

Audit Date:	
Audit Description:	
Lead Auditor:	
Audit Team Members:	

<p><b>ISO 9001:2008 Auditable Clauses</b></p> <p>(Tick those to be evaluated during this audit)</p> <p>Each auditor should complete the section of the checklist they have been assigned by the Quality Manager or Lead Auditor [delete as appropriate]. The auditor may provide additional notes and questions regarding the audit trail for each element in the blank space on the checklist.</p> <p>The Quality Manager or Lead Auditor [delete as appropriate] is responsible for reviewing completed sections of the checklist and to organize all individual sections into one sequential checklist at the conclusion of the audit.</p>	<a href="#">4.1</a>		<a href="#">4.2.1</a>		<a href="#">4.2.2</a>		<a href="#">4.2.3</a>		<a href="#">4.2.4</a>	
	<a href="#">5.1</a>		<a href="#">5.2</a>		<a href="#">5.3</a>		<a href="#">5.4.1</a>		<a href="#">5.4.2</a>	
	<a href="#">5.5.1</a>		<a href="#">5.5.2</a>		<a href="#">5.5.3</a>		<a href="#">5.6.1</a>		<a href="#">5.6.2</a>	
	<a href="#">5.6.3</a>		<a href="#">6.1</a>		<a href="#">6.2.1</a>		<a href="#">6.2.2</a>		<a href="#">6.3</a>	
	<a href="#">6.4</a>		<a href="#">7.1</a>		<a href="#">7.2.1</a>		<a href="#">7.2.2</a>		<a href="#">7.2.3</a>	
	<a href="#">7.3.1</a>		<a href="#">7.3.2</a>		<a href="#">7.3.3</a>		<a href="#">7.3.4</a>		<a href="#">7.3.5</a>	
	<a href="#">7.3.6</a>		<a href="#">7.3.7</a>		<a href="#">7.4.1</a>		<a href="#">7.4.2</a>		<a href="#">7.4.3</a>	
	<a href="#">7.5.1</a>		<a href="#">7.5.2</a>		<a href="#">7.5.3</a>		<a href="#">7.5.4</a>		<a href="#">7.5.5</a>	
	<a href="#">7.6</a>		<a href="#">8.1</a>		<a href="#">8.2.1</a>		<a href="#">8.2.2</a>		<a href="#">8.2.3</a>	
	<a href="#">8.2.4</a>		<a href="#">8.3</a>		<a href="#">8.4</a>		<a href="#">8.5.1</a>		<a href="#">8.5.2</a>	
	<a href="#">8.5.3</a>									

**PRODUCT REALIZATION PROCESS EXCLUSIONS**

<p><b>ISO 9001:2008 Permissible Exclusions</b></p> <p>(Tick those applicable, if any)</p>	7.1		7.2.1		7.2.2		7.2.3		7.3.1	
	7.3.2		7.3.3		7.3.4		7.3.5		7.3.6	
	7.3.7		7.4.1		7.4.2		7.4.3		7.5.1	
	7.5.2		7.5.3		7.5.4		7.5.5		7.6	

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Legend

**A** = Opportunity for Improvement    **B** = Minor Non-conformance    **C** = Major Non-conformance    SQ = Supplementary Question

Conformance:	Adherence with the requirements of the standard. No major or minor non-conformances found
Opportunity for Improvement (OFI):	<p>A situation or condition of a management system that may be weak, cumbersome, redundant, overly complex, or in some other manner, may, in the opinion of the auditor, offer an opportunity for an organization to improve its current status.</p> <p>OFIs do not require any action on the part of the organization; however, the organization should give them serious consideration in view of the auditor's knowledge and exposure to similar systems.</p> <p>An OFI may be an improvement to the management system or could prevent future problems.</p>
Minor Non-conformance:	<p>A non-conformity that, based on the judgment and experience of the auditor, is not likely to result in the failure of the management system or reduce its ability to assure controlled processes or products.</p> <p>It may be either:</p> <p>A failure in some part of the supplier's management system relative to a specified requirement.</p> <p>A single observed lapse in following one item of a company's management system.</p>
Major Non-conformance:	<p>The absence (omission, not addressed) or total breakdown (commission, failure, not implemented) of a system to meet a specified requirement.</p> <p>A number of minor non-conformities against one requirement can represent a total breakdown of the system and thus be considered a major non-conformity.</p> <p>Any non-compliance that would result in the probable shipment of a non-conforming product. Conditions that may result in the failure of or materially reduce the usability of the products or services for their intended purpose.</p> <p>A non-compliance that, in the judgment and experience of the auditor, is likely to either to result in the failure of the management system or to materially reduce its ability to assure controlled processes and products.</p>

