

E6 External issues, examples could include:

ISO 9001:2015 Internal Audit Checklist

The internal audit checklist ensures your internal audits concisely compare your management system against the requirements of ISO 9001:2015.
 Answer questions 1 to 305 to determine conformance. The audit results are summarized in the 'Audit Results' worksheet.

Each ISO 9001:2015 'shall' requirement has been re-phrased as a question to elicit a response that can be represented as an 'x'.
 The error tracking cells in Column 'M' display an error message when more than 1 response is entered in Columns 'F', 'G' and 'H', or whether a response has yet to be entered. See the summary in Cell 'M3'.

The general guidance and examples shown in Column 'E' should be referred to when undertaking an internal audit as described by ISO 9001:2015, Clause 9.2.
 This guidance is not intended to add to, subtract from, or in any way modify the stated requirements of ISO 9001:2015. The examples shown are things to consider when asking audit the questions and looking for objective audit evidence to record.

Enter the letter 'x' into either Column 'F', 'G' or 'H', to express your answer to each audit question.
 The scoring formula assumes each requirement conforms, until an 'x' is entered into Column 'G' or 'H'.
 Any issues that an audit must be documented in the 'Audit Results' worksheet. Provide a reference to justify each audit finding of any minor or major non-conformance.

Clause	Clause Title	Question	Audit Question	Guidance & Suggestions	Conforms	Minor NC	Major NC	OFI	Audit
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4	Context of the Organization								
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4.1	Organizational Context	1	Has your organization determined external and internal issues relevant to its purpose and its strategic direction that affect its ability to achieve the intended result(s) of its quality management system?	<p>Sources of evidence could come from SWOT or PESTLE analysis results, business strategy plans; quality plans; information provided on your organization's website; annual reports; management meeting minutes; documented procedure; and lists of external and internal issues and conditions.</p> <p>Records of meetings where context is routinely discussed and monitored, e.g. as part of the structured management review process or within each of the respective function of the organization (Purchase, HR, Engineering, Sales, Finance etc.).</p> <p>Interviews with relevant top management in relation to the organization's context and its strategic direction are also a good source of compliance evidence, such as: individual strategy or tactical plan documents written to underpin the organization's policies and provide a road map for achieving future goals.</p>	x				
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4.1	Organizational Context	2	Does your organization monitor and review information about these external and internal issues?	<p>External issues, examples could include:</p> <ol style="list-style-type: none"> 1. Reports relating to the your organization's competitive environment, new technologies, new markets, customer expectations, supplier intelligence, economic conditions, political considerations, investment opportunities, social factors; 2. Identification of factors relating to changing legislation and regulation; 3. Feedback relating to product/service performance and lessons learned; 4. Register of identified external risks and their treatment. <p>Internal issues, examples could include:</p> <ol style="list-style-type: none"> 1. Organizational structure, identification of roles/responsibilities and governance arrangements; 2. Reports on how well the organization is performing, statements relating to mission, vision and core values; 4. Feedback obtained from employees, e.g. survey results; 5. Information and processes for capturing and sharing knowledge and lessons learned; 6. Organizational capability studies: load/capacity, resource requirements to achieve demand; 7. Register of identified internal risks and their treatment. 	x				
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			Does your organization determine the interested parties that are relevant to the organization's purpose and strategic direction?	Examples of interested parties include: customers, partners, end users, external providers, owners, shareholders,					
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