INSERT COMPANY NAME/LOGO HERE

ISO 9001:2015 Quality Management Systems - The Internal Audit Checklist

This checklist is based on the information provided in the ISO 9001:2015 international standard. The checklist is best used by trained and practicing auditors to evaluate or assess Quality Management Systems requirements based on the standard.
You will see questions on the checklist that refer to the standard and for each clause provisions are made for additional questions.

The auditors are expected to use a great deal of discretion and therefore must be careful and thoughtful prior to establishing a deficiency against a requirement. Evidence for visible top management leadership, commitment and quality management action must be looked for.

The **bold** numbers and titles used in the first two columns of the checklist indicate the "Requirements" and may be referred to on nonconformity reports prepared by the auditor.

During assessment of each requirement, auditors record the status of the evaluation by indicating in the right hand column a

Yes - for Acceptable Condition or **No -** for Deficient Condition

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	QUALITY MANAGEMENT SYSTEM	OBSERVATIONS / COMMENTS	STATUS
4	**CONTEXT OF THE ORGANIZATION**		
4.1	**Understanding the organization and its context**		
	Has your company determined the external and internal issues that are relevant to your purpose and strategic direction? Have you considered the relevant issues that affect your ability to achieve the intended results of the Quality Management System (QMS)? How do you monitor and review the information related to the external and internal issues?		

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	Additional Questions		
4.2	**Understanding the needs and expectations of interested parties**		
	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, have you determined: • The interested parties that are relevant to the QMS? • The requirements of these interested parties that are relevant to the QMS? How do you monitor and review the information about the interested parties and their relevant requirements?		
	Additional Questions		
4.3	**Determining the scope of the quality management system**		
	To establish the scope of the QMS, has your company determined the boundaries and applicability of the QMS? When determining the scope of the QMS, have you considered the: • External and internal issues (per 4.1)? • Requirements of relevant interested parties (per 4.2)?		

	• The products and services of your company?		
	When a requirement of ISO 9001:2015 can be applied, has your company applied the requirement?		
	When requirements cannot be applied, and in order to claim conformity to ISO 9001:2015, 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?		
	In the scope of the QMS, have you stated the products and services covered by the QMS?		
	Has your company provided justification for any instance where a requirement of the standard cannot be applied?		
	Additional Questions		
4.4	**Quality management system and its processes**		
4.4.1	Has your company obtained the current version of the ISO 9001:2015 international standard?		
	As required by the standard, have you established, documented implemented, maintained and continually improved the QMS?		
	Have you determined the processes needed for the QMS, their interactions and applications throughout		