

[organization name]

Appendix 1 – Internal Audit Checklist for ISO 9001:2015

ISO 9001 Clause	Requirement of the standard	Compliant Yes/No	Evidence
4.1-1	Did the organization determine external and internal issues relevant to its purpose?		
4.1-2	Does the organization monitor and review information about internal and external issues relevant to its purpose?		
4.2-1	Did the organization determine interested parties that are relevant to its QMS?		
4.2-2	Did the organization determine relevant needs and expectations of the interested parties?		
4.2-3			
4.3	Has the organization determined boundaries and applicability of its QMS?		
4.3-1	When determining the scope, had the organization considered external and internal issues referred to in 4.1?		
4.3-2			
4.3-3	When determining the scope, had the organization determined its services and products?		
4.3-4			
4.3-5	Did the organization exclude any requirement from the scope of its QMS?		
4.4-1			
4.4-2	Did the organization determine processes needed for its QMS?		
4.4-3			
4.4-4	Did the organization determine required inputs?		
4.4-5	Did the organization determine expected outputs from its processes?		
4.4-6			
4.4-7	Does the organization determine and apply the criteria and methods needed to ensure the effective operation and control of its processes?		
4.4-8			

Commented [9A1]: 1) Note 1: The term “documented information” means that the standard requires the organization to establish, document, apply, and maintain the procedure.

- 2)
- a)
- b)
- c)

3) Note 3: Documentation can be in any form and any type of medium.

Commented [9A2]: These are the requirements of the ISO 9001:2015 standard; you should also insert the specific requirements from your own documentation.

Commented [9A4]: To be filled in during the audit – records, verbal statements, or auditor’s personal observations that confirm the finding.

Commented [9A3]: To be filled in during the audit – fill in Yes or No depending on whether the company is compliant or not.

[organization name]

4.4-9	Did the organization determine the resources needed for its processes and ensure their availability?		
4.4-10			
4.4-11	Did the organization address the risks and opportunities as determined in accordance with the requirements of 6.1?		
4.4-12			
4.4-13			
4.4-14	Does the organization retain documented information to have confidence that the processes are being carried out as planned?		
5.1.1-1			
5.1.1-2	Does the top management take accountability for the effectiveness of the QMS?		
5.1.1-3			
5.1.1-4	Does the top management ensure that the Quality Policy and quality objectives are compatible with the context and strategic direction of the organization?		
5.1.1-5			
5.1.1-6			
5.1.1-7	Does the top management ensure availability of resources needed for the QMS?		
5.1.1-8			
5.1.1-9	Does the top management ensure that the QMS achieves its intended results?		
5.1.1-10			
5.1.1-11	Does the top management promote QMS improvement?		
5.1.1-12			

[organization name]

5.1.2-1			
5.1.2-2			
5.1.2-3	Did the top management ensure that risk and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed?		
5.1.2-4			
5.2.1-1	Did the top management establish, implement, and maintain the Quality Policy?		
5.2.1-2			
5.2.1-3			
5.2.1-4	Did the top management ensure that the Quality Policy includes a commitment to satisfy applicable requirements?		
5.2.1-5			
5.2.2-1	Did the organization ensure that the Quality Policy is maintained as documented information?		
5.2.2-2			
5.2.2-3	Does the organization ensure that the Quality Policy is available to relevant interested parties, as appropriate?		
5.3-1			
5.3-2	Does the top management assign responsibility and authority to ensure that the QMS conforms to the requirements of ISO 9001:2015?		
5.3-3			
5.3-4	Does the top management assign responsibility		

[organization name]

	and authority to ensure reporting on the performance of the QMS and on opportunities for improvement, in particular to top management?		
5.3-5	[Redacted]		
5.3-6	[Redacted]		
6.1.1-1	When planning for the QMS, did the organization consider the issues from 4.1 and 4.2 and determine the risks and opportunities?		
6.1.1-2	[Redacted]		
6.1.1-3	[Redacted]		
6.1.1-4	Does the organization prevent or reduce undesired effects?		
6.1.1-5	[Redacted]		
6.1.2-1	[Redacted]		
6.1.2-2	Does the organization plan how to integrate and implement the actions into its QMS processes?		
6.1.2-3	[Redacted]		
6.1.2-4	[Redacted]		
6.2.1-1	Did the organization establish quality objectives at relevant functions, levels, and processes needed for the QMS?		
6.2.1-2	[Redacted]		
6.2.1-3	[Redacted]		
6.2.1-4	When setting quality objectives, did the organization take into account applicable requirements?		
6.2.1-5	[Redacted]		
6.2.1-6	[Redacted]		
6.2.1-7	Does the organization communicate its quality objectives?		
6.2.1-8	[Redacted]		

