

Supplier:	Address:
Phone:	Fax:
Prime Contact/Title:	e-mail address
Sales Contact/Title:	e-mail address
Quality Contact/Title:	e-mail address

1. Type of Business: _____	
a) Number of years in business? _____	
b) Company is <input type="checkbox"/> Publicly held <input type="checkbox"/> Privately owned	
c) Disadvantaged Business(Only for Business operating in the USA): Small <input type="checkbox"/> , Small Women Owned <input type="checkbox"/> , Small Minority Owned <input type="checkbox"/> , Small Disabled Veteran Owned <input type="checkbox"/> Small Disabled Owned <input type="checkbox"/> , HUBzone Supplier <input type="checkbox"/> , SBA certified/ registered <input type="checkbox"/> . List other certifications under comments.	
d) This facility, size (ft <sup>2</sup> ) _____	f) Major customers _____
g) Commodities supplied? _____	
Supplier Changes/comments: _____	

2. Headcount breakdown by group:			
R&D		Purchasing	
Engineering		Production Control	
Manufacturing, Direct		Quality Assurance	
Manufacturing, Indirect		Facilities	

To be completed by RubberCraft Inc. Review Date: \_\_\_\_\_

Supplier Status:  Approved  Not Approved  Pending

Comments: \_\_\_\_\_

Reviewed by: \_\_\_\_\_ Next Review Date: \_\_\_\_\_

Signature: \_\_\_\_\_

		YES	NO	N/A
<b>3.0</b>	<b>CERTIFICATIONS</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Are you certified to an ISO or AS organization? If yes, indicate applicable series: <input type="checkbox"/> ISO 9001/2008 <input type="checkbox"/> AS9100 <input type="checkbox"/> D1-9000 <input type="checkbox"/> Mil-I-45208 <input type="checkbox"/> NADCAP <input type="checkbox"/> Other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Certificate# : _____ Date of certification: _____			
	Is the certification issued by an accredited registrar?			
	Registrar's name: _____			
	<b>NOTE:</b> If ISO9000/AS9100 certified by accredited registrar and in good standing (current), NO NEED to proceed. Complete this section and the Cover Sheet <b>ONLY</b> and return them with a copy of your registration certification via email or fax.			

QUALITY MANAGEMENT SYSTEM		YES	NO	NA
<b>4</b>	<b>CONTEXT OF THE ORGANIZATION</b>			
<b>4.1</b>	<b>Understanding the organization and its context</b>			
	Does your company determine the external and internal issues that are relevant to your purpose and strategic direction?			
	Do you consider the relevant issues that affect your ability to achieve the intended results of the Quality Management System (QMS)?			
	Does your company monitor and review the information related to the external and internal issues?			
<b>4.2</b>	<b>Understanding the needs and expectations of interested parties</b>			
	With consideration given to their impact or potential impact on your company's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, do you determine:			
	<ul style="list-style-type: none"> <li>The interested parties that are relevant to the QMS?</li> </ul>			
	<ul style="list-style-type: none"> <li>The requirements of these interested parties that are relevant to the QMS?</li> </ul>			
	Does your company monitor and review the information about these interested parties and their relevant requirements?			
<b>4.3</b>	<b>Determining the scope of the quality management system</b>			
	To establish the scope of the QMS, does your company determine the boundaries and applicability of the QMS?			
	When determining the scope of the QMS, do you consider the:			
	<ul style="list-style-type: none"> <li>External and internal issues (per above clause 4.1)?</li> </ul>			
	<ul style="list-style-type: none"> <li>Requirements of relevant interested parties (per above clause 4.2)?</li> </ul>			
	<ul style="list-style-type: none"> <li>The products and services of your company?</li> </ul>			
	When a requirement of AS 9100 D can be applied, is the requirement applied by your company?			
	When requirements cannot be applied, and in order to claim conformity to AS 9100 D, how do you determine if your ability or responsibility to ensure conformity of products and services are not affected?			
	Is the scope of the QMS available and maintained as documented information?			
	Does the scope state the products and services covered by the QMS?			
	Does your company provide justification for any instance where a requirement of the standard cannot be applied?			
<b>4.4</b>	<b>Quality management system and its processes</b>			
4.4.1	As required by the standard, do you establish, document, implement, maintain and continually improve the QMS?			
	Does the QMS also address customer and applicable statutory and regulatory quality management system requirements?			
	Does your company determine the processes needed for the QMS, their interactions and applications throughout your company?			
	That is, for the QMS processes do you determine the:			
	<ul style="list-style-type: none"> <li>Inputs required and the outputs expected from the processes?</li> </ul>			
	<ul style="list-style-type: none"> <li>Sequence and interaction of the processes?</li> </ul>			
	<ul style="list-style-type: none"> <li>Criteria, methods, including measurements and related performance indicators needed to ensure the effective operation, and control of the processes?</li> </ul>			
	<ul style="list-style-type: none"> <li>Resources needed and ensure they are available?</li> </ul>			
	<ul style="list-style-type: none"> <li>Assignment of the responsibilities and authorities for these processes?</li> </ul>			
	<ul style="list-style-type: none"> <li>Risks and opportunities (per 6.1), and plans to implement the appropriate actions to address them?</li> </ul>			

	<ul style="list-style-type: none"> <li>• Methods for monitoring, measuring, and evaluation of processes and, if needed, the changes to processes to ensure that they achieve intended results?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Opportunities for improvement of the processes and the QMS?</li> </ul>			
	Does your company maintain the necessary documented information to support the operation of processes?			
4.4.2	Does your company maintain and retain the necessary documented information to provide the confidence that the processes are being carried out as planned?			
	Does the documented information include:			
	<ul style="list-style-type: none"> <li>• General description of relevant interested parties (see above clause 4.2 a)?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Scope of the QMS, including boundaries and applicability (see above clause 4.3)?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Description of the processes needed for the QMS and their application throughout the organization?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Sequence and interaction of the processes?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Assignment of the responsibilities and authorities for these processes?</li> </ul>			
	Note: The above description of the QMS can be compiled in a single source of documented information and referred to as a quality manual.			
<b>5</b>	<b>LEADERSHIP</b>			
<b>5.1.1</b>	<b>General</b>			
	Does top management demonstrate leadership and commitment with respect to the QMS by:			
	<ul style="list-style-type: none"> <li>• Taking accountability for the effectiveness of the QMS?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Ensuring that the quality policy and quality objectives are established for the QMS and are compatible with the strategic direction and the context of the organization?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Ensuring that the quality policy is communicated, understood and applied within the company?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Ensuring the integration of the QMS requirements into the company's business processes?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Promoting the use of both the process approach and risk-based thinking?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Ensuring that the resources needed for the QMS are available?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Communicating the importance of effective quality management and of conforming to the QMS requirements?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Ensuring that the QMS achieves its intended results?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Engaging, directing and supporting persons to contribute to the effectiveness of the QMS?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Promoting continual improvement?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility?</li> </ul>			
<b>5.1.2</b>	<b>Customer focus</b>			
	Does top management demonstrate leadership and commitment with respect to customer focus by ensuring that the:			
	<ul style="list-style-type: none"> <li>• Customer requirements and applicable statutory and regulatory requirements are determined and met?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Focus on consistently providing products and services that meet customer and applicable statutory &amp; regulatory requirements are maintained?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Focus on enhancing customer satisfaction is maintained?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Product and service conformity and on-time delivery performance are measured and appropriate action is taken if planned results are not, or will not be, achieved?</li> </ul>			
<b>5.2</b>	<b>Policy</b>			