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#### 4.1 General Requirements

Question No.	Clause Ref.	Audit Question	Finding			Audit Evidence
			YES	NO		
				A	B	
N.B. Provide references to documentation where necessary						
1	4.1	Has the organization established, documented, implemented and maintained a QMS and continually improved its effectiveness?				
2	4.1a	Has the organization identified the processes needed for the QMS and their application throughout the organization?				
3	4.1b	Has the organization determined the sequence and interaction of QMS processes?				
4	4.1c	What are the criteria and methods the organization uses to ensure that the operation and control of QMS processes are effective?				
5	4.1d	Has the organization provided resources and information needed to support the operation and monitoring of QMS processes?				
6	4.1e	Does the organization monitor, measure and analyze QMS processes?				

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Question No.	Clause Ref.	Audit Question	Finding			Audit Evidence
			YES	NO		
				A	B	C
7	4.1f	Has the organization implemented actions necessary to achieve planned results and continual improvement of processes needed for the QMS?				
8	4.1	Are processes needed for the QMS managed by the organization in accordance with the requirements of ISO 9001:2008?				
9	4.1	How does the organization maintain control over outsourced processes?				
10	4.1	Are the necessary controls for outsourced processes that affect product conformity with requirements identified within the QMS?				
11	4.1	Does organization have adequate control over outsourced processes to ensure conformity to all customer requirements?				

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**4.2.1 General**

Question No.	Clause Ref.	Audit Question	Finding			Audit Evidence
			YES	NO		
				A	B	
N.B. Provide references to documentation where necessary						
1	4.2.1a	Does the organization have a documented quality policy?				
2	4.2.1a	Does the organization have a set of documented quality objectives?				
3	4.2.1b	Does the organization have a quality manual?				
4	4.2.1c	Does the organization operate a set of documented procedures?				
5	4.2.1d	Are adequate documents in place to ensure the effective planning, operation and control of organization's processes?				
6	4.2.1d	Does documentation include the records required by ISO 9001:2008?				

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#### 4.2.2 Quality Manual

Question No.	Clause Ref.	Audit Question	Finding			Audit Evidence	
			YES	NO			
				A	B		C
						N.B. Provide references to documentation where necessary	
1	4.2.2a	Where in the quality manual is the scope of the QMS identified, including details of and justification for exclusions?					
2	4.2.2b	Where does the quality manual contain or reference the documented procedures established for the QMS?					
3	4.2.2c	Where does the quality manual include a description of the interaction between the processes of the QMS?					

#### 4.2.3 Control of Documents

Question No.	Clause Ref.	Audit Question	Finding			Audit Evidence	
			YES	NO			
				A	B		C
						N.B. Provide references to documentation where necessary	
1	4.2.3	Does the organization operate an establish document control procedure? (If yes, proceed with questions 22 to 28)					

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Question No.	Clause Ref.	Audit Question	Finding			Audit Evidence
			YES	NO		
				A	B	C
2	4.2.3a	Does the document control procedure define the controls needed to approve documents for adequacy prior to issue?				
3	4.2.3b	Does the document control procedure define the controls needed to review and update as necessary and re-approve documents?				
4	4.2.3c	Does the document control procedure define the controls needed to ensure that changes and the current revision status of documents are identified?				
5	4.2.3d	Does the document control procedure define the controls needed to ensure that relevant versions of applicable documents are available at points of use?				
6	4.2.3e	Does the document control procedure define the controls needed to ensure that documents remain legible and readily identifiable?				
7	4.2.3f	Does the document control procedure define the controls needed to ensure that documents of external origin are identified and their distribution controlled?				
8	4.2.3g	Does the document control procedure define the controls needed to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose?				

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