[organization name]

6.2.1-9			
6.2.2-1			
6.2.2-1	When planning how to achieve its quality objectives, did the organization determine what resources will be required?		
6.2.2-2			
6.2.2-3	When planning how to achieve its quality objectives, did the organization determine completion date?		
6.2.2-4			
6.3-1	Did the organization carry out needed changes in a planned manner?		
6.3-2			
6.3-3	Does the organization consider the integrity of the QMS?		
6.3-4			
6.3-5	Does the organization ensure proper allocation or reallocation of responsibilities and authorities?		
7.1.1-1			
7.1.1-2	Does the organization consider the capabilities of, and constraints on, existing internal resources?		
7.1.2-1			
7.1.2-2	Does the organization determine and provide the persons necessary for the effective operation and control of its processes?		
7.1.3-1			
7.1.3-2			
7.1.4-1	Does the organization determine, provide, and maintain the environment necessary for achieving		

[organization name]

	operation and conformity of its processes?		
7.1.5.1-1	[blurred text]		
7.1.5.1-2	[blurred text]		
7.1.5.1-3	[blurred text]		
7.1.5.1-4	Does the organization retain appropriate documented information as evidence of the fitness for purpose of the monitoring and measurement resources?		
7.1.5.2-1	[blurred text]		
7.1.5.2-2	[blurred text]		
7.1.5.2-3	Does the organization safeguard its measuring equipment from adjustments, damage, or deterioration that would invalidate the calibration status and subsequent measurement results?		
7.1.5.2-4	Does the organization take appropriate action when measuring equipment is found to be unfit for its intended purpose?		
7.1.6-1	[blurred text]		
7.1.6-2	[blurred text]		
7.2-1	Does the organization determine necessary competence of its employees?		
7.2-2	[blurred text]		
7.2-3	[blurred text]		
7.2-4	[blurred text]		
7.3-1	Are employees aware of the Quality Policy?		
7.3-2	Are employees aware of relevant quality		

[organization name]

	objectives?		
7.3-3			
7.3-4			
7.4-1	Does the organization determine what it will communicate?		
7.4-2			
7.4-3	How does the organization determine with whom to communicate?		
7.4-4			
7.5.1-1	Does the organization's QMS include documented information required by the ISO 9001:2015 standard?		
7.5.1-2			
7.5.2-1			
7.5.2-2	Does the organization ensure appropriate format when creating and updating documented information?		
7.5.2-3			
7.5.3.1-1			
7.5.3.1-2	Does the organization ensure that its documented information is adequately protected?		
7.5.3.2-1			
7.5.3.2-2			
7.5.3.2-3	Does the organization address control of changes of its documented information in order to control it?		
7.5.3.2-4			
7.5.3.2-5	Does the organization control and identify documented information of external origin that is necessary for the planning and operation of the		

[organization name]

	QMS?		
7.5.3.2-6			
8.1-1			
8.1-2	Does the organization determine the requirements for its products and services?		
8.1-3			
8.1-4			
8.1-5	Does the organization determine the resources needed to achieve conformity to the product and service requirements?		
8.1-6			
8.1-7			
8.1-8	Does the organization determine and keep documented information to the extent necessary to demonstrate the conformity of products and services to their requirements?		
8.1-9			
8.1-10			
8.2.1-1	Does the communication with customers include providing information relating to products and services?		
8.2.1-2			
8.2.1-3			
8.2.1-4	Does the communication with customers include handling or controlling customer property?		
8.2.1-5			
8.2.2-1			

[organization name]

8.2.2-2			
8.2.2-3			
8.2.2-4	Can the organization meet the claims for the products and services it offers?		
8.2.3.1-1			
8.2.3.1-2			
8.2.3.1-3	Does the organization conduct a review of requirements not stated by the customer, but necessary for intended use, before committing to supply products and services to a customer?		
8.2.3.1-4			
8.2.3.1-5	Does the organization conduct a review of statutory and regulatory requirements applicable to products and services, before committing to supply products and services to a customer?		
8.2.3.1-6			
8.2.3.1-7	Does the organization ensure that contract or order requirements differing from those previously defined are resolved?		
8.2.3.1-8			
8.2.3.2-1	Does the organization retain documented information on any new requirements for the products and services?		
8.2.3.2-2			
8.2.4			

[organization name]

8.3.1			
8.3.2-1			
8.3.2-2	Does the organization consider the required process stages, including applicable design and development reviews?		
8.3.2-3			
8.3.2-4	Does the organization consider responsibilities and authorities involved in the design and development process?		
8.3.2-5			
8.3.2-6	Does the organization consider the need for involvement of customers and users in the design and development process?		
8.3.2-7			
8.3.2-8			
8.3.2-9	Does the organization consider the documented information needed to demonstrate that design and development requirements have been met in determining the stages and control for design and development?		
8.3.3-1			
8.3.3-2			
8.3.3-3	Does the organization consider information derived from previous similar design and development activities?		
8.3.3-4			
8.3.3-5			
8.3.3-6	Does the organization consider potential		

[organization name]

	consequences of failure due to the nature of the products and services?		
8.3.3-7			
8.3.3-8			
8.3.4-1	Does the organization apply controls to the design and development process to ensure that the results to be achieved are defined?		
8.3.4-2			
8.3.4-3			
8.3.4-4	Does the organization apply controls to the design and development process to ensure that validation activities are conducted, to ensure that the resulting products and services meet the requirements?		
8.3.4-5			
8.3.4-6			
8.3.5-1	Does the organization ensure that design and development outputs meet the input requirements?		
8.3.5-2			
8.3.5-3			
8.3.5-4			

[organization name]

8.3.5-5			
8.3.6-1			
8.3.6-2	Does the organization retain documented information on design and development changes?		
8.3.6-3			
8.3.6-4			
8.3.6-5	Does the organization retain documented information about the actions taken to prevent adverse impacts?		
8.4.1-1			
8.4.1-2	Does the organization apply controls to externally provided processes, services, or products when such kind of products and services are intended for incorporation into the organization's products and services?		
8.4.1-3			
8.4.1-4			
8.4.1-5			
8.4.1-6	Does the organization retain documented information of these activities and any necessary actions arising from the evaluations?		
8.4.2-1			
8.4.2-2			

[organization name]

8.4.2-3	Does the organization communicate to external providers its requirements for the approval of the release of products and services?		
8.4.2-4	Does the organization communicate to external providers its requirements for the control and monitoring of the external providers' performance to be applied by the organization?		
8.4.2-5	Does the organization communicate to external providers its requirements for the approval of the release of products and services?		
8.4.2-6	Does the organization communicate to external providers its requirements for the control and monitoring of the external providers' performance to be applied by the organization?		
8.4.2-7	Does the organization communicate to external providers its requirements for the approval of the release of products and services?		
8.4.2-8	Does the organization communicate to external providers its requirements for the control and monitoring of the external providers' performance to be applied by the organization?		
8.4.2-9	Does the organization communicate to external providers its requirements for the approval of the release of products and services?		
8.5.1-1	Do the organization's controlled conditions include the availability of documented information that defines the results to be achieved?		
8.5.1-2	Do the organization's controlled conditions include the availability of documented information that defines the results to be achieved?		
8.5.1-3	Do the organization's controlled conditions include the availability of documented information that defines the results to be achieved?		
8.5.1-4	Do the organization's controlled conditions include the availability of documented information that defines the results to be achieved?		
8.5.1-5	Do the organization's controlled conditions include the availability of documented information that defines the results to be achieved?		
8.5.1-6	Do the organization's controlled conditions include the availability of documented information that defines the results to be achieved?		
8.5.1-7	Do the organization's controlled conditions include the availability of documented information that defines the results to be achieved?		

[organization name]

	the appointment of competent persons, including any required qualifications?		
8.5.1-8	[blurred text]		
8.5.1-9	[blurred text]		
8.5.1-10	[blurred text]		
8.5.2-1	Does the organization use suitable means to identify outputs when it is necessary to ensure the conformity of products and services?		
8.5.2-2	[blurred text]		
8.5.2-3	[blurred text]		
8.5.2-4	Does the organization retain the documented information necessary to enable traceability?		
8.5.3-1	[blurred text]		
8.5.3-2	[blurred text]		
8.5.3-3	[blurred text]		
8.5.3-4	Does the organization retain documented information on what occurred when a customer's or external provider's property is lost, damaged, or otherwise found to be unsuitable for use?		
8.5.4-1	[blurred text]		
8.5.5-1	[blurred text]		
8.5.5-2	Does the organization consider statutory and		

[organization name]

	regulatory requirements in determining the extent of post-delivery activities that are required?		
8.5.5-3			
8.5.5-4			
8.5.5-5			
8.5.5-6	Does the organization consider customer feedback in determining the extent of post-delivery activities that are required?		
8.5.6-1			
8.5.6-2			
8.6-1	Does the organization implement planned arrangements, at appropriate stages, to verify that the product and service requirements have been met?		
8.6-2			
8.6-3			
8.6-4	Does the documented information on the release of products and services include evidence of conformity with the acceptance criteria?		
8.6-5			
8.7.1-1			
8.7.1-2	Does the organization take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services?		

[organization name]

8.7.1-3	[blurred text]		
8.7.1-4	[blurred text]		
8.7.1-5	[blurred text]		
8.7.1-6	Does the organization deal with nonconforming outputs by informing the customer?		
8.7.1-7	[blurred text]		
8.7.1-8	Does the organization verify conformity to the requirements when nonconforming outputs are corrected?		
8.7.2-1	[blurred text]		
8.7.2-2	[blurred text]		
8.7.2-3	Does the organization retain documented information that describes any concessions obtained?		
8.7.2-4	[blurred text]		
9.1.1-1	[blurred text]		
9.1.1-2	Does the organization determine the methods for monitoring, measurement, analysis, and evaluation needed to ensure valid results?		
9.1.1-3	[blurred text]		
9.1.1-4	[blurred text]		
9.1.1-5	Does the organization evaluate the performance and effectiveness of its QMS?		
9.1.1-6	[blurred text]		
9.1.2-1	[blurred text]		
9.1.2-2	Did the organization determine the methods for		

[organization name]

	obtaining, monitoring, and reviewing customer satisfaction information?		
9.1.3-1			
9.1.3-2			
9.1.3-3			
9.1.3-4	Does the organization use results of analysis to evaluate the performance and effectiveness of its QMS?		
9.1.3-5			
9.1.3-6			
9.1.3-7			
9.1.3-8	Does the organization use results of analysis to evaluate the need for improvements to its QMS?		
9.2.1-1	Does the organization establish, implement, and maintain an internal audit program(s)?		
9.2.1-2			
9.2.2-1			
9.2.2-2			
9.2.2-3	Did the organization define the audit criteria and scope of each audit?		
9.2.2-4			
9.2.2-5			
9.2.2-6			
9.3.2-1	When planning and carrying out management review, does the organization take into consideration the status of actions from previous management reviews?		
9.3.2-2			




[organization name]

9.3.2-3	When planning and carrying out management review, does the organization take into consideration information on the performance and effectiveness of its QMS?		
9.3.2-4			
9.3.2-5			
9.3.2-6			
9.3.2-7	When planning and carrying out management review, does the organization take into consideration information on nonconformities and corrective actions?		
9.3.2-8			
9.3.2-9			
9.3.2-10			
9.3.2-11	When planning and carrying out management review, does the organization take into consideration information on the adequacy of resources?		
9.3.2-12			
9.3.2-13			
9.3.3-1	Do management review outputs include decisions and actions related to opportunities for		

[organization name]

	improvement?		
9.3.3-2			
9.3.3-3			
9.3.3-4			
10.1-1	Does the organization determine and select opportunities for improvement?		
10.1-2	Does the organization implement any necessary actions to meet customer requirements and enhance customer satisfaction?		
10.1-3			
10.1-4			
10.1-5			
10.2.1-1	Does the organization take actions to control and correct any existing nonconformity?		
10.2.1-2			
10.2.1-3			
10.2.1-4	Does the organization determine the causes of the nonconformity?		
10.2.1-5			
10.2.1-6			
10.2.1-7			
10.2.1-8	When a nonconformity occurs, does the organization update risks and opportunities determined during planning (if necessary)?		
10.2.1-9			
10.2.1-10			
10.2.2-1	Does the organization retain documented		

[organization name]

	information as evidence of the nature of the nonconformities?		
10.2.2-2			
10.2.2-3			
10.3-1			
10.3-2	Does the organization consider the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities that should be addressed as part of continual improvement?		