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ISO 9001:2015 into AS 9120 Rev B - Quality Management Systems -- The Gap Analysis Checklist

This gap analysis checklist is prepared for use in evaluating a Quality Management System (QMS) against the requirements of the new Aerospace standard. The AS 9120 Rev B standard includes the requirements of ISO 9001:2015 and specifies additional aviation, space, and defense (ASD) industry requirements.

In the checklist, each requirement is expressed as a question that the user (auditor / assessor) can use to evaluate your QMS capabilities. You will need to have copies of the AS 9120 B and ISO 9001:2015 standards to use along with this checklist so that, if required, you can refer to the requirements and the clarification sections of Annex A.

While the structure of the AS and ISO standards are the same when comparing the contents, the additional ASD requirements are highlighted in yellow in the relevant sections of the checklist and the intent of the main clauses of the new standard is shown in blue font.

After you have prepared an audit schedule, and assigned responsibility to your auditors for different areas or processes to audit, copy each section of the checklist for the auditors working with that section. As you work through the checklist take notes on what is in place, and what needs to be developed.

In the space for 'currently in place', list or reference the procedures or other documents, or evidence that you have reviewed and that will provide information for the new QMS. Take notes on the status of the documents, that is, will they need to be revised for the new system, or can they be used as is? Also, note where processes are in place, but documentation is needed. Focus on what is in place, and what needs to be developed.

While you do want to know if documented information is in place and if procedures and processes are being complied with, compliance is not your focus for this audit. Remember that the outcome of this audit should be a list of things that your company needs to do to comply with the AS 9120 Rev B standard.

---	QUALITY MANAGEMENT SYSTEMS REQUIREMENTS	Currently in Place	Compliant YES / NO?	If No - % Completed	Items Needed
4	CONTEXT OF THE ORGANIZATION				
Intend of clause	This first clause introduces two sub-clauses relating to the context of the organization, (1) understanding the organization and its context and (2) understanding the needs and expectations of interested parties. Together they require that you determine the issues and requirements that can impact on the planning of the Quality Management System (QMS). In addition, the scope of the QMS and the QMS processes along with their applicability and interactions need to be determined.				
4.1	Understanding the organization and its context				

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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"> • Inputs required and the outputs expected from the processes? 				
<ul style="list-style-type: none"> • Sequence and interaction of the processes? 				
<ul style="list-style-type: none"> • Criteria, methods, including measurements and related performance indicators needed to ensure the effective operation, and control of the processes? 				
<ul style="list-style-type: none"> • Resources needed and ensure they are available? 				
<ul style="list-style-type: none"> • Assignment of the responsibilities and authorities for these processes? 				
<ul style="list-style-type: none"> • Risks and opportunities (per 6.1), and plans to implement the appropriate actions to address them? 				
<ul style="list-style-type: none"> • Methods for monitoring, measuring, and evaluation of processes and, if needed, the changes to processes to ensure that they achieve intended results? 				
<ul style="list-style-type: none"> • Opportunities for improvement of the processes and the QMS? 				

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4.4.2	Does your company maintain the necessary documented information to support the operation of processes?				
	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"> • General description of relevant interested parties, per see 4.2 a? 				
	<ul style="list-style-type: none"> • Scope of the QMS, including boundaries and applicability, per see 4.3? 				
	<ul style="list-style-type: none"> • Description of the processes needed for the QMS and their application throughout the organization? 				
	<ul style="list-style-type: none"> • Sequence and interaction of the processes? 				
	<ul style="list-style-type: none"> • Assignment of the responsibilities and authorities for these processes? 				
	With reference to the Note in section 4.4.2:				
	<ul style="list-style-type: none"> • Do you compile the above items of the QMS in a single source of documented information and referred to as a quality manual? 				
5	LEADERSHIP				

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Intent of clause	This clause requires that your top management demonstrates leadership and commitment with respect to the QMS. In addition, top management is required to demonstrate leadership and commitment with respect to customer focus. This section also asks top management to establish, implement and maintain both a quality policy and a safety policy that is appropriate to your company and to ensure that the responsibilities and authorities for relevant roles are assigned, communicated, and understood. In addition, top management needs to identify a responsible person as the Management Representative.			
5.1	Leadership and commitment			
5.1.1	General			
	Does top management demonstrate leadership and commitment with respect to the QMS by:			
	<ul style="list-style-type: none"> • Taking accountability for the effectiveness of the QMS? 			
	<ul style="list-style-type: none"> • 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? 			
	<ul style="list-style-type: none"> • Ensuring that the quality policy is communicated, understood, and applied within the company? 			
	<ul style="list-style-type: none"> • Ensuring the integration of the QMS requirements into the company's business processes? 			
	<ul style="list-style-type: none"> • Promoting the use of both the process approach and risk-based thinking? 			
	<ul style="list-style-type: none"> • Ensuring that the resources needed for the QMS are available? 			