

ISO 9001:2015 Master Internal Audit Checklist

The internal audit checklist will ensure your audits concisely appraise your management system and processes 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 audit question phrases each ISO 9001:2015 'shall' requirement as a question, in order to elicit either a 'yes' or 'no' response, that can be represented as an 'x'. The scoring formula assumes each requirement conforms, until an 'x' is entered into Column F or G.

Enter 'x' into Column E, F or G. Capture OFIs in Column H.

Audit Finding

Describe the possible cause of the minor or major nonconformance.

Provide a reference to the documentation, records, observations, questioning, etc. supporting the answer each audit finding.

Note any process or practice that seems weak, cumbersome, redundant or complex.

Audit Risk Score

Clause	Clause Title	Q-No	Audit Question	Audit Finding				Possible Root-cause	Audit Evidence & Notes	Opportunities to Improve	Status %
				Conform	Minor NC	Major NC	OFI				
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?	x						100	
4.1	Organizational Context	2	Does your organization monitor and review information about these external and internal issues?	x						100	
4.2	Relevant Interested Parties	3	Does your organization determine the interested parties that are relevant to the quality management system?	x						100	
4.2	Relevant Interested Parties	4	Does your organization determine the requirements of these interested parties that are relevant to the quality management system?	x						100	
4.2	Relevant Interested Parties	5	Does your organization monitor and review information about these interested parties and their relevant requirements?	x						100	
4.3	Management System Scope	6	Does your organization determine the boundaries and applicability of the quality management system to establish its scope?	x						100	
4.3	Management System Scope	7	When determining this scope, has your organization considered the external and internal issues referred to in 4.1?	x						100	
4.3	Management System Scope	8	When determining this scope, has your organization considered the requirements of relevant interested parties referred to in 4.2?	x						100	
4.3	Management System Scope	9	When determining this scope, has your organization considered all relevant products, services and work-related activities, functions and physical boundaries to the quality management system?	x						100	
4.3	Management System Scope	10	Has your organization applied all the requirements of ISO 9001:2015 if they are applicable within the determined scope of the quality management system?	x						100	
4.3	Management System Scope	11	Does the scope state the types of products and services covered, and provide justification for any requirement of ISO 9001:2015 that your organization determines is not applicable to the scope of its quality management system?	x						100	
4.3	Management System Scope	12	Is the scope of your organization's quality management system available and maintained as documented information and available to interested parties and workers? (See 7.5.1a)	x						100	
4.4	Management System Processes	13	Has your organization established, implemented, maintained and continually improved its quality management system, including the processes needed and their interactions, in accordance with the requirements of ISO 9001:2015?	x						100	
4.4	Management System Processes	14	Has your organization determined the process required for the quality management system, including their interactions, in accordance with requirements and their application throughout the organization?	x			x			100	
4.4	Management System Processes	15	Has your organization determined the inputs required and the outputs expected from these processes?	x						100	
4.4	Management System Processes	16	Has your organization determined the sequence and interaction of these processes?		x					75	
4.4	Management System Processes	17	Has your organization determined and applied the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes?	x			x			100	
4.4	Management System Processes	18	Has your organization determined the resources needed for these processes and ensure their availability?			x				25	
4.4	Management System Processes	19	Has your organization assigned responsibilities and authorities for these processes?	x						100	
4.4	Management System Processes	20	Has your organization addressed the risks and opportunities as determined in accordance with the requirements of 6.1?	x						100	
4.4	Management System Processes	21	Has your organization evaluated these processes and implement any changes needed to ensure that these processes achieve their intended results?	x			x	Human - Understands, but did not follow procedure(s)		100	
4.4	Management System Processes	22	Does your organization improve the processes and the quality management system?	x				Materials - Not appropriate for the task		100	
4.4	Management System Processes	23	To the extent necessary, does your organization maintain documented information to support the operation of its processes?		x			Human - Inadequate management involvement		75	
4.4	Management System Processes	24	To the extent necessary, does your organization retain documented information to have confidence that the processes are being carried out as planned?	x				Human - Stress demands		100	
5.1.1	General	25	Has Top Management demonstrated leadership and commitment to the quality management system by taking accountability for the effectiveness of your organization's quality management system?	x				Materials - Not appropriate for the task		100	
5.1.1	General	26	Has Top Management demonstrated leadership and commitment to the quality management system by ensuring that your organization's environmental policies and objectives are established and documented, and are compatible your organization's goals (See 6.2) and its context (See 4.0)?	x				Human - Knowledge or training not adequate for the task		100	
5.1.1	General	27	Has Top Management demonstrated leadership and commitment to the quality management system by ensuring that quality requirements are integrated into your organization's business processes?			x		Environment - Disorderly workplace		25	
5.1.1	General	28	Does Top management demonstrate leadership and commitment with respect to the quality management system by promoting the use of the process approach and risk-based thinking?	x				Materials - Lack of raw material		100	
5.1.1	General	29	Has Top Management demonstrated leadership and commitment to the quality management system by ensuring that your organization has the required resources to implement it?	x			x	Machinery - Improper equipment installation		100	