier personnel?</li> <li>◆ If so, can you show where the requirement is documented?</li> <li>◆ Do you have any QMS requirements of your suppliers?</li> <li>◆ If so, can you show me where they are required?</li> </ul>
7.4.2q2	The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.	<ul style="list-style-type: none"> <li>◆ How does Supplier ensure the adequacy of purchasing requirements before communicating them to the supplier?</li> </ul>

7.4.3 Verification of purchased product		
7.4.3q1	The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.	<ul style="list-style-type: none"> <li>◆ What inspection or other activities are used to ensure that purchased product meets your purchasing requirements?</li> </ul>
7.4.3q2	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.	<ul style="list-style-type: none"> <li>◆ Do you ever perform product verification at the supplier's site?</li> <li>◆ If so, where are the verification arrangements and method of product release identified?</li> </ul>
7.4.3.1 Incoming product quality		
T7.4.3.1q1	<p>The organization shall have a process to assure the quality of purchased product (see 7.4.3) utilizing one or more of the following methods:</p> <ul style="list-style-type: none"> <li>- receipt of, and evaluation of, statistical data by the organization;</li> <li>- receiving inspection and/or testing such as sampling based on performance;</li> <li>- second- or third-party assessments or audits of supplier sites, when coupled with records of acceptable delivered product quality;</li> <li>- part evaluation by a designated laboratory;</li> <li>- another method agreed with the customer.</li> </ul>	<ul style="list-style-type: none"> <li>◆ What processes are in place to assure the quality of purchased product?</li> </ul> <p>(Must include one or more of following:</p> <ul style="list-style-type: none"> <li>- evaluation of supplier statistical data</li> <li>- receiving inspection and/or testing</li> <li>- second- or third-party audits of suppliers, along with records of acceptable quality</li> <li>- laboratory part evaluation</li> <li>- another method agreed with the customer)</li> </ul>
7.4.3.2 Supplier monitoring		
T7.4.3.2q1	<p>Supplier performance shall be monitored through the following indicators:</p> <ul style="list-style-type: none"> <li>- delivered product quality;</li> <li>- customer disruptions including field returns;</li> <li>- delivery schedule performance (including incidents of premium freight);</li> <li>- special status customer notifications related to quality or delivery issues.</li> </ul>	<ul style="list-style-type: none"> <li>◆ How do you monitor supplier performance?</li> </ul> <p>(Must include the following indicators:)</p> <ul style="list-style-type: none"> <li>- delivered product quality</li> <li>- customer disruptions including field returns</li> <li>- delivery schedule performance (including incidents of premium freight)</li> <li>- special status customer notifications related to quality or delivery issues</li> </ul>
T7.4.3.2q2	The organization shall promote supplier monitoring of the performance of their manufacturing processes.	<ul style="list-style-type: none"> <li>◆ How do you promote supplier monitoring of the performance of their manufacturing processes?</li> </ul>

7.5 Production and service provision		
7.5.1 Control of production and service provision		
7.5.1q1a	<p>The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable</p> <ol style="list-style-type: none"> <li>the availability of information that describes the characteristics of the product,</li> <li>the availability of work instructions, as necessary,</li> <li>the use of suitable equipment,</li> <li>the availability and use of monitoring and measuring devices,</li> <li>the implementation of monitoring and measurement, and</li> <li>the implementation of release, delivery and post-delivery activities.</li> </ol>	<ul style="list-style-type: none"> <li>◆ When carrying out production (or service) are <u>all</u> of the following controlled conditions in place? <ol style="list-style-type: none"> <li>Is information that describes the characteristics of the product available?</li> <li>Are appropriate work instructions available (if needed)? (See 7.5.1.2)</li> <li>Is suitable equipment used for carrying out production (or service)?</li> <li>Are appropriate gages, etc. used in production (or service)? (See 7.6)</li> <li>Are appropriate kinds of monitoring and measurement done? (See 8.2.4)</li> <li>Are proper release, delivery and post-delivery activities in place?</li> </ol> </li> </ul>
<b>7.5.1.1 Control plan</b>		
T7.5.1.1q1	<p>The organization shall</p> <ul style="list-style-type: none"> <li>- 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</li> <li>- have a control plan for pre-launch and production that takes into account the design FMEA and manufacturing process FMEA outputs.</li> </ul>	<ul style="list-style-type: none"> <li>◆ Can you show me control plans for system, subsystem, and component/ material levels for product supplied?</li> <li>◆ Can you show me control plans for both pre-launch and production?</li> <li>◆ Can you show how the control plans take into consideration design FMEA and process FMEA information? (See annex A)</li> </ul>
T7.5.1.1q2	<p>The control plan shall</p> <ul style="list-style-type: none"> <li>- list the controls used for the manufacturing process control,</li> <li>- include methods for monitoring of control exercised over special characteristics (see 7.3.2.3) defined both by the customer and the organization,</li> <li>- include the customer-required information, if any, and</li> <li>- initiate the specified reaction plan (see 8.2.3.1) when the process becomes unstable or not statistically capable.</li> </ul>	<p>(Review control plans to ensure they:</p> <ul style="list-style-type: none"> <li>- list controls used for manufacturing process control</li> <li>- include methods for monitoring of control of special characteristics</li> <li>- include customer-required information, if any)</li> <li>◆ Can you show that specified reaction plans have been carried out when a process becomes unstable or not statistically capable?</li> </ul>
T7.5.1.1q3	<p>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).</p>	<ul style="list-style-type: none"> <li>◆ What conditions initiate the review and update of control plans?</li> </ul>

	NOTE Customer approval may be required after review or update of the control plan.	
	<b>7.5.1.2 Work instructions</b>	
T7.5.1.2q1	The organization shall prepare documented work instructions for all employees having responsibilities for the operation of processes that impact product quality. These instructions shall be accessible for use at the work station.	<ul style="list-style-type: none"> <li>◆ Do all employees responsible for processes that impact product quality have documented work instructions? (Verify throughout audit)</li> <li>◆ Are they accessible for use at the workstation?</li> </ul>
T7.5.1.2q2	These instructions shall be derived from sources such as the quality plan, the control plan and the product realization process.	<ul style="list-style-type: none"> <li>◆ How are the work instructions developed?</li> </ul>
	<b>7.5.1.3 Verification of job set-ups</b>	
T7.5.1.3q1	Job set-ups shall be verified whenever performed, such as an initial run of a job, material changeover or job change.	<ul style="list-style-type: none"> <li>◆ Can you show me records of job setups that are being performed?</li> <li>◆ Do they occur at the initial run of a job, material changeover, or job change?</li> </ul>
T7.5.1.3q2	Work instructions shall be available for set-up personnel.	<ul style="list-style-type: none"> <li>◆ What work instructions do you have for job setup personnel?</li> </ul>
T7.5.1.3q3	The organization shall use statistical methods of verification where applicable.	<ul style="list-style-type: none"> <li>◆ What statistical methods are used to verify job setups?</li> </ul>
	NOTE Last-off-part comparisons are recommended.	
	<b>7.5.1.4 Preventive and predictive maintenance</b>	
T7.5.1.4q1	The organization shall identify key process equipment and provide resources for machine/equipment maintenance and develop an effective planned total preventive maintenance system.	<ul style="list-style-type: none"> <li>◆ How do you identify key process equipment?</li> <li>◆ Can you walk me through your total preventive maintenance system?</li> </ul>
T7.5.1.4q2	As a minimum, this system shall include the following: <ul style="list-style-type: none"> <li>- planned maintenance activities;</li> <li>- packaging and preservation of equipment, tooling and gauging;</li> <li>- availability of replacement parts for key manufacturing equipment;</li> <li>- documenting, evaluating and improving maintenance objectives.</li> </ul>	(Verify that the PM system includes the following: <ul style="list-style-type: none"> <li>- planned maintenance activities</li> <li>- packaging and preservation of equipment, tooling and gauging</li> <li>- availability of replacement parts for key manufacturing equipment</li> <li>- documenting, evaluating and improving maintenance objectives)</li> </ul>

T7.5.1.4q3	The organization shall utilize predictive maintenance methods to continually improve the effectiveness and the efficiency of production equipment.	<ul style="list-style-type: none"> <li>◆ What predictive maintenance methods do you use?</li> <li>◆ Can you demonstrate that predictive maintenance has resulted in continual improvement of the effectiveness and efficiency of production equipment?</li> </ul>	
<b>7.5.1.5 Management of production tooling</b>			
T7.5.1.5q1	The organization shall provide resources for tool and gauge design, fabrication and verification activities.	<ul style="list-style-type: none"> <li>◆ What resources have Supplier provided for tool and gage design, fabrication and verification activities?</li> </ul>	
T7.5.1.5q2	<p>The organization shall establish and implement a system for production tooling management including:</p> <ul style="list-style-type: none"> <li>- maintenance and repair facilities and personnel;</li> <li>- storage and recovery,</li> <li>- set-up;</li> <li>- tool-change program for perishable tools;</li> <li>- tool design modification documentation, including engineering change level;</li> <li>- tool modification and revision to documentation;</li> <li>- tool identification, defining the status, such as production, repair or disposal.</li> </ul>	<ul style="list-style-type: none"> <li>◆ Does the production tooling management system include: <ul style="list-style-type: none"> <li>- maintenance and repair facilities and personnel</li> <li>- storage and recovery</li> <li>- set-up</li> <li>- perishable tool change programs</li> <li>- tool design modification documentation, including engineering change level</li> <li>- tool modification and revision to documentation</li> <li>- tool identification, defining the status, such as production, repair or disposal.</li> </ul> </li> </ul>	
T7.5.1.5q3	The organization shall implement a system to monitor these activities if any work is outsourced.	<ul style="list-style-type: none"> <li>◆ Are any tooling management activities outsourced?</li> <li>◆ If so, how are these activities monitored?</li> </ul>	
NOTE This requirement also applies to the availability of tools for vehicle service parts.			
<b>7.5.1.6 Production scheduling</b>			
T7.5.1.6q1	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.	<ul style="list-style-type: none"> <li>◆ Can you demonstrate that customer scheduling requirements (such as just-in-time) are being met?</li> </ul>	
<b>7.5.1.7 Feedback of information from service</b>			
T7.5.1.7q1	A process for communication of information on service concerns to manufacturing, engineering and design activities shall be established and maintained.	<ul style="list-style-type: none"> <li>◆ What is your process to communicate information on service concerns to manufacturing, engineering, and design?</li> </ul>	
NOTE The intent of the addition of "service concerns" to this sub-clause is to ensure that the organization is aware of nonconformities that occur external to its organization.			

	<b>7.5.1.8 Service agreement with customer</b>	
T7.5.1.8q1	When there is a service agreement with the customer, the organization shall verify the effectiveness of - any organization service centers, - any special-purpose tools or measurement equipment, and - the training of service personnel.	<ul style="list-style-type: none"> <li>◆ Do you have any service agreement(s) with customers? If so, how do you verify the effectiveness of <ul style="list-style-type: none"> <li>- any Supplier service centers,</li> <li>- any special-purpose tools or measurement equipment, and</li> <li>- the training of service personnel?</li> </ul> </li> </ul>
	<b>7.5.2 Validation of processes for production and service provision</b>	
7.5.2q1	The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered.	<ul style="list-style-type: none"> <li>◆ Do you have any production or service processes where the resulting output cannot be verified later? (This applies to <a href="#">all processes in TS 16949</a>)</li> <li>◆ If so, how to you validate them?</li> </ul>
7.5.2q2	Validation shall demonstrate the ability of these processes to achieve planned results.	<ul style="list-style-type: none"> <li>◆ Can you show me records that demonstrate that the validation done has met the requirements?</li> </ul>
7.5.2q3a	The organization shall establish arrangements for these processes including, as applicable a) defined criteria for review and approval of the processes, 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.	<ul style="list-style-type: none"> <li>◆ How are these special processes reviewed and approved?</li> <li>◆ Can you show me records of personnel and equipment qualification?</li> <li>◆ Where are specific methods and procedures defined?</li> <li>◆ Can you show me <b>records</b> for these processes?</li> <li>◆ When changes are made to processes, how do you revalidate them?</li> </ul>
	<b>7.5.2.1 Validation of processes for production and service provision – Supplemental</b>	
T7.5.2.1q1	The requirements of 7.5.2 shall apply to all processes for production and service provision.	<ul style="list-style-type: none"> <li>◆ Are <u>all</u> production processes validated per 7.5.2 above?</li> </ul>
	<b>7.5.3 Identification and traceability</b>	<b>7.5.3 Identification and traceability</b>
7.5.3q1	Where appropriate, the organization shall identify the product by suitable means throughout product realization.	<ul style="list-style-type: none"> <li>◆ How do you identify product throughout your processes? (Verify in production, storage, segregation areas, etc.)</li> </ul>

7.5.3q2	The organization shall identify the product status with respect to monitoring and measurement requirements.	◆ How is product inspection status identified? (Verify in production, storage, segregation areas, etc.)	
7.5.3q3	Where traceability is a requirement, the organization shall control and record the unique identification of the product (see 4.2.4).	◆ Can you show me unique identification <b>records</b> for products requiring traceability?	
	NOTE In some industry sectors, configuration management is a means by which identification and traceability are maintained.		
X	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.		
X	<b>7.5.3.1 Identification and traceability – Supplemental</b>		
X	The words "Where appropriate" in 7.5.3 above, shall not apply.	◆ Is <u>all</u> product suitably identified?	
	<b>7.5.4 Customer property</b>		
7.5.4q1	The organization shall exercise care with customer property while it is under the organization's control or being used by the organization.	◆ Do you use any customer-owned property? (Product, packaging, drawings, tooling, gages...) (If so, ask questions below)	
7.5.4q2	The organization shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product.	◆ How do you ensure that customer-owned property is identified, verified, protected, and safeguarded?	
7.5.4q3	If any customer property is lost, damaged or otherwise found to be unsuitable for use, this shall be reported to the customer and records maintained (see 4.2.4).	◆ If any customer property is lost, damaged etc., how is it reported to the customer? Can you show me <b>records</b> regarding this?	
	NOTE Customer property can include intellectual property.		
	NOTE Customer-owned returnable packaging is included in this clause.		
	<b>7.5.4.1 Customer-owned production tooling</b>		
T7.5.4.1q1	Customer-owned tools, manufacturing, test, inspection tooling and equipment shall be permanently marked so that the ownership of each item is visible, and can be determined.	◆ How are customer-owned tools and equipment identified?	
	<b>7.5.5 Preservation of product</b>		
7.5.5q1	The organization shall preserve the conformity of product during internal processing and delivery to the intended destination.	◆ How do you preserve the conformity of product during internal processing and delivery? (Verify product throughout audit)	
7.5.5q2	This preservation shall include identification, handling, packaging, storage and protection.	◆ How do identification, handling, packaging, storage and protection address the preservation of product?	

7.5.5q3	Preservation shall also apply to the constituent parts of a product.	◆ Does this also apply to component parts?	
<b>7.5.5.1 Storage and inventory</b>			
T7.5.5.1q1	In order to detect deterioration, the condition of product in stock shall be assessed at appropriate planned intervals.	◆ How do you assess the condition of product in stock to detect deterioration?	
T7.5.5.1q2	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).	◆ Can you walk me through your inventory management system? ◆ How does the system optimize inventory turns over time and assure stock rotation?	
T7.5.5.1q3	Obsolete product shall be controlled in a similar manner to nonconforming product.	◆ How is obsolete product controlled to prevent its unintended use or delivery? (See 8.3)	
<b>7.6 Control of monitoring and measuring devices</b>			
7.6q1	The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements (see 7.2.1).	◆ How do you determine the measurements to be taken and the measuring equipment needed to demonstrate conformity with requirements?	
7.6q2	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.	◆ What process is in place to ensure that measurements are taken per the requirements?	
7.6q3a	Where necessary ensure valid results, measuring equipment shall a) be calibrated or verified 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; b) be adjusted or re-adjusted as necessary; c) be identified to enable the calibration status to be determined; d) be safeguarded from adjustments that would invalidate the measurement result; e) be protected from damage and deterioration during handling, maintenance and storage.	a) How do you ensure that measuring and test equipment is calibrated or verified proper frequencies with NIST traceable standards? If no such standards exist, where do you <b>record</b> the basis used for calibration or verification? b) What process is used to adjust or re-adjust measuring and test equipment when needed? c) How are measuring tools identified to enable the calibration status to be determined? d) How do you safeguard measuring equipment from adjustments that would invalidate the measurement results? e) How do you ensure that measuring its test equipment is protected from damage and deterioration during handling, maintenance and storage?	

7.6q4	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.	<ul style="list-style-type: none"> <li>◆ When equipment is found to be out of calibration, how do you assess and record the validity of the previous measuring results?</li> </ul>	
7.6q5	The organization shall take appropriate action on the equipment and any product affected.	<ul style="list-style-type: none"> <li>◆ What actions do you take on the equipment and any product affected?</li> </ul>	
7.6q6	Records of the results of calibration and verification shall be maintained (see 4.2.4).	<ul style="list-style-type: none"> <li>◆ Can I see your <b>records</b> of the results of calibration and verification?</li> </ul>	
7.6q7	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.	<ul style="list-style-type: none"> <li>◆ Do you use computer software for monitoring and measurement?</li> <li>◆ If so, is its ability to perform that function confirmed prior to initial use and reconfirmed as necessary?</li> </ul>	
NOTE See ISO 10012-1 and ISO 10012-2 for guidance.			
NOTE A number or other identifier traceable to the device calibration record meets the intent of requirement c) above.			
<b>7.6.1 Measurement system analysis</b>			
T7.6.1q1	<p>Statistical studies shall be conducted to analyse the variation present in the results of each type of measuring and test equipment system.</p> <p>This requirement shall apply to measurement systems referenced in 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.</p>	<ul style="list-style-type: none"> <li>◆ Can you show me R&amp;R studies for each type of measuring and test equipment system referenced in the control plan? (Or other statistical studies analyzing the variation in measurement &amp; test results)</li> <li>◆ Do the methods and acceptance criteria conform to those in customer reference manuals on MSA or does the customer approve them?</li> </ul>	
<b>7.6.2 Calibration/verification records</b>			
T7.6.2q1	<p>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</p> <ul style="list-style-type: none"> <li>- equipment identification, including the measurement standard against which the equipment is calibrated,</li> <li>- revisions following engineering changes,</li> <li>- any out-of-specification readings as received for calibration/verification,</li> <li>- an assessment of the impact of out-of-specification condition,</li> <li>- statements of conformity to specification after calibration/verification, and</li> <li>- notification to the customer if suspect product or material has been shipped.</li> </ul>	<ul style="list-style-type: none"> <li>◆ Can you show that calibration records include: <ul style="list-style-type: none"> <li>- equipment identification, including the measurement standard against which the equipment is calibrated,</li> <li>- revisions following engineering changes,</li> <li>- any out-of-specification readings as received for calibration/verification,</li> <li>- an assessment of the impact of out-of-specification condition,</li> <li>- statements of conformity to specification after calibration/verification, and</li> <li>- notification to the customer if suspect product or material has been shipped?</li> </ul> </li> </ul>	

<b>7.6.3 Laboratory requirements</b>		
<b>7.6.3.1 Internal laboratory</b>		
T7.6.3.1q1	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.	<ul style="list-style-type: none"> <li>◆ Does Supplier have an internal laboratory?</li> <li>◆ If so, can you show me a documented laboratory scope including its capability to perform inspection, test, or calibration services?</li> </ul>
T7.6.3.1q2	The laboratory shall specify and implement, as a minimum, technical requirements for <ul style="list-style-type: none"> <li>- adequacy of laboratory procedures,</li> <li>- competency of the laboratory personnel,</li> <li>- testing of the product,</li> <li>- capability to perform these services correctly, traceable to the relevant process standard (such as ASTM, EN, etc.), and</li> <li>- review of the related records.</li> </ul>	<ul style="list-style-type: none"> <li>◆ Where are laboratory technical requirements specified for <ul style="list-style-type: none"> <li>- adequacy of laboratory procedures,</li> <li>- competency of the laboratory personnel,</li> <li>- testing of the product,</li> <li>- capability to perform these services correctly, traceable to the relevant process standard, and</li> <li>- review of the related records?</li> </ul> </li> <li>◆ Have these requirements been implemented?</li> </ul>
NOTE Accreditation to ISO/IEC 17025 may be used to demonstrate supplier in-house laboratory conformity to this requirement but is not mandatory.		
<b>7.6.3.2 External laboratory</b>		
T7.6.3.2q1	External/commercial/independent laboratory facilities used for inspection, test or calibration services by the organization shall have a defined laboratory scope that includes the capability to perform the required inspection, test or calibration, and either <ul style="list-style-type: none"> <li>- there shall be evidence that the external laboratory is acceptable to the customer, or</li> <li>- the laboratory shall be accredited to ISO/IEC 17025 or national equivalent.</li> </ul>	<ul style="list-style-type: none"> <li>◆ Can you show me laboratory scope(s) for external/commercial/independent laboratory facilities that include the capability to perform the required inspection, test or calibration?</li> <li>◆ Can I see evidence that each laboratory is either accredited, or is acceptable to the customer(s)?</li> </ul>
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.		

<b>8 Measurement, analysis and improvement</b>		
<b>8.1 General</b>		
8.1q1a	The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed <b>a)</b> to demonstrate conformity of the product,	<ul style="list-style-type: none"> <li>◆ How do you plan and implement measurement, analysis and improvement processes needed to demonstrate products conform to requirements?</li> </ul>
8.1q1b	The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed <b>b)</b> to ensure conformity of the quality management system, and	<ul style="list-style-type: none"> <li>◆ How do you plan and implement measurement, analysis and improvement processes needed to ensure conformity of the QMS?</li> </ul>
8.1q1c	The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed <b>c)</b> to continually improve the effectiveness of the quality management system.	<ul style="list-style-type: none"> <li>◆ How do you plan and implement measurement, analysis and improvement processes needed to continually improve the effectiveness of the QMS?</li> </ul>
8.1q2	This shall include determination of applicable methods, including statistical techniques, and the extent of their use.	<ul style="list-style-type: none"> <li>◆ How do you determine what methods to use, including statistical techniques? How do you determine the extent of their use?</li> </ul>
<b>8.1.1 Identification of statistical tools</b>		
T8.1.1q1	Appropriate statistical tools for each process shall be determined during advance quality planning and included in the control plan.	<ul style="list-style-type: none"> <li>◆ Have appropriate statistical tools for each process been determined and included in the control plan? (see 7.5.1.1)</li> </ul>
<b>8.1.2 Knowledge of basic statistical concepts</b>		
T8.1.2q1	Basic statistical concepts, such as variation, control (stability), process capability and over-adjustment shall be understood and utilized throughout the organization.	<ul style="list-style-type: none"> <li>◆ How does Supplier ensure that basic statistical concepts are understood and utilized throughout Supplier? (verify throughout audit)</li> </ul>
<b>8.2 Monitoring and measurement</b>		
<b>8.2.1 Customer satisfaction</b>		
8.2.1q1	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.	<ul style="list-style-type: none"> <li>◆ How do you obtain information about customer perception as to whether Supplier has met customer requirements?</li> <li>◆ How is this information used?</li> </ul>

	NOTE Consideration should be given to both internal and external customers.	
<b>8.2.1.1 Customer satisfaction — Supplemental</b>		
T8.2.1.1q1	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.	<ul style="list-style-type: none"> <li>◆ What realization process performance indicators are used to monitor customer satisfaction?</li> <li>◆ Do they include at least: <ul style="list-style-type: none"> <li>- delivered part quality performance,</li> <li>- customer disruptions including field returns,</li> <li>- delivery schedule performance (including incidents of premium freight), and</li> <li>- customer notifications related to quality or delivery issues?</li> </ul> </li> </ul>
T8.2.1.1q2	The organization shall monitor the performance of manufacturing processes to demonstrate compliance with customer requirements for product quality and efficiency of the process.	<ul style="list-style-type: none"> <li>◆ How do you monitor manufacturing processes to demonstrate compliance with customer requirements for product quality and process efficiency?</li> </ul>
<b>8.2.2 Internal audit</b>		
8.2.2q1	The organization shall conduct internal audits at planned intervals to determine whether the quality management system 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 b) is effectively implemented and maintained.	<ul style="list-style-type: none"> <li>◆ Are internal audits being conducted at planned intervals?</li> <li>◆ Do they determine whether the QMS conforms to the requirements of ISO 9001 and to the other requirements established by Supplier? (Review records to demonstrate conformance)</li> <li>◆ Do they determine whether the QMS is effectively implemented and maintained? (Review records)</li> </ul>
8.2.2q2	An audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits.	<ul style="list-style-type: none"> <li>◆ Can you show me an audit plan that takes into consideration the importance of the processes and areas to be audited, and the results of previous audits?</li> </ul>
8.2.2q3	The audit criteria, scope, frequency and methods shall be defined.	<ul style="list-style-type: none"> <li>◆ Where are the audit criteria, scope, frequency and methods defined?</li> </ul>
8.2.2q4	Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.	<ul style="list-style-type: none"> <li>◆ Can you demonstrate that selection of auditors and the conduct of audits are objective and impartial, and that auditors don't audit their own work?</li> </ul>

8.2.2q5	The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) shall be defined in a documented procedure.	<ul style="list-style-type: none"> <li>◆ Can you show me your internal audit <b>procedure</b>?</li> <li>◆ Can you show me the <b>records</b> of internal QMS audits?</li> </ul>	
8.2.2q6	The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes.	<ul style="list-style-type: none"> <li>◆ Who ensures that actions are taken to eliminate detected nonconformities and their causes?</li> <li>◆ Are they being taken care of in a timely manner? (verify with records)</li> </ul>	
8.2.2q7	Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2).	<ul style="list-style-type: none"> <li>◆ What activities are done to verify the actions taken, and how are the verification results reported?</li> </ul>	
NOTE See ISO 10011-1, ISO 10011-2 and ISO 10011-3 for guidance.			
<b>8.2.2.1 Quality management system audit</b>			
T8.2.2.1q1	The organization shall audit its quality management system to verify compliance with this Technical Specification and any additional quality management system requirements.	<ul style="list-style-type: none"> <li>◆ Do you have audit records showing that the entire QMS is being audited?</li> </ul>	
<b>8.2.2.2 Manufacturing process audit</b>			
T8.2.2.2q1	The organization shall audit each manufacturing process to determine its effectiveness.	<ul style="list-style-type: none"> <li>◆ Do you have records showing that each manufacturing process is being audited to determine its effectiveness?</li> </ul>	
<b>8.2.2.3 Product audit</b>			
T8.2.2.3q1	The organization shall audit products at appropriate stages of production and delivery to verify conformity to all specified requirements, such as product dimensions, functionality, packaging and labelling, at a defined frequency.	<ul style="list-style-type: none"> <li>◆ Are there records showing that products are being audited at appropriate stages of production and delivery?</li> <li>◆ Do the audits verify conformity to <u>all</u> specified requirements?</li> </ul>	
<b>8.2.2.4 Internal audit plans</b>			
T8.2.2.4q1	Internal audits shall cover all quality management related processes, activities and shifts, and shall be scheduled according to an annual plan.	<ul style="list-style-type: none"> <li>◆ Can you show me an annual audit plan?</li> <li>◆ Does it show that audits cover all QMS processes, activities and shifts?</li> </ul>	

T8.2.2.4q2	When internal/external nonconformities or customer complaints occur, the audit frequency shall be appropriately increased.	♦ Is there evidence that audit frequency is increased due to nonconformances or customer complaints?	
	NOTE Specific checklists should be used for each audit.	Are specific checklists used for each audit?	
<b>8.2.2.5 Internal auditor qualification</b>			
T8.2.2.5q1	The organization shall have internal auditors who are qualified to audit the requirements of this Technical Specification (see 6.2.2.2).	♦ How do you determine competence of internal auditors to audit the requirements of TS 16949? (See 6.2.2.2 – also customer specific requirements).	
<b>8.2.3 Monitoring and measurement of processes</b>			
8.2.3q1	The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes.	♦ What methods are used to monitor and measure the QMS processes?	
8.2.3q2	These methods shall demonstrate the ability of the processes to achieve planned results.	♦ Can you show that they have achieved the desired results?	
8.2.3q3	When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product.	♦ When the desired results are not achieved, what actions are taken to ensure that the product meets requirements?	
<b>8.2.3.1 Monitoring and measurement of manufacturing processes</b>			
T8.2.3.1q1	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.	♦ Can you show me process studies that have been performed on new manufacturing processes?	
T8.2.3.1q2	The results of process studies shall be documented with specifications, where applicable, for means of production, measurement and test, and maintenance instructions.	♦ Can you show examples of results of process studies being documented with specifications? Are they used for instructions?	
T8.2.3.1q3	These documents shall include objectives for manufacturing process capability, reliability, maintainability and availability, as well as acceptance criteria.	♦ Do the documents include objectives for manufacturing process capability, reliability, maintainability, availability, and acceptance criteria?	
T8.2.3.1q4	The organization shall maintain manufacturing process capability or performance as specified by the customer part approval process requirements.	♦ Do records show that manufacturing process capability or original customer-approved performance is being maintained?	
T8.2.3.1q5	The organization shall ensure that the control plan and process flow diagram are implemented, including adherence to the specified <ul style="list-style-type: none"> <li>- measurement techniques,</li> <li>- sampling plans,</li> <li>- acceptance criteria, and</li> <li>- reaction plans when acceptance criteria are not met.</li> </ul>	♦ May I have a copy of the process flow diagram and control plan for ( <i>mfg. process</i> ) to review the production line with? (Review for adherence to specified requirements)	

T8.2.3.1q6	Significant process events, such as tool change or machine repair, shall be recorded.	<ul style="list-style-type: none"> <li>Can you show that process events like tool changes or machine repairs are being recorded (on control charts)?</li> </ul>	
T8.2.3.1q7	The organization shall initiate a reaction plan from the control plan for characteristics that are either not statistically capable or are unstable. These reaction plans shall include containment of product and 100 % inspection as appropriate.	<ul style="list-style-type: none"> <li>Can you show me that reaction plans have been followed for characteristics that are not statistically capable or are unstable?</li> <li>Do the reaction plans include containment of product and 100 % inspection as appropriate?</li> </ul>	
T8.2.3.1q8	A corrective action plan shall then be completed by the organization, indicating specific timing and assigned responsibilities to assure that the process becomes stable and capable.	<ul style="list-style-type: none"> <li>Have corrective action plan(s) been completed by the Supplier, with timing and responsibilities to assure that processes become stable and capable?</li> </ul>	
T8.2.3.1q9	The plans shall be reviewed with and approved by the customer when so required.	<ul style="list-style-type: none"> <li>When required, have CA plans been reviewed and approved by the customer?</li> </ul>	
T8.2.3.1q10	The organization shall maintain records of effective dates of process changes.	<ul style="list-style-type: none"> <li>Can you show me records of effective dates of process changes?</li> </ul>	
<b>8.2.4 Monitoring and measurement of product</b>			
8.2.4q1	The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met.	<ul style="list-style-type: none"> <li>What characteristics are checked to verify that product requirements have been met?</li> </ul>	
8.2.4q2	This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1).	<ul style="list-style-type: none"> <li>At what stages of the product realization process do monitoring and measuring activities take place?</li> </ul>	
8.2.4q3	Evidence of conformity with the acceptance criteria shall be maintained.	<ul style="list-style-type: none"> <li>How is evidence of conformity with acceptance criteria maintained?</li> </ul>	
8.2.4q4	Records shall indicate the person(s) authorizing release of product (see 4.2.4).	<ul style="list-style-type: none"> <li>Can you show me <b>records</b> that indicate who has authorized release of product to the next stage of the process?</li> </ul>	
8.2.4q5	Product release and service delivery 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.	<ul style="list-style-type: none"> <li>How do you ensure that product is not released until the all requirements have been met? If product must be released prior to this, how is it approved?</li> </ul>	
	NOTE When selecting product parameters to monitor compliance to specified internal and external requirements, the organization determines the types of product characteristics, leading to <ul style="list-style-type: none"> <li>the types of measurement,</li> <li>suitable measurement means, and</li> <li>the capability and skills required.</li> </ul>		

<b>8.2.4.1 Layout inspection and functional testing</b>		
T8.2.4.1q1	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.	<ul style="list-style-type: none"> <li>◆ Can you show me layout inspection and functional verification results?</li> <li>◆ Do they address applicable customer specifications and correlate with the control plan requirements?</li> <li>◆ Are results available for customer review?</li> </ul>
NOTE Layout inspection is the complete measurement of all product dimensions shown on the design records.		
<b>8.2.4.2 Appearance items</b>		
T8.2.4.2q1	For organizations manufacturing parts designated by the customer as “appearance items”, the organization shall provide <ul style="list-style-type: none"> <li>- appropriate resources including lighting for evaluation,</li> <li>- masters for colour, grain, gloss, metallic brilliance, texture, distinctness of image (DOI), as appropriate,</li> <li>- maintenance and control of appearance masters and evaluation equipment, and</li> <li>- verification that personnel making appearance evaluations are competent and qualified to do so.</li> </ul>	<ul style="list-style-type: none"> <li>◆ Do you provide parts designated by customer(s) as appearance items?</li> <li>◆ If so can you show that you have: <ul style="list-style-type: none"> <li>- appropriate resources including lighting for evaluation,</li> <li>- masters for color, grain, gloss, metallic brilliance, texture, distinctness of image (DOI), as appropriate,</li> <li>- maintenance and control of appearance masters and evaluation equipment, and</li> <li>- verification that personnel making appearance evaluations are competent and qualified to do so</li> </ul> </li> </ul>
<b>8.3 Control of nonconforming product</b>		
8.3q1	The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery.	<ul style="list-style-type: none"> <li>◆ How do you ensure that nonconforming products are identified and controlled to prevent unintended use or delivery? (Verify product throughout audit)</li> </ul>
8.3q2	The controls and related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure.	<ul style="list-style-type: none"> <li>◆ Can you show me your <b>documented procedure</b> defining the controls for dealing with nonconforming product?</li> <li>◆ Does it include related responsibilities and authorities?</li> </ul>
8.3q3	The organization shall deal with nonconforming product by one or more of the following ways: <ol style="list-style-type: none"> <li>a) by taking action to eliminate the detected nonconformity;</li> <li>c) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer;</li> <li>d) by taking action to preclude its original intended use or application.</li> </ol>	<ul style="list-style-type: none"> <li>◆ When you have nonconforming product, what methods do you use to deal with it?</li> </ul>

8.3q4	Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).	<ul style="list-style-type: none"> <li>◆ Can you show me <b>records</b> of nonconforming product and any actions taken?</li> <li>◆ Are there any <b>records</b> of concessions obtained?</li> </ul>	
8.3q5	When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.	<ul style="list-style-type: none"> <li>◆ When nonconforming product is corrected, can you demonstrate that it is re-verified to ensure it conforms to requirements?</li> </ul>	
8.3q6	When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity.	<ul style="list-style-type: none"> <li>◆ When nonconforming product is detected after shipment, what actions are taken, such as containment? (Verify corrective action records)</li> </ul>	
<b>8.3.1 Control of nonconforming product — Supplemental</b>			
T8.3.1q1	Product with unidentified or suspect status shall be classified as nonconforming product (see 7.5.3).	<ul style="list-style-type: none"> <li>◆ How are unidentified or suspect products treated?</li> </ul>	
<b>8.3.2 Control of reworked product</b>			
T8.3.2q1	Instructions for rework, including re-inspection requirements, shall be accessible to and utilized by the appropriate personnel.	<ul style="list-style-type: none"> <li>◆ Can you show me instructions for rework?</li> <li>◆ Do they include re-inspection requirements?</li> <li>◆ Are they accessible and utilized?</li> </ul>	
<b>8.3.3 Customer information</b>			
T8.3.3q1	Customers shall be informed promptly in the event that nonconforming product has been shipped.	<ul style="list-style-type: none"> <li>◆ Do you have evidence that customers are promptly notified if nonconforming product is shipped?</li> </ul>	
<b>8.3.4 Customer waiver</b>			
T8.3.4q1	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.	<ul style="list-style-type: none"> <li>◆ Can you show me records of customer approvals prior to processing, whenever deviations from approved product or manufacturing processes occur?</li> </ul>	
T8.3.4q2	The organization shall maintain a record of the expiration date or quantity authorized.	<ul style="list-style-type: none"> <li>◆ Do the records indicate expiration date and/or quantity authorized?</li> </ul>	
T8.3.4q3	The organization shall also ensure compliance with the original or superseding specifications and requirements when the authorization expires.	<ul style="list-style-type: none"> <li>◆ How do you ensure that original requirements are met when the authorization expires?</li> </ul>	
T8.3.4q4	Material shipped on an authorization shall be properly identified on each shipping container.	<ul style="list-style-type: none"> <li>◆ How do you identify material shipped on an authorization?</li> </ul>	

T8.3.4q5	This applies equally to purchased product. The organization shall agree with any requests from suppliers before submission to the customer.	<ul style="list-style-type: none"> <li>◆ Do you have records that this process is applied to purchased products also?</li> <li>◆ Do you review and agree with supplier deviation requests before submitting them to the customer for approval?</li> </ul>	
<b>8.4 Analysis of data</b>			
8.4q1	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 quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources.	<ul style="list-style-type: none"> <li>◆ What data is collected and analyzed to demonstrate the suitability and effectiveness of the QMS and to evaluate where continual improvement of its effectiveness can be made?</li> </ul>	
8.4q2a	The analysis of data shall provide information relating to <ul style="list-style-type: none"> <li>a) customer satisfaction (see 8.2.1),</li> <li>b) conformity to product requirements (see 7.2.1),</li> <li>c) characteristics and trends of processes and products including opportunities for preventive action, and</li> <li>d) suppliers.</li> </ul>	<ul style="list-style-type: none"> <li>◆ What information does this analysis provide relating to: <ul style="list-style-type: none"> <li>- customer satisfaction? (See 5.6)</li> <li>- conformity to product requirements? (See 5.6)</li> <li>- characteristics and trends of processes and products? (See 5.6)</li> <li>- suppliers? (See 7.4.1)</li> </ul> </li> </ul>	
<b>8.4.1 Analysis and use of data</b>			
T8.4.1q1	Trends in quality and operational performance shall be compared with progress toward objectives and lead to action to support the following: <ul style="list-style-type: none"> <li>- development of priorities for prompt solutions to customer-related problems;</li> <li>- determination of key customer-related trends and correlation for status review, decision-making and longer term planning;</li> <li>- an information system for the timely reporting of product information arising from usage.</li> </ul>	<ul style="list-style-type: none"> <li>◆ How do you compare trends in quality and operational performance with progress toward objectives?</li> <li>◆ Does the comparison lead to action to supporting the following? <ul style="list-style-type: none"> <li>- development of priorities for prompt solutions to customer-related problems;</li> <li>- determination of key customer-related trends and correlation for status review, decision-making and longer term planning;</li> <li>- an information system for the timely reporting of product information arising from usage.</li> </ul> </li> </ul>	
NOTE Data should be compared with those of competitors and/or appropriate benchmarks.			

	<b>8.5 Improvement</b>		
	<b>8.5.1 Continual improvement</b>		
8.5.1q1	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.	<ul style="list-style-type: none"> <li>◆ Can you demonstrate that Supplier's QMS effectiveness continually improves?</li> <li>◆ What tools do you use? (See 5.6, 8.2.2, 8.4, 8.5.2, 8.5.3)</li> </ul>	
	<b>8.5.1.1 Continual improvement of the Supplier</b>		
T8.5.1.1q1	The organization shall define a process for continual improvement (see examples in annex B of ISO 9004:2000).	<ul style="list-style-type: none"> <li>◆ Where has Supplier defined a process for continual improvement?</li> </ul>	
	<b>8.5.1.2 Manufacturing process improvement</b>		
T8.5.1.2q1	Manufacturing process improvement shall continually focus upon control and reduction of variation in product characteristics and manufacturing process parameters.	<ul style="list-style-type: none"> <li>◆ Can you show that CI efforts focus on control and reduction of variation in product and process characteristics (<u>after</u> capability, stability, and conformity)?</li> </ul>	
	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.		
	<b>8.5.2 Corrective action</b>	<b>8.5.2 Corrective action</b>	
8.5.2q1	The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence.	<ul style="list-style-type: none"> <li>◆ Do corrective actions records identify and address root cause(s)? (Do root causes match actions?)</li> </ul>	
8.5.2q2	Corrective actions shall be appropriate to the effects of the nonconformities encountered.	<ul style="list-style-type: none"> <li>◆ Are actions taken appropriate to the severity of the problem?</li> </ul>	
8.5.2q3	A documented procedure shall be established to define requirements for <ul style="list-style-type: none"> <li>a) reviewing nonconformities (including customer complaints),</li> <li>b) determining the causes of nonconformities,</li> <li>c) evaluating the need for action to ensure that nonconformities do not recur,</li> <li>d) determining and implementing action needed,</li> <li>e) records of the results of action taken (see 4.2.4), and</li> <li>f) reviewing corrective action taken.</li> </ul>	<ul style="list-style-type: none"> <li>◆ Can you show me a <b>documented procedure</b> defining requirements for each of the following? <ul style="list-style-type: none"> <li>a) reviewing nonconformities (including customer complaints)</li> <li>b) determining the causes of nonconformities</li> <li>c) evaluating the need for action to ensure that nonconformities do not recur</li> <li>d) determining and implementing action needed</li> <li>e) records of the results of action taken</li> <li>f) reviewing corrective action taken</li> </ul> </li> </ul>	

8.5.2q4	e) records of the results of action taken (see 4.2.4)	<ul style="list-style-type: none"> <li>Can you show me <b>records</b> of corrective actions taken?</li> </ul>	
<b>8.5.2.1 Problem solving</b>			
T8.5.2.1q1	The organization shall have a defined process for problem solving leading to root cause identification and elimination.	<ul style="list-style-type: none"> <li>Where is the process for problem solving defined?</li> <li>Does it lead to root cause identification and elimination? (Review records)</li> </ul>	
T8.5.2.1q2	If a customer-prescribed problem-solving format exists, the organization shall use the prescribed format.	<ul style="list-style-type: none"> <li>If one or more customer requires a specific problem-solving format can you show me records documented as required?</li> </ul>	
<b>8.5.2.2 Error-proofing</b>			
T8.5.2.2q1	The organization shall use error-proofing methods in their corrective action process.	<ul style="list-style-type: none"> <li>Can you show that error-proofing methods are used in the corrective action process?</li> </ul>	
<b>8.5.2.3 Corrective action impact</b>			
T8.5.2.3q1	The organization shall apply to other similar processes and products the corrective action, and controls implemented, to eliminate the cause of a nonconformity.	<ul style="list-style-type: none"> <li>Can you show that corrective actions are applied to other similar processes and products?</li> </ul>	
<b>8.5.2.4 Rejected product test/analysis</b>			
T8.5.2.4q1	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.	<ul style="list-style-type: none"> <li>Can you show me <b>records</b> of analysis of parts rejected by customer manufacturing plants, engineering facilities and dealerships?</li> <li>How long does the analysis take?</li> <li>Are records made available (to customers) upon request?</li> <li>Is the time consistent with the determination of root cause, corrective action and monitoring the effectiveness of implementation?</li> </ul>	
	NOTE Cycle time related to rejected product analysis should be consistent with the determination of root cause, corrective action and monitoring the effectiveness of implementation.		

8.5.3 Preventive action		8.5.3 Preventive action	
8.5.3q1	The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence.	<ul style="list-style-type: none"> <li>◆ How do you determine potential nonconformities to take action on?</li> <li>◆ Do preventive action records identify and address root cause(s)?</li> </ul>	
8.5.3q2	Preventive actions shall be appropriate to the effects of the potential problems.	<ul style="list-style-type: none"> <li>◆ Are actions taken appropriate to the severity of the problem?</li> </ul>	
8.5.3q3	A documented procedure shall be established to define requirements for <ol style="list-style-type: none"> <li>a) determining potential nonconformities and their causes,</li> <li>b) evaluating the need for action to prevent occurrence of nonconformities,</li> <li>c) determining and implementing action needed,</li> <li>d) records of results of action taken (see 4.2.4), and</li> <li>e) reviewing preventive action taken.</li> </ol>	<ul style="list-style-type: none"> <li>◆ Can you show me a <b>documented procedure</b> defining requirements for each of the following?               <ol style="list-style-type: none"> <li>a) determining potential nonconformities and their causes,</li> <li>b) evaluating the need for action to prevent occurrence of nonconformities,</li> <li>c) determining and implementing action needed,</li> <li>d) records of results of action taken (see 4.2.4), and</li> <li>e) reviewing preventive action taken.</li> </ol> </li> </ul>	
8.5.3q4	d) records of results of action taken (see 4.2.4)	<ul style="list-style-type: none"> <li>◆ Can you show me <b>records</b> of preventive actions taken?</li> </ul>	
<b>Annex A – Control plan</b>			
<b>A.1 Phases of the control plan</b>			
TAXA.1q1	The control plan shall cover three distinct phases as appropriate. <ol style="list-style-type: none"> <li>a) Prototype: a description of the dimensional measurements, material and performance tests that will occur during building of the prototype. The organization shall have a prototype control plan if required by the customer.</li> <li>b) Pre-launch: a description of the dimensional measurements, material and performance tests that occur after prototype and before full production. Pre-launch is defined as a production phase in the process of product realization which may be required after prototype build.</li> <li>c) Production: documentation of product/process characteristics, process controls, tests and measurement systems that occur during mass production.</li> </ol>	<ul style="list-style-type: none"> <li>◆ Can you show me control plans that cover prototype, pre-launch, and production?</li> <li>◆ If all three types are not used, does Supplier's scope of certification justify their absence?</li> </ul>	
TAXA.1q2	Each part shall have a control plan but, in many cases, family control plans may cover a number of similar parts produced using a common process.	<ul style="list-style-type: none"> <li>◆ Can you show me the control plan for (<i>part x</i>)?</li> <li>◆ Do you have family control plans?</li> </ul> <p>(If so, are the only differences in the parts dimensional – not form, application or function?)</p>	

TAXA.1q3	Control plans are an output of the quality plan.	◆ Are control plans outputs of the quality plan?	
<b>A.2 Elements of the control plan</b>			
TAXA.1q1	<p>The organization shall develop a control plan that includes, as a minimum, the following contents.</p> <p>a) General data</p> <ul style="list-style-type: none"> <li>- control plan number,</li> <li>- issue date, and revision date, if any,</li> <li>- customer information (see customer requirements),</li> <li>- organization's name/site designation,</li> <li>- part number(s),</li> <li>- part name/description,</li> <li>- engineering change level,</li> <li>- phase covered (prototype, pre-launch, production),</li> <li>- key contact,</li> <li>- part/process step number,</li> <li>- process name/operation description.</li> </ul> <p>b) Product control</p> <ul style="list-style-type: none"> <li>- product-related special characteristics,</li> <li>- other characteristics for control (number, product or process),</li> <li>- specification/tolerance.</li> </ul> <p>c) Process control</p> <ul style="list-style-type: none"> <li>- process parameters,</li> <li>- process-related special characteristics,</li> <li>- machines, jigs, fixtures, tools for manufacturing.</li> </ul> <p>d) Methods</p> <ul style="list-style-type: none"> <li>- evaluation measurement technique,</li> <li>- error-proofing,</li> <li>- sample size and frequency,</li> <li>- control method.</li> </ul> <p>e) Reaction plan and corrective actions</p> <ul style="list-style-type: none"> <li>- reaction plan (include or reference),</li> <li>- corrective action.</li> </ul>	<p>◆ Do the control plans include the following minimum contents:</p> <p>a) General data</p> <ul style="list-style-type: none"> <li>- control plan number,</li> <li>- issue date, and revision date, if any,</li> <li>- customer information (see customer requirements),</li> <li>- Supplier's name/site designation,</li> <li>- part number(s),</li> <li>- part name/description,</li> <li>- engineering change level,</li> <li>- phase covered (prototype, pre-launch, production),</li> <li>- key contact,</li> <li>- part/process step number,</li> <li>- process name/operation description.</li> </ul> <p>b) Product control</p> <ul style="list-style-type: none"> <li>- product-related special characteristics,</li> <li>- other characteristics for control (number, product or process),</li> <li>- specification/tolerance.</li> </ul> <p>c) Process control</p> <ul style="list-style-type: none"> <li>- process parameters,</li> <li>- process-related special characteristics,</li> <li>- machines, jigs, fixtures, tools for manufacturing.</li> </ul> <p>d) Methods</p> <ul style="list-style-type: none"> <li>- evaluation measurement technique,</li> <li>- error-proofing,</li> <li>- sample size and frequency,</li> <li>- control method.</li> </ul> <p>e) Reaction plan and corrective actions</p> <ul style="list-style-type: none"> <li>- reaction plan (include or reference),</li> <li>- corrective action.</li> </ul>	