<b>5.2.1</b>	<b>Developing the quality policy</b>			
	Has your top management established, implemented and maintained a quality policy that:			
	<ul style="list-style-type: none"> <li>Is appropriate to the purpose and context of the organization?</li> </ul>			
	<ul style="list-style-type: none"> <li>Provides a framework for setting and reviewing quality objectives?</li> </ul>			
	<ul style="list-style-type: none"> <li>Includes a commitment to satisfy applicable requirements?</li> </ul>			
	<ul style="list-style-type: none"> <li>Includes a commitment to continual improvement of the QMS?</li> </ul>			
<b>5.2.2</b>	<b>Communicating the quality policy</b>			
	Is your quality policy:			
	<ul style="list-style-type: none"> <li>Communicated, understood and applied within your company?</li> </ul>			
	<ul style="list-style-type: none"> <li>Available as documented information?</li> </ul>			
	<ul style="list-style-type: none"> <li>Available to relevant interested parties?</li> </ul>			
<b>5.3</b>	<b>Organizational roles, responsibilities and authorities</b>			
	Does the top management ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the company?			
	Does top management assign the responsibility and authority for:			
	<ul style="list-style-type: none"> <li>Ensuring that the QMS conforms to the requirements of AS 9100 D standards?</li> </ul>			
	<ul style="list-style-type: none"> <li>Ensuring that the processes are delivering their intended outputs?</li> </ul>			
	<ul style="list-style-type: none"> <li>Reporting on the performance of the QMS on opportunities for improvement and for reporting to top management?</li> </ul>			
	<ul style="list-style-type: none"> <li>Ensuring the promotion of customer focus throughout your company?</li> </ul>			
	<ul style="list-style-type: none"> <li>Ensuring that the integrity of the QMS is maintained when changes to the QMS are planned and implemented?</li> </ul>			
	Has the top management appointed a specific member of management, identified as the management representative, who will have the responsibility and authority for oversight of the above requirements?			
	Does the management representative have the organizational freedom and unrestricted access to top management to resolve quality management issues? NOTE: The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.			
<b>6</b>	<b>PLANNING</b>			
<b>6.1</b>	<b>Actions to address risks and opportunities</b>			
6.1.1	When planning for the QMS, does your company consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed?			
	Is this performed to:			
	<ul style="list-style-type: none"> <li>Give assurance that the QMS can achieve its intended results?</li> </ul>			
	<ul style="list-style-type: none"> <li>Enhance desirable effects?</li> </ul>			
	<ul style="list-style-type: none"> <li>Prevent, or reduce undesired effects?</li> </ul>			
	<ul style="list-style-type: none"> <li>Achieve improvement?</li> </ul>			
6.1.2	Does the company plan:			
	<ul style="list-style-type: none"> <li>Actions to address these risks and opportunities?</li> </ul>			
	<ul style="list-style-type: none"> <li>How to integrate, implement the actions into the QMS processes and evaluate the effectiveness of these actions?</li> </ul>			
	Do you take actions to address risks and opportunities that are proportionate to the potential impact on the conformity of products and services?			
<b>6.2</b>	<b>Quality objectives and planning to achieve them</b>			

6.2.1	Does your company establish quality objectives at relevant functions, levels and processes?			
	Do you consider the following:			
	<ul style="list-style-type: none"> <li>Are the quality objectives consistent with the quality policy?</li> </ul>			
	<ul style="list-style-type: none"> <li>Are the objectives measurable?</li> </ul>			
	<ul style="list-style-type: none"> <li>Do they consider applicable requirements?</li> </ul>			
	<ul style="list-style-type: none"> <li>Are they relevant to conformity of products and services and the enhancement of customer satisfaction?</li> </ul>			
	<ul style="list-style-type: none"> <li>Are they monitored, communicated, and updated as required?</li> </ul>			
	<ul style="list-style-type: none"> <li>Do you retain documented information for the quality objectives?</li> </ul>			
6.2.2	When planning how to achieve the quality objectives, does your company determine:			
	<ul style="list-style-type: none"> <li>What will be done?</li> </ul>			
	<ul style="list-style-type: none"> <li>What resources will be required?</li> </ul>			
	<ul style="list-style-type: none"> <li>Who will be responsible?</li> </ul>			
	<ul style="list-style-type: none"> <li>When it will be completed?</li> </ul>			
	<ul style="list-style-type: none"> <li>How the results will be evaluated?</li> </ul>			
<b>6.3</b>	<b>Planning of changes</b>			
	When your company determines the need for changes to the QMS, do you carry out the changes in a planned manner?			
	Do you consider the:			
	<ul style="list-style-type: none"> <li>Purpose of the change and any of its potential consequences?</li> </ul>			
	<ul style="list-style-type: none"> <li>Integrity of the QMS?</li> </ul>			
	<ul style="list-style-type: none"> <li>Availability of resources?</li> </ul>			
	<ul style="list-style-type: none"> <li>Allocation or reallocation of responsibilities and authorities?</li> </ul>			
<b>7</b>	<b>SUPPORT</b>			
<b>7.1</b>	<b>Resources</b>			
<b>7.1.1</b>	<b>General</b>			
	Does your company determine and provide the resources needed to establish, implement, maintain and continually improve the QMS?			
	Do you consider:			
	<ul style="list-style-type: none"> <li>The capabilities of, and constraints on, existing internal resources?</li> </ul>			
	<ul style="list-style-type: none"> <li>What needs to be obtained from external providers?</li> </ul>			
<b>7.1.2</b>	<b>People</b>			
	To ensure that your company can consistently meet customer and applicable statutory and regulatory requirements, do you determine and provide the persons necessary for the effective operation of the QMS, including the processes needed?			
<b>7.1.3</b>	<b>Infrastructure</b>			
	To achieve conformity of products and services, does your company determine, provide and maintain the infrastructure for the operation of the processes?			
	Is the following considered as infrastructure:			
	<ul style="list-style-type: none"> <li>Buildings and associated utilities?</li> </ul>			
	<ul style="list-style-type: none"> <li>Equipment including hardware and software?</li> </ul>			
	<ul style="list-style-type: none"> <li>Transportation?</li> </ul>			
	<ul style="list-style-type: none"> <li>Information and communication technology?</li> </ul>			

<b>7.1.4</b>	<b>Environment for the operation of processes</b>			
	Does your company determine, provide and maintain the environment necessary for the operation of the processes and to achieve conformity of products and services?			
	For the environment for the operation of processes, do you consider the applicable physical, social, and psychological factors?			
<b>7.1.5</b>	<b>Monitoring and measuring resources</b>			
<b>7.1.5.1</b>	<b>General</b>			
	When measuring or monitoring is used for evidence of conformity of products and services, does your company determine the resources needed to ensure valid and reliable monitoring and measuring results?			
	Do you ensure that resources provided are:			
	<ul style="list-style-type: none"> <li>Suitable for the type of monitoring and measurement activities being undertaken?</li> </ul>			
	<ul style="list-style-type: none"> <li>Maintained to ensure their continued fitness for their purpose?</li> </ul>			
	What documented information does your company retain as evidence of fitness for purpose of monitoring and measurement resources?			
<b>7.1.5.2</b>	<b>Measurement traceability</b>			
	When measurement traceability is a requirement, such as with a statutory or regulatory requirement, a customer or relevant interested party expectation, or considered by your company to be an essential part of providing confidence in the validity of measurement results, do you manage the measuring instruments as follows:			
	<ul style="list-style-type: none"> <li>Verified or calibrated at specified intervals or prior to use against measurement standards traceable to international or national measurement standards.</li> </ul>			
	<ul style="list-style-type: none"> <li>Where no such standards exist, do you retain documented information for the basis used for calibration or verification?</li> </ul>			
	<ul style="list-style-type: none"> <li>Identified in order to determine their calibration status?</li> </ul>			
	<ul style="list-style-type: none"> <li>Safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results?</li> </ul>			
	Have you established, implemented, and maintained a process for the recall of monitoring and measuring equipment requiring calibration or verification?			
	Is a register of the monitoring and measuring equipment maintained?			
	Does the register include the equipment type, unique identification, location, and the calibration or verification method, frequency, and acceptance criteria?			
	Is calibration or verification of monitoring and measuring equipment carried out under suitable environmental conditions?			
	When an instrument is found to be out of calibration, does your company determine if the validity of previous measurement results has been adversely affected?			
	Do you take corrective action in such cases?			
<b>7.1.6</b>	<b>Organizational knowledge</b>			
	Does your company determine the knowledge necessary for the operation of the processes and to achieve conformity of products and services?			
	Is this knowledge maintained and made available as necessary?			
	When addressing changing needs and trends, does your company consider its current knowledge and determine how to acquire or access the necessary additional knowledge?			
	For organizational knowledge, do you consider information such as intellectual property and lessons learned?			
	To obtain needed knowledge, do you consider:			
	<ul style="list-style-type: none"> <li>Internal sources, such as learning from failures and successful projects, capturing undocumented knowledge and experience of topical experts within the company?</li> </ul>			

