

[organization name]

Appendix 1 – ISO 9001:2015 Internal Audit Checklist

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			
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			
4.3-4	Does the organization maintain documented information about the scope of its QMS?		
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			
4.4-6	Did the organization determine sequence and interaction of its processes?		
4.4-7			

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) Note 2: Scope of QMS can differ from one organization to another and depends on:

- a) Size and type of organization
- b) Complