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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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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? 				

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8.1	Operational planning and control				
	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"> • Determining requirements for the product and services? 				
	See the 1 st Note in section 8.1:				
	<p style="background-color: yellow;">When determining the requirements for products and services do you consider:</p> <ul style="list-style-type: none"> • Personal and product safety? • Availability and inspect-ability? • Product obsolescence? • Prevention, detection, and removal of foreign objects? • Handling, packaging, and preservation? • Recycling or final disposal of the product at the end of its life? 				
	<ul style="list-style-type: none"> • Establishing criteria for the processes and for the acceptance of products and services? 				
	See the 2nd Note in section 8.1:				
	<p style="background-color: yellow;">Depending on the nature of the product and on the specified requirements, are statistical techniques used to support process control with process capability</p>				

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	<ul style="list-style-type: none"> Does documented information provide traceability to the personnel authorizing release of products and services for delivery to the customer? 				
	Does the company ensure that all documented information required to accompany the products and services are present at delivery?				
	See the Note in section 8.6:				
	<ul style="list-style-type: none"> When there is a formal agreement with the customer, do you deliver a certifying statement that references the original manufacturer's certificate of conformity and documented information that is retained and traceable to your company? 				
	<ul style="list-style-type: none"> Do the certifying statements indicate that defined requirements have been met throughout your processes? 				
8.7	Control of nonconforming outputs				
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?				
	See the 1 st Note in section 8.7.1:				
	<ul style="list-style-type: none"> Do you recognize that the term Nonconforming Outputs includes nonconforming product or service generated internally, received from external providers, identified by a customer? 				