	<ul style="list-style-type: none"> <li>External sources, such as standards, academia, conferences, gathering knowledge with customers or providers?</li> </ul>			
<b>7.2</b>	<b>Competence</b>			
	Does your company determine the necessary competence of the personnel doing work that affects quality performance?			
	Do you ensure that these persons are competent based on appropriate education, training, or experience?			
	Does your company take actions to acquire the necessary competence?			
	Do you consider, for example, the provision of training to, the mentoring of, or the re assignment of employees, or the hiring or contracting of competent persons, as relevant actions?			
	Do you evaluate the effectiveness of the actions taken?			
	Does your company retain documented information as evidence of competence?			
	Is consideration given to the periodic review of the needed competence?			
<b>7.3</b>	<b>Awareness</b>			
	Does your company ensure that personnel performing work under your control are aware of:			
	<ul style="list-style-type: none"> <li>The quality policy and the relevant quality objectives?</li> </ul>			
	<ul style="list-style-type: none"> <li>Their contribution to the effectiveness of the QMS, including the benefits of improved quality performance?</li> </ul>			
	<ul style="list-style-type: none"> <li>The implications of not conforming to the QMS requirements?</li> </ul>			
	<ul style="list-style-type: none"> <li>Relevant QMS documented information and changes to it?</li> </ul>			
	<ul style="list-style-type: none"> <li>Their contribution to product or service conformity?</li> </ul>			
	<ul style="list-style-type: none"> <li>Their contribution to product safety?</li> </ul>			
	<ul style="list-style-type: none"> <li>The importance of ethical behavior?</li> </ul>			
<b>7.4</b>	<b>Communication</b>			
	Does your company determine the internal and external communications relevant to the QMS that include:			
	<ul style="list-style-type: none"> <li>On what it will communicate?</li> </ul>			
	<ul style="list-style-type: none"> <li>When to communicate?</li> </ul>			
	<ul style="list-style-type: none"> <li>With whom to communicate?</li> </ul>			
	<ul style="list-style-type: none"> <li>How to communicate?</li> </ul>			
	Note: Communication include internal and external feedback relevant to the QMS			
<b>7.5</b>	<b>Documented information</b>			
<b>7.5.1</b>	<b>General</b>			
	Does your QMS include:			
	<ul style="list-style-type: none"> <li>Documented information required by the AS 9100 D standard?</li> </ul>			
	<ul style="list-style-type: none"> <li>Documented information determined by your company as necessary for an effective QMS?</li> </ul>			
	For the documented information of the QMS, do you consider the:			
	<ul style="list-style-type: none"> <li>Size of your company and the type of activities, processes, products and services?</li> </ul>			
	<ul style="list-style-type: none"> <li>Complexity of processes and their interactions?</li> </ul>			
	<ul style="list-style-type: none"> <li>Competence of personnel?</li> </ul>			
<b>7.5.2</b>	<b>Creating and updating</b>			
	When creating and updating documented information, does the company ensure:			



	Identification and description, such as a title, date, author, or reference number?			
	<ul style="list-style-type: none"> <li>Format, such as language, software version, graphics and media, such as paper, electronic?</li> </ul>			
	<ul style="list-style-type: none"> <li>Review and approval for suitability and adequacy?</li> </ul>			
	NOTE: Approval implies authorized persons and approval methods are identified for the relevant types of documented information, as determined by the organization.			
<b>7.5.3</b>	<b>Control of documented information</b>			
7.5.3.1	Do you control the documented information required by the QMS and by the AS 9100 D standard to ensure that it is:			
	<ul style="list-style-type: none"> <li>Available and suitable for use, where and when it is needed?</li> </ul>			
	<ul style="list-style-type: none"> <li>Adequately protected, such as from loss of confidentiality, improper use, or loss of integrity?</li> </ul>			
7.5.3.2	For the control of documented information, does your company address the following:			
	<ul style="list-style-type: none"> <li>Distribution, access, retrieval and use?</li> </ul>			
	<ul style="list-style-type: none"> <li>Storage and preservation, including preservation of legibility?</li> </ul>			
	<ul style="list-style-type: none"> <li>Control of changes such as version control?</li> </ul>			
	<ul style="list-style-type: none"> <li>Retention and disposition?</li> </ul>			
	<ul style="list-style-type: none"> <li>Prevention of the unintended use of obsolete documented information by removal or by application of suitable identification or controls if kept for any purpose?</li> </ul>			
	Does your company identify and control the documented information from external origin and determined by your company to be necessary for the planning and operation of the QMS?			
	Is documented information retained as evidence of conformity protected from unintended alterations?			
	When documented information is managed electronically, are data protection processes identified?			
	Do you consider protection from loss, unauthorized changes, unintended alteration, corruption, & physical damage?			
	NOTE: Access can imply a decision regarding the permission to view the documented information only, or the permission and authority to view and change the documented information.			
<b>8</b>	<b>OPERATION</b>			
<b>8.1</b>	<b>Operational planning and control</b>			
	Does your company plan, implement and control the processes needed to meet requirements for the provision of products and services and to implement the actions to address risks and opportunities by:			
	<ul style="list-style-type: none"> <li>Determining requirements for the product and services?</li> </ul>			
	When determining the requirements for products and services do you consider:			
	<ul style="list-style-type: none"> <li>Personal and product safety?</li> <li>Producibility and inspectability?</li> <li>Reliability, availability, and maintainability?</li> <li>Suitability of parts and materials used in the product?</li> <li>Selection and development of embedded software?</li> <li>Product obsolescence?</li> <li>Prevention, detection, and removal of foreign objects?</li> <li>Handling, packaging, and preservation?</li> <li>Recycling or final disposal of the product at the end of its life?</li> </ul>			

	<ul style="list-style-type: none"> <li>Establishing criteria for the processes and for the acceptance of products and services?</li> </ul>			
	<p>Depending on the nature of the product and specified requirements, are statistical techniques used to support:</p> <ul style="list-style-type: none"> <li>Design verification, such as reliability, maintainability, product safety?</li> <li>Process control?</li> <li>Selection and verification of key characteristics?</li> <li>Process capability measurements?</li> <li>Statistical process control?</li> <li>Design of experiments?</li> <li>Verification?</li> <li>Failure mode, effects, and criticality analysis?</li> </ul>			
	<ul style="list-style-type: none"> <li>Determining the resources needed to achieve conformity to product and service requirements?</li> </ul>			
	<ul style="list-style-type: none"> <li>Determining the resources needed to meet on-time delivery of products and services?</li> </ul>			
	<ul style="list-style-type: none"> <li>Implementing control of the processes in accordance with the criteria?</li> </ul>			
	<ul style="list-style-type: none"> <li>Retaining documented information to provide the confidence that the processes have been carried out as planned and to demonstrate conformity of products and services to requirements?</li> </ul>			
	<ul style="list-style-type: none"> <li>Determining the processes and controls required to manage critical items, including production process controls for identified key characteristics?</li> </ul>			
	<ul style="list-style-type: none"> <li>Engaging representatives of affected organization functions for operational planning and control?</li> </ul>			
	<ul style="list-style-type: none"> <li>Determining the process and resources to support the use and maintenance of the products and services?</li> </ul>			
	<ul style="list-style-type: none"> <li>Determining the products and services to be obtained from external providers?</li> </ul>			
	<ul style="list-style-type: none"> <li>Establishing the controls needed to prevent the delivery of nonconforming products and services to the customer?</li> </ul>			
	<p>Within schedule and resource constraints, have you planned and managed product and service provision in a structured and controlled manner including scheduled events performed in a planned sequence to meet requirements at acceptable risk?</p>			
	<p>Do you provide the output of the planning in a format that is suitable to your operations?</p> <p>NOTE: As an output of this planning, documented information specifying the processes of the QMS and the resources to be applied to a specific product, service, project, or contract can be referred to as a quality plan.</p>			
	<p>How do you control planned changes and review the consequences of unintended changes?</p>			
	<ul style="list-style-type: none"> <li>When required, do you take action to mitigate any adverse effects?</li> </ul>			
	<p>Does your company ensure that outsourced processes are controlled in accordance with clause 8.4)?</p>			
	<p>Have you established, implemented, and maintained a process to plan and control the temporary or permanent transfer of work, to ensure the continuing conformity of the work to requirements?</p>			
	<p>How do you ensure that work transfer impacts and risks are managed?</p>			
	<p>For the control of work transfer from the organization to an external provider, or from an external provider to another external provider, are controls applied to external providers, per 8.4?</p>			
	<p>For the control of work transfer from one organization facility to another, or from an external provider to the organization, are controls applied to production and service provision, per 8.5?</p>			

8.1.1 Operational Risk Management				
	Have you planned, implemented, and controlled a process for managing operational risks to the achievement of applicable requirements associated with the operational processes needed for the provision of products and services?			
	Does this process include:			
	<ul style="list-style-type: none"> <li>• Assignment of responsibilities for operational risk management?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Definition of risk assessment criteria, such as likelihood, consequences, risk acceptance?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Identification, assessment, and communication of risks throughout operations?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Identification, implementation, and management of actions to mitigate risks that exceed the defined risk acceptance criteria?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Acceptance of risks remaining after implementation of mitigating actions?</li> </ul>			
8.1.2 Configuration Management				
	Have you planned, implemented, and controlled a process for configuration management as appropriate to the products and services in order to ensure the identification and control of physical and functional attributes throughout the product lifecycle?			
	Does this process:			
	<ul style="list-style-type: none"> <li>• Control product identity and traceability to requirements, including the implementation of identified changes?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Ensure that the documented information, such as requirements, design, verification, validation &amp; acceptance documentation is consistent with the actual attributes of the products and services?</li> </ul>			
8.1.3 Product Safety				
	Have you planned, implemented, and controlled the processes needed to assure product safety during the entire product life cycle?			
	Do the processes include:			
	<ul style="list-style-type: none"> <li>• Assessment of hazards and management of associated risks (see also 8.1.1)?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Management of safety critical items?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Analysis and reporting of occurred events affecting safety?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Communication of these events and training of persons?</li> </ul>			
8.1.4 Prevention of Counterfeit Parts				
	Have you planned, implemented, and controlled processes for the prevention of counterfeit or suspect counterfeit part use and their inclusion in product delivered to the customer?			
	Do the processes consider:			
	<ul style="list-style-type: none"> <li>• Training in the awareness and prevention of counterfeit parts?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Application of a parts obsolescence monitoring program?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Requirements for assuring traceability of parts and components to their original authorized manufacturers?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Controls for acquiring externally provided product from original manufacturers, authorized distributors, or other approved sources?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Verification and test methods to detect counterfeit parts?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Monitoring of counterfeit parts reporting from external sources?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Quarantine and reporting of suspect or detected counterfeit parts?</li> </ul>			
8.2 Requirements for products and services				
8.2.1 Customer communication				

	Does your company establish the processes for communicating with customers in relation to:			
	<ul style="list-style-type: none"> <li>Information relating to products and services?</li> </ul>			
	<ul style="list-style-type: none"> <li>Enquiries, contracts or order handling, including changes?</li> </ul>			
	<ul style="list-style-type: none"> <li>Obtaining customer feedback, including customer complaints (9.1.2)?</li> </ul>			
	<ul style="list-style-type: none"> <li>The handling or treatment of customer property, when applicable (per 8.5.3)?</li> </ul>			
	<ul style="list-style-type: none"> <li>Specific requirements for contingency actions, when relevant?</li> </ul>			
<b>8.2.2</b>	<b>Determining the requirements related to products and services</b>			
	Does your company establish, implement and maintain a process to determine the requirements for the products and services to be offered to customers?			
	Do you ensure that product and service requirements (including those considered necessary by your company), and applicable statutory and regulatory requirements, are defined?			
	Do you ensure that your company has the ability to meet the defined requirements and can meet the claims for the products and services offered?			
	Do you ensure that your company has determined any special requirements for the products and services?			
	Do you ensure that operational risks such as new technology, ability and capacity to provide, short delivery time frame are identified?			
<b>8.2.3</b>	<b>Review of requirements related to products and services</b>			
8.2.3.1	To ensure that you can meet requirements, do you conduct the review prior to your company's commitment to supply products and services to the customer?			
	Does your company review:			
	<ul style="list-style-type: none"> <li>Requirements specified by the customer, including the requirements for delivery and post-delivery activities (8.5.5)?</li> </ul>			
	<ul style="list-style-type: none"> <li>Requirements not stated by the customer, but necessary for the customers' specified or intended use, when known?</li> </ul>			
	<ul style="list-style-type: none"> <li>Requirements specified by your company?</li> </ul>			
	<ul style="list-style-type: none"> <li>Additional statutory and regulatory requirements applicable to the products and services?</li> </ul>			
	<ul style="list-style-type: none"> <li>Contract or order requirements differing from those previously expressed?</li> </ul>			
	Do you coordinate the review with relevant functions in the company?			
	If the review determines that some customer requirements cannot be met or can only partially be met, do you negotiate a mutually acceptable requirement with the customer?			
	Does the review ensure that contract or order requirements differing from those previously defined are resolved?			
	When the customer does not provide a documented statement of their requirements, do you confirm the customer requirements before accepting an order?			
8.2.3.2	Does your company retain documented information describing the results of the review, including any new or changed requirements for the products and services?			
<b>8.2.4</b>	<b>Changes to requirements for products and services</b>			
	When requirements for products and services are changed, does your company ensure that relevant documented information is amended?			
	Do you make the relevant personnel aware of the changed requirements?			
<b>8.3</b>	<b>Design and development of products and services</b>			
<b>8.3.1</b>	<b>General</b>			
	Has your company established, implemented, and maintained a design and development process to ensure the subsequent provision of products and services?			
<b>8.3.2</b>	<b>Design and development planning</b>			

	In determining the stages and controls for design and development, does your company consider the:			
	<ul style="list-style-type: none"> <li>Nature, duration and complexity of the design and development activities?</li> </ul>			
	<ul style="list-style-type: none"> <li>Requirements that specify process stages, including applicable design and development reviews?</li> </ul>			
	<ul style="list-style-type: none"> <li>Required design and development verification and validation?</li> </ul>			
	<ul style="list-style-type: none"> <li>Responsibilities and authorities involved in the design and development process?</li> </ul>			
	<ul style="list-style-type: none"> <li>Internal and external resources needed for the design and development process?</li> </ul>			
	<ul style="list-style-type: none"> <li>Need to control interfaces between individuals and parties involved in the design and development process?</li> </ul>			
	<ul style="list-style-type: none"> <li>Need for involvement of customer and user groups in the design and development process?</li> </ul>			
	<ul style="list-style-type: none"> <li>Requirements for subsequent provision of products and services?</li> </ul>			
	<ul style="list-style-type: none"> <li>Level of control expected by customers or other interested parties?</li> </ul>			
	<ul style="list-style-type: none"> <li>Necessary documented information to confirm that design and development requirements have been met?</li> </ul>			
	Do you divide the design and development effort into distinct activities and, for each activity, define the tasks, necessary resources, responsibilities, design content, and inputs and outputs?			
	Does design and development planning consider the ability to provide, verify, test and maintain products and services?			
<b>8.3.3</b>	<b>Design and development Inputs</b>			
	Does your company determine the:			
	<ul style="list-style-type: none"> <li>Requirements essential for the specific type of products and services being designed and developed, including, as required, functional and performance requirements?</li> </ul>			
	<ul style="list-style-type: none"> <li>Applicable statutory and regulatory requirements?</li> </ul>			
	<ul style="list-style-type: none"> <li>Information derived from previous similar design and development?</li> </ul>			
	<ul style="list-style-type: none"> <li>Standards or codes of practice that your company is committed to implement?</li> </ul>			
	<ul style="list-style-type: none"> <li>Internal and external resource needs for the design and development of products and services?</li> </ul>			
	<ul style="list-style-type: none"> <li>Potential consequences of failure due to the nature of the products and services?</li> </ul>			
	<ul style="list-style-type: none"> <li>Potential consequences of obsolescence such as materials, processes, components, equipment, and products?</li> </ul>			
	<ul style="list-style-type: none"> <li>Level of control expected of the design and development process by customers and other relevant interested parties?</li> </ul>			
	Do you ensure that the inputs for design and development purposes are complete and not ambiguous and resolve conflicts in inputs?			
	Has your company retained documented information on design and development inputs?			
	Do you also consider as design and development inputs other information such as benchmarking, external provider feedback, internally generated data, and in-service data?			
<b>8.3.4</b>	<b>Design and development controls</b>			
	Do the controls you apply to the design and development process ensure that the:			
	<ul style="list-style-type: none"> <li>Results to be achieved by the design and development activities are clearly defined?</li> </ul>			
	<ul style="list-style-type: none"> <li>Design and development reviews are conducted as planned to evaluate the ability of results of design and development to meet requirements?</li> </ul>			
	<ul style="list-style-type: none"> <li>Verification is conducted to ensure that the design and development outputs have met the design and development input requirements?</li> </ul>			

	<ul style="list-style-type: none"> <li>Validation is conducted to ensure that the resulting products and services can meet the requirements for the specified application or intended use?</li> </ul>			
	<ul style="list-style-type: none"> <li>Necessary actions taken on problems determined during the reviews, verifications, validations?</li> </ul>			
	<ul style="list-style-type: none"> <li>Do you retain documented information on design &amp; development control activities?</li> </ul>			
	<ul style="list-style-type: none"> <li>Progression to the next stage is authorized?</li> </ul>			
	Do the participants in design and development reviews represent the functions concerned with the design and development stage(s) being reviewed?			
	As suitable to your products and services, how do you conduct reviews, verifications, and validations? Are those activities conducted separately or in combination?			
8.3.4.1	When tests for verification and validation are required, are these tests planned, controlled, reviewed, and documented?			
	Do you ensure and prove that:			
	<ul style="list-style-type: none"> <li>Test plans or specifications identify the test item being tested and the resources being used, define test objectives and conditions, parameters to be recorded and relevant acceptance criteria?</li> </ul>			
	<ul style="list-style-type: none"> <li>Test procedures describe the test methods to be used, how to perform the test, and how to record of the results?</li> </ul>			
	<ul style="list-style-type: none"> <li>The correct configuration of the test item is submitted for the test?</li> </ul>			
	<ul style="list-style-type: none"> <li>The requirements of the test plan and the test procedures are observed?</li> </ul>			
	<ul style="list-style-type: none"> <li>The acceptance criteria are met?</li> </ul>			
	Are the monitoring and measuring devices used for testing controlled (as defined in clause 7.1.5)?			
	At the completion of design & development, do you ensure that reports, calculations, test results, etc., can demonstrate that the design for the product or service meets the requirements for all identified operational conditions?			
<b>8.3.5</b>	<b>Design and development outputs</b>			
	Does your company ensure that design and development outputs:			
	<ul style="list-style-type: none"> <li>Meet the input requirements for design and development?</li> </ul>			
	<ul style="list-style-type: none"> <li>Are adequate for the subsequent processes for the provision of products and services?</li> </ul>			
	<ul style="list-style-type: none"> <li>Include or reference monitoring and measuring requirements, and acceptance criteria, as applicable?</li> </ul>			
	<ul style="list-style-type: none"> <li>Specify product or service characteristics essential for their intended purpose and their safe and proper provision?</li> </ul>			
	<ul style="list-style-type: none"> <li>Specify any critical items, including any key characteristics, and specific actions to be taken for these items?</li> </ul>			
	<ul style="list-style-type: none"> <li>Are approved by authorized person(s) prior to release?</li> </ul>			
	Have you defined the data required to allow the product to be identified, manufactured, verified, used, and maintained?			
	Does the data include items such as: <ul style="list-style-type: none"> <li>the drawings, part lists, and specifications necessary to define the configuration and the design features of the product?</li> <li>the material, process, manufacturing, assembly, handling, packaging, and preservation data needed to provide and maintain a conforming product or service?</li> <li>the technical data and repair schemes for operating and maintaining the product?</li> </ul>			
	Does your company retain the documented information on the design and development outputs?			
<b>8.3.6</b>	<b>Design and development changes</b>			

	Does your company review control and identify changes made during, or subsequent to the design and development of products and services?			
	Do you review, control and identify the changes to ensure that there are no adverse impacts on conformity to requirements?			
	Have you implemented a process and criteria for notifying the customer, prior to the implementation of changes that affect customer requirements?			
	Are design and development changes controlled in accordance with the configuration management process requirements, per 8.1.2?			
	Is documented information retained for: <ul style="list-style-type: none"> <li>• Design and development changes?</li> <li>• Results of reviews?</li> <li>• Authorization of changes?</li> <li>• Actions taken to prevent adverse impacts?</li> </ul>			
<b>8.4</b>	<b>Control of externally provided processes, products and services</b>			
<b>8.4.1</b>	<b>General</b>			
	Does your company ensure that externally provided processes, products, and services conform to specified requirements?			
	Does your organization accept the responsibility for the conformity of all externally provided processes, products, and services, including from sources defined by the customer?			
	How do you ensure that customer designated or approved external providers, including sources for special processes, are used?			
	Do you identify and manage the risks associated with the external provision of processes, products, and services, as well as the selection and use of external providers, such as direct and sub-tier external providers, sources identified by the customer?			
	Do you require that external providers apply appropriate controls to their direct and sub-tier external providers, to ensure requirements are met?			
	Do you apply the specified requirements for the control of externally provided products and services when: <ul style="list-style-type: none"> <li>• Products and services are provided by external providers for incorporation into your own products and services?</li> <li>• Products and services are provided directly to the customer(s) by external providers on behalf of your company?</li> <li>• A process or part of a process is provided by an external provider as a result of your decision to outsource a process or function?</li> </ul>			
	Do you establish and apply criteria for the evaluation, selection, monitoring of performance and re-evaluation of external providers based on their ability to provide processes or products and services in accordance with specified requirements?			
	Does your company retain appropriate documented information of the results of the evaluations, monitoring of the performance and re-evaluations of the external providers?			
8.4.1.1	For external provider evaluation and selection, do you: <ul style="list-style-type: none"> <li>• Define the process, responsibilities, and authority for the approval status decision, changes of the approval status, and conditions for a controlled use of external providers?</li> <li>• Maintain a register of external providers that includes approval status, such as approved, conditional, disapproved, and the scope of the approval, such as product type, process family?</li> <li>• Periodically review external provider performance including process, product and service conformity, and on-time delivery performance?</li> <li>• Define the necessary actions to take when dealing with external providers that do not meet requirements?</li> </ul>			

	<ul style="list-style-type: none"> <li>Define the requirements for controlling documented information created by and/or retained by external providers?</li> </ul>			
	For the provider evaluation and selection, do you consider the use of quality data from objective and reliable external sources, such as:			
	<ul style="list-style-type: none"> <li>Information from accredited quality management system or process certification bodies?</li> </ul>			
	<ul style="list-style-type: none"> <li>External provider approvals from government authorities or customers?</li> </ul>			
	In such cases, do you remain responsible for verifying that externally provided processes, products, and services meet specified requirements?			
<b>8.4.2</b>	<b>Type and extent of control</b>			
	How does your company ensure that externally provided processes, products and services do not adversely affect your ability to consistently deliver conforming products and services to customers?			
	Does your company:			
	<ul style="list-style-type: none"> <li>Ensure that externally provided processes remain within the control of the QMS?</li> </ul>			
	<ul style="list-style-type: none"> <li>Define both the controls that are intended to be applied to external providers and those that are intended to be applied to the resulting output?</li> </ul>			
	When determining the type and extent of controls to be applied, do you consider:			
	<ul style="list-style-type: none"> <li>The potential impact of the externally provided processes, products and services on your ability to consistently meet customer and applicable statutory and regulatory requirements?</li> </ul>			
	<ul style="list-style-type: none"> <li>The effectiveness of the controls applied by the external provider?</li> </ul>			
	<ul style="list-style-type: none"> <li>The results of the periodic review of external provider performance?</li> </ul>			
	Has your company determined the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements?			
	Are the verification activities of externally provided processes, products, and services performed according to the risks identified by the organization?			
	Do the activities include inspection or periodic testing, as applicable, when there is high risk of nonconformities including counterfeit parts?  Refer to Note 1 and Note 2 in the standard			
	When externally provided product is released for production use pending completion of all required verification activities, is it identified and recorded to allow recall and replacement if it is subsequently found that the product does not meet requirements?			
	When your company delegates verification activities to the external provider, is the scope and requirements for delegation defined and a register of delegations maintained?			
	Do you periodically monitor the external provider's delegated verification activities?			
	When external provider test reports are used to verify externally provided products, do you implement a process to evaluate the data in the test reports to confirm that the product meets requirements?			
	When a customer or organization has identified raw material as a significant operational risk, such as critical items, have you implemented a process to validate the accuracy of test reports?			
<b>8.4.3</b>	<b>Information for external providers</b>			
	How does your company ensure the adequacy of specified requirements prior to their communication to the external provider?			
	Does your company communicate to external providers the following requirements:			
	<ul style="list-style-type: none"> <li>The processes, products and services to be provided including the identification of relevant technical data, such as specifications, drawings, process requirements, and work instructions?</li> </ul>			
	<ul style="list-style-type: none"> <li>Approval or release of products and services, methods, processes or equipment?</li> </ul>			



	<ul style="list-style-type: none"> <li>• Competence of personnel, including necessary qualification and their interactions with your QMS?</li> </ul>			
	<ul style="list-style-type: none"> <li>• The control and monitoring of the external provider's performance to be applied by your company?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Verification activities that your company or your customer intends to perform at the external provider's premises?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Design and development control?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Special requirements, critical items, or key characteristics?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Test, inspection, and verification, including production process verification?</li> </ul>			
	<ul style="list-style-type: none"> <li>• The use of statistical techniques for product acceptance and related instructions for acceptance?</li> </ul>			
	<ul style="list-style-type: none"> <li>• The requirement to:             <ul style="list-style-type: none"> <li>- Implement a QMS?</li> </ul> </li> </ul>			
	<ul style="list-style-type: none"> <li>- use customer-designated or approved external providers, including process sources, such as special processes?</li> </ul>			
	<ul style="list-style-type: none"> <li>- notify the company of nonconforming processes, products, or services and obtain approval for their disposition?</li> </ul>			
	<ul style="list-style-type: none"> <li>- prevent the use of counterfeit parts?</li> </ul>			
	<ul style="list-style-type: none"> <li>- notify the company of changes to processes, products, or services, including changes of their external providers or location of manufacture, and obtain the company's approval?</li> </ul>			
	<ul style="list-style-type: none"> <li>- flow down to the external providers the applicable requirements including customer requirements?</li> </ul>			
	<ul style="list-style-type: none"> <li>- provide test specimens for design approval, inspection/verification, investigation, or auditing?</li> </ul>			
	<ul style="list-style-type: none"> <li>- retain documented information, including retention periods and disposition requirements?</li> </ul>			
	<ul style="list-style-type: none"> <li>• The right of access by the company, their customer, and regulatory authorities to the applicable areas of facilities and to applicable documented information, at any level of the supply chain?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Ensuring that persons are aware:             <ul style="list-style-type: none"> <li>- of their contribution to product or service conformity?</li> <li>- of their contribution to product safety?</li> <li>- of the importance of ethical behavior?</li> </ul> </li> </ul>			
<b>8.5</b>	<b>Production and service provision</b>			
<b>8.5.1</b>	<b>Control of production and service provision</b>			
	Does your company implement the controlled conditions for production and service provision?			
	Do the controlled conditions include the:			
	<ul style="list-style-type: none"> <li>• Availability of documented information that defines the characteristics of the products and services?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Availability of documented information that defines the activities to be performed and the results to be achieved?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Availability and use of monitoring and measurement resources?</li> </ul>			
	<ul style="list-style-type: none"> <li>• The implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes and process outputs, and acceptance criteria for products and services, have been met?</li> </ul>			
	Does verification of above include:			
	<ul style="list-style-type: none"> <li>• Ensuring that documented information for product acceptance includes:             <ul style="list-style-type: none"> <li>- criteria for acceptance and rejection?</li> </ul> </li> </ul>			

	- where in the sequence verification is to be performed?			
	- measurement results to be retained as an indication of acceptance or rejection?			
	- any specific equipment required and instructions associated with their use?			
	<ul style="list-style-type: none"> <li>Ensuring that when sampling is used to accept product, the sampling plan is justified based on recognized statistical principles and appropriate for use, such as matching the sampling plan to the criticality of the product and to the process capability?</li> </ul>			
	<ul style="list-style-type: none"> <li>Use and control of suitable infrastructure and process environment such as product specific tooling and software programs?</li> </ul>			
	<ul style="list-style-type: none"> <li>Availability and use of suitable monitoring and measuring resources?</li> </ul>			
	<ul style="list-style-type: none"> <li>Appointment of competent personnel, including any required qualifications?</li> </ul>			
	<ul style="list-style-type: none"> <li>Validation, and periodic revalidation, of the ability to achieve planned results of any process for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement?</li> </ul> <p>Note: Above are referred to as special processes (also in 8.5.1.2)</p>			
	<ul style="list-style-type: none"> <li>Implementation of actions to prevent human errors?</li> </ul>			
	<ul style="list-style-type: none"> <li>Implementation of products and services release, delivery and post-delivery activities?</li> </ul>			
	<ul style="list-style-type: none"> <li>Establishment of criteria for workmanship such as written standards, representative samples, illustrations?</li> </ul>			
	<ul style="list-style-type: none"> <li>Accountability for all products during production such as parts quantities, split orders, nonconforming product?</li> </ul>			
	<ul style="list-style-type: none"> <li>Control and monitoring of identified critical items, including key characteristics?</li> </ul>			
	<ul style="list-style-type: none"> <li>Determination of methods to measure variable data such as tooling, on-machine probing, inspection equipment?</li> </ul>			
	<ul style="list-style-type: none"> <li>Identification of in-process inspection / verification points when adequate verification of conformity cannot be performed at later stages?</li> </ul>			
	<ul style="list-style-type: none"> <li>Availability of evidence that all production and inspection / verification operations have been completed as planned, or as otherwise documented and authorized?</li> </ul>			
	<ul style="list-style-type: none"> <li>Provision for the prevention, detection, and removal of foreign objects?</li> </ul>			
	<ul style="list-style-type: none"> <li>Control and monitoring of utilities and supplies such as water, compressed air, electricity, chemical products, if they affect conformity to product requirements?</li> </ul>			
	<ul style="list-style-type: none"> <li>Identification and recording of products released for subsequent production use pending completion of measuring and monitoring activities, to allow recall and replacement if it is later found that the product does not meet requirements?</li> </ul>			
<b>8.5.1.1</b>	<b>Control of equipment, tools, and software programs</b>			
	Do you validate, prior to release for production the equipment, tools, and software programs used to automate, control, monitor, or measure production processes?			
	Is there a maintenance program for the equipment, tools, and software programs?			
	Have you defined the storage requirements for production equipment or tooling in storage including any needed periodic preservation or condition checks?			
<b>8.5.1.2</b>	<b>Validation and control of special processes</b>			
	For special processes where the resulting output cannot be verified by subsequent monitoring or measurement, have you established the following, as applicable:			
	<ul style="list-style-type: none"> <li>Definition of criteria for the review and approval of the processes?</li> </ul>			
	<ul style="list-style-type: none"> <li>Determination of conditions to maintain the approval?</li> </ul>			
	<ul style="list-style-type: none"> <li>Approval of facilities and equipment?</li> </ul>			
	<ul style="list-style-type: none"> <li>Qualification of persons?</li> </ul>			

	<ul style="list-style-type: none"> <li>• Use of specific methods and procedures for implementation and monitoring the processes?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Requirements for documented information to be retained?</li> </ul>			
<b>8.5.1.3</b>	<b>Production process verification</b>			
	Have you implemented production process verification activities such as risk assessments, capacity studies, capability studies, and control plans to ensure the production process can produce products that meet requirements?			
	For first article inspection (FAI), do you use a representative item from a first production run of a new part or assembly to verify that the production processes, production documentation, and tooling can produce parts and assemblies that meet requirements?			
	Is this (FAI) activity repeated when changes occur that invalidate the original results such as engineering changes, production process changes, tooling changes?			
	Is documented information on the results of production process verification retained?			
<b>8.5.2</b>	<b>Identification and traceability</b>			
	When required to ensure conformity of products and services, does your company use suitable means to identify process outputs?			
	Do you maintain the identification of the configuration of the products and services to identify any differences between the actual configuration and the required configuration?			
	When acceptance authority media are used such as stamps, electronic signatures, passwords, have you established controls for the media?			
	Do you identify the status of process outputs with respect to monitoring and measurement requirements throughout production and service provision?			
	When traceability is required, do you control the unique identification of process outputs?			
	Do you retain the documented information needed to maintain traceability?			
	<p>In considering traceability requirements, do you include:</p> <ul style="list-style-type: none"> <li>- Identification maintained throughout the product life?</li> <li>- Ability to trace all products manufactured from the same batch of raw material, or from the same manufacturing batch, to the destination such as delivery, scrap?</li> <li>- For an assembly, the ability to trace its components to the assembly and then to the next higher assembly?</li> <li>- For a product, a sequential record of its production such as manufacture, assembly, inspection / verification to be retrievable?</li> </ul> <p>Note: Configuration management as a means of identification and traceability – (see also 8.1.2).</p>			
<b>8.5.3</b>	<b>Property belonging to customers or external providers</b>			
	Does your company exercise care with property belonging to the customer or external providers while it is under your control?			
	Do you identify, verify, protect and safeguard the external property provided for use or incorporation into the products and services?			
	When external property is incorrectly used, lost, damaged or otherwise found to be unsuitable for use, do you report this to the customer or external provider?			
	Do you retain documented information on such events?			
	Do you consider customer property as including material, components, tools and equipment, customer premises, intellectual property and personal data?			
<b>8.5.4</b>	<b>Preservation</b>			
	Does your company ensure preservation of process outputs during production and service provision, as needed to maintain conformity to requirements?			
	Do you consider preservation as including identification, handling, packaging, storage, transmission or transportation, and protection?			

	Does the preservation of outputs also include, when applicable, provisions for:			
	<ul style="list-style-type: none"> <li>• Cleaning?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Prevention, detection, and removal of foreign objects?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Special handling and storage for sensitive products?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Marking and labeling, including safety warnings and cautions?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Shelf life control and stock rotation?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Special handling and storage for hazardous materials?</li> </ul>			
<b>8.5.5</b>	<b>Post-delivery activities</b>			
	Does your company meet requirements for post-delivery activities associated with the products and services?			
	When determining your post-delivery activities, do you consider the:			
	<ul style="list-style-type: none"> <li>• Statutory and regulatory requirements?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Potential undesired consequences associated with the products and services?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Nature, use and intended lifetime of the products and services?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Customer requirements and feedback?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Collection and analysis of in-service data such as performance, reliability, lessons learned?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Control, updating, and provision of technical documentation relating to product use, maintenance, repair, and overhaul?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Controls required for work undertaken external to the organization such as off-site work?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Product / customer support such as queries, training, warranties, maintenance, replacement parts, resources, obsolescence?</li> </ul>			
	When problems are detected after delivery, the organization shall take appropriate action including investigation and reporting.			
	Do you consider post-delivery activities as including actions under warranty provisions, contractual obligations such as maintenance services, and other services such as recycling or final disposal?			
<b>8.5.6</b>	<b>Control of changes</b>			
	Does your company review and control changes for production or service provision to ensure continuing conformity with specified requirements?  NOTE: Production or service provision changes can include the changes affecting processes, production equipment, tools, or software programs.			
	Do you identify the persons authorized to approve production or service provision changes?			
	Do you retain documented information describing the results of the review of those changes, the personnel authorizing the change, and any necessary actions?			
<b>8.6</b>	<b>Release of products and services</b>			
	Does your company implement the planned arrangements at appropriate stages to verify that product and service requirements have been met?			
	Do you ensure that the release of products and services to the customer does not proceed until the planned verification of conformity has been satisfactorily completed?			
	Is documented information on the release of products and services retained:			
	<ul style="list-style-type: none"> <li>• Does the documented information include the evidence of conformity with the acceptance criteria?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Does documented information provide traceability to the person(s) authorizing release of products and services for delivery to the customer?</li> </ul>			
	When required to demonstrate product qualification, how do you ensure that retained documented information provides evidence that the products and services meet the defined requirements?			

	How do you ensure that all documented information required to accompany the products and services are present at delivery?			
<b>8.7</b>	<b>Control of nonconforming outputs</b>			
8.7.1	Does your company ensure that outputs that do not conform to requirements are identified and controlled to prevent their unintended use or delivery?			
	Do you take corrective action based on the nature of the nonconformity and the impact on the conformity of products and services?			
	Do you also apply corrective action to non-conforming products and services detected after delivery of the products or during the provision of the service?			
	Is your nonconformity control process maintained as documented information and includes provisions for:			
	<ul style="list-style-type: none"> <li>Defining the responsibility and authority for the review and disposition of nonconforming outputs and the process for approving persons making the decisions?</li> </ul>			
	<ul style="list-style-type: none"> <li>Taking actions necessary to contain the effect of the nonconformity on other processes, products and services?</li> </ul>			
	<ul style="list-style-type: none"> <li>Prompt reporting of nonconformities affecting delivered products and services to the customer and to relevant interested parties?</li> </ul>			
	<ul style="list-style-type: none"> <li>Defining corrective actions for nonconforming products and services detected after delivery, as appropriate to their impacts?</li> </ul>			
	Does your company deal with non-conforming outputs in one or more of the following:			
	<ul style="list-style-type: none"> <li>Correction?</li> </ul>			
	<ul style="list-style-type: none"> <li>Segregation, containment, return or suspension of provision of products and services?</li> </ul>			
	<ul style="list-style-type: none"> <li>Informing the customer?</li> </ul>			
	<ul style="list-style-type: none"> <li>Obtaining authorization for acceptance with a concession by a relevant authority and if applicable by the customer?</li> </ul>			
	Is the dispositions of use-as-is or repair for the acceptance of nonconforming products only implemented after approval by an authorized representative of the company responsible for design or by persons having delegated authority from the design organization?			
	Is the dispositions of use-as-is or repair only implemented after authorization by the customer, if the nonconformity results in a departure from the contract requirements?			
	Is product for disposition as scrap conspicuously and permanently marked, or positively controlled, until physically rendered unusable?			
	How do you control counterfeit, or suspect counterfeit parts to prevent reentry into the supply chain?			
	After correcting nonconforming process outputs, products and services, do you verify that the requirements are met?			
8.7.2	Do you retain documented information of actions taken on nonconforming process outputs, products and services?			
	Do you retain documented information on any concessions obtained and on the person or authority that made the decision regarding dealing with the nonconformity?			
<b>9</b>	<b>PERFORMANCE EVALUATION</b>			
<b>9.1</b>	<b>Monitoring, measurement, analysis and evaluation</b>			
<b>9.1.1</b>	<b>General</b>			
	Does your company determine:			
	<ul style="list-style-type: none"> <li>What needs to be monitored and measured?</li> </ul>			
	<ul style="list-style-type: none"> <li>The methods for monitoring, measurement, analysis and evaluation to ensure valid results?</li> </ul>			
	<ul style="list-style-type: none"> <li>When the monitoring and measuring are to be performed?</li> </ul>			
	<ul style="list-style-type: none"> <li>When the results from monitoring and measurement are analyzed and evaluated?</li> </ul>			

	Do you ensure that monitoring and measurement activities are implemented to meet the determined requirements?			
	Does your company evaluate the quality performance and the effectiveness of the QMS?			
	Do you retain appropriate documented information as evidence of the results?			
<b>9.1.2</b>	<b>Customer satisfaction</b>			
	Does your company monitor customer satisfaction to determine the perception of the degree to which their needs and expectations have been met?			
	Do you obtain information relating to customer views and opinions of your company and your products and services?			
	Do you determine the methods for obtaining and using this information?			
	Do you consider information related to customer views as including customer satisfaction or opinion surveys, customer data on the quality of delivered products or services, market-share analysis, warranty claims, dealer reports and compliments?			
	Does the information to be monitored and used for the evaluation of customer satisfaction include, and is not limited to:			
	<ul style="list-style-type: none"> <li>• Product and service conformity?</li> </ul>			
	<ul style="list-style-type: none"> <li>• On-time delivery performance?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Customer complaints?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Corrective action requests?</li> </ul>			
	Has your organization developed and implemented plans for customer satisfaction improvement that address deficiencies identified by these evaluations, and assess the effectiveness of the results?			
<b>9.1.3</b>	<b>Analysis and evaluation</b>			
	Does your company analyze and evaluate the data and information resulting from monitoring, measurement?  NOTE: Data can include information on product and service problems reported by external sources such as government / industry alerts, advisories.			
	Do you use the results of analysis to evaluate:			
	<ul style="list-style-type: none"> <li>• Conformity of products and services to requirements?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Degree of customer satisfaction?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Performance and effectiveness of the QMS?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Planning has been effectively implemented?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Effectiveness of actions taken to address risks and opportunities?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Performance of external providers?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Need for improvements to the QMS?</li> </ul>			
	Do you consider statistical techniques as a method for the analysis of data			
<b>9.2</b>	<b>Internal audit</b>			
9.2.1	Does your company conduct internal audits at planned intervals to determine whether the QMS:			
	<ul style="list-style-type: none"> <li>• Conforms to your QMS requirements, including customer and applicable statutory QMS requirements and to the AS 9100 D requirements?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Is effectively implemented and maintained?</li> </ul> <p>Note: As determined with the evaluation of performance indicators</p>			
9.2.2	Does your company:			
	<ul style="list-style-type: none"> <li>• Plan, establish, implement and maintain an audit program that includes the frequency, methods, responsibilities, planning requirements and reporting?</li> </ul>			
	<ul style="list-style-type: none"> <li>• Consider the importance of the processes concerned, changes impacting on your company, and the results of previous audits?</li> </ul>			

	<ul style="list-style-type: none"> <li>Define the audit criteria and scope for each audit?</li> </ul>			
	<ul style="list-style-type: none"> <li>Select auditors and conduct audits to ensure objectivity and the impartiality of the audit process?</li> </ul>			
	<ul style="list-style-type: none"> <li>Ensure that the results of the audits are reported to relevant management?</li> </ul>			
	<ul style="list-style-type: none"> <li>Take timely correction and corrective actions without undue delay?</li> </ul>			
	Do you retain documented information as evidence of the implementation of the audit program and the audit results?			
<b>9.3</b>	<b>Management review</b>			
<b>9.3.1</b>	<b>General</b>			
	Does the top management review the QMS at planned intervals, to ensure that it continues to be suitable, adequate and effective and aligned with the strategic direction of your company?			
<b>9.3.2</b>	<b>Management review inputs</b>			
	As inputs for the planning and conducting management reviews, do you consider the following:			
	<ul style="list-style-type: none"> <li>The status of actions from previous management reviews?</li> </ul>			
	<ul style="list-style-type: none"> <li>Changes in external and internal issues that are relevant to the QMS?</li> </ul>			
	Do you also consider information on the quality performance, including trends in:			
	<ul style="list-style-type: none"> <li>Customer satisfaction and feedback from interested parties?</li> </ul>			
	<ul style="list-style-type: none"> <li>Extent to which quality objectives have been met?</li> </ul>			
	<ul style="list-style-type: none"> <li>Process performance and conformity of products and services?</li> </ul>			
	<ul style="list-style-type: none"> <li>Nonconformities and corrective actions?</li> </ul>			
	<ul style="list-style-type: none"> <li>Monitoring and measurement results?</li> </ul>			
	<ul style="list-style-type: none"> <li>Audit results?</li> </ul>			
	<ul style="list-style-type: none"> <li>Performance of external providers?</li> </ul>			
	<ul style="list-style-type: none"> <li>On-time delivery performance?</li> </ul>			
	Adequacy of resources?			
	Does the management review include the review of the effectiveness of actions taken to address risks & opportunities (per 6.1)?			
	Do you include new potential opportunities for continual improvement?			
<b>9.3.3</b>	<b>Management review outputs</b>			
	As outputs of your management reviews do you include decisions and actions related to:			
	<ul style="list-style-type: none"> <li>Continual improvement opportunities?</li> </ul>			
	<ul style="list-style-type: none"> <li>Any need for changes to the QMS, including needs for resources?</li> </ul>			
	<ul style="list-style-type: none"> <li>Identified risks?</li> </ul>			
	Does your company retain documented information as evidence of the results of management reviews?			
<b>10</b>	<b>IMPROVEMENT</b>			
<b>10.1</b>	<b>General</b>			
	Does your company determine and select opportunities for improvement and implement actions needed to meet customer requirements and enhance customer satisfaction?			
	Do you include:			
	<ul style="list-style-type: none"> <li>Improving products and services to meet requirements as well as addressing future needs and expectations?</li> </ul>			
	<ul style="list-style-type: none"> <li>Correcting, preventing or reducing undesired effects?</li> </ul>			

	<ul style="list-style-type: none"> <li>Improving the performance and effectiveness of the QMS?</li> </ul>			
	Do you consider improvement as events:			
	<ul style="list-style-type: none"> <li>That can be effected reactively, such as corrective action?</li> </ul>			
	<ul style="list-style-type: none"> <li>Incrementally, such as continual improvement?</li> </ul>			
	<ul style="list-style-type: none"> <li>By-step-change, such as breakthrough?</li> </ul>			
	<ul style="list-style-type: none"> <li>Creatively, such as innovation?</li> </ul>			
	<ul style="list-style-type: none"> <li>Transformation such as re-organization?</li> </ul>			
<b>10.2</b>	<b>Nonconformity and corrective action</b>			
10.2.1	When nonconformities occur, including those resulting from complaints, does your company:			
	<ul style="list-style-type: none"> <li>React to the nonconformity, and as needed take action to control and correct it and deal with the consequences of the nonconformity?</li> </ul>			
	<ul style="list-style-type: none"> <li>Evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:</li> </ul>			
	-- Reviewing and analyzing the nonconformity?			
	-- Determining the cause of the nonconformity, including the ones related to human factors?			
	<ul style="list-style-type: none"> <li>-- Determining if similar nonconformities exist, or could potentially occur?</li> </ul>			
	<ul style="list-style-type: none"> <li>Implement any action needed?</li> </ul>			
	<ul style="list-style-type: none"> <li>Review the effectiveness of any corrective action taken?</li> </ul>			
	<ul style="list-style-type: none"> <li>Update risks and opportunities identified during the planning?</li> </ul>			
	<ul style="list-style-type: none"> <li>Make changes to the QMS if needed?</li> </ul>			
	<ul style="list-style-type: none"> <li>Flow down corrective action requirements passed on to a supplier when it is determined that the supplier is responsible for the nonconformity?</li> </ul>			
	<ul style="list-style-type: none"> <li>Specific actions where timely and/or effective corrective actions are not achieved?</li> </ul>			
	Does your company take corrective actions that are appropriate to the effects of the nonconformities encountered?			
	Do you maintain documented information that defines the nonconformity and corrective action management processes?			
	10.2.2 Does your company retain documented information as evidence of the:			
	<ul style="list-style-type: none"> <li>Nature of the nonconformities and any subsequent actions taken?</li> </ul>			
	<ul style="list-style-type: none"> <li>Results of any corrective action?</li> </ul>			
<b>10.3</b>	<b>Continual improvement</b>			
	Does your company continually improve the suitability, adequacy, and effectiveness of the QMS?			
	Do you consider the results of analysis and evaluation, and the outputs from management review, to determine if there are needs and opportunities to be addressed as part of continual improvement?			
	Has your organization monitored the implementation of improvement activities and evaluated the effectiveness of the results?  NOTE: Examples of continual improvement opportunities can include lessons learned, problem resolutions, and the benchmarking of best practices.			



**Comments:**

***SURVEY COMPLETED BY:***

***SIGNATURE:***

***DATE:***

***SURVEY REVIEWED BY:***

***SIGNATURE:***

***DATE:***