

<b>Document and Record Control (7.5)</b>	<b>Y</b>	<b>N</b>	<b>Actions/Notes</b>
Do you have a current process for controlling documents and records?			
Are documents and records available when needed for use?			
Are documents and records protected?			
Are there IT controls in place such as regular updates, appropriate network permissions and secure backup in place to prevent data loss?			
Are changes controlled?			
Is there a process for periodic review?			
Do you have an index/inventory of all controlled documents?			

<b>Nonconformance/ Corrective Action (8.7)</b>	<b>Y</b>	<b>N</b>	<b>Notes</b>
Is there a process to document Nonconformances?			
Is root cause determined and documented?			
Are corrective measures documented?			
Are corrective actions verified to be effective?			
Is there a process for documented management approval?			
Are permanent changes communicated?			
Does the management team review nonconformances to look for trend/analysis? Opportunities to improve?			



<b>Customer Communication (Feedback/ Complaints) (8.2)</b>	<b>Y</b>	<b>N</b>	<b>Notes</b>
Has the organization determined needed external communications?			
Is there a process to record customer feedback including complaints?			
Is there a process for tracking customer complaints through closure?			
Does the management team review customer feedback including trends? What is the frequency of review?			

<b>Manage Change (6.3)</b>	<b>Y</b>	<b>N</b>	<b>Notes</b>
Is there a process to control changes to production and service delivery processes? <i>Examples include equipment installations, changes to shop floor layouts and raw material changes.</i>			
Are the activities recorded?			
Is there a process for management approval and communication to effected personnel?			

<b>Training (7.2)</b>	<b>Y</b>	<b>N</b>	<b>Notes</b>
Do you have a current process to record employee training?			
If yes, does that process meet ISO 9001:2015 requirements?			



<b>Design (8.3)</b>	<b>Y</b>	<b>N</b>	<b>Notes</b>
Is your organization responsible for Design of products or services? (i.e., Have you included it in your scope?)			
Is there a process for design planning? Are records maintained?			
Are there records showing design requirements inputs, outputs, verification and validation?			
Are there clear acceptance criteria for each stage of the design process?			

<b>Engineering Changes (8.3)</b>	<b>Y</b>	<b>N</b>	<b>Notes</b>
Is there a process to control engineering changes?			
Are records maintained?			
Is there a process for approval and communication to effected personnel?			

<b>Purchasing (8.4)</b>	<b>Y</b>	<b>N</b>	<b>Notes</b>
Is there a process for the selection, of external providers based on their ability to provide processes or products and services in accordance with specified requirements?			
Is there a criteria-based process for monitoring the performance and re-evaluation of external providers?			
Is the re-evaluation occurring at planed intervals?			
Are the evaluations and re-evaluations recorded?			
Is there a Supplier Corrective Action (SCAR) process?			



<b>Calibration (7.1.5)</b>	<b>Y</b>	<b>N</b>	<b>Notes</b>
If measurement traceability is a requirement, are national standards specified and documented?			
If there are no national standards, is the basis for calibration documented?			
Do you have a Calibration Log listing all calibrated equipment, ID/Serial Number, Frequency, last date of calibration?			
Are records of calibration available?			
If outsourced, is there evidence that you have reviewed the calibration certificates? (Initial/date)			
Is there a process to alert personnel of upcoming calibration expirations?			
Are there defined actions planned for an out of tolerance finding?			
Is the "as found" condition documented? Pass/Fail			

<b>Preventive Maintenance/Infrastructure (7.1.3)</b>	<b>Y</b>	<b>N</b>	<b>Notes</b>
Is there an asset register? (Including IT and network assets)			
Does it keep track of when maintenance should be done?			
Does it define whether the assets are inactive or out for repair?			
Does it contain Maintenance Tasks associated with the asset?			
Are Maintenance Records readily available?			
Are controls for physical security in place? (Locks on cabinets and doors, security cameras, limited access, etc.)			
Are regular updates performed on company applications and Operating Systems?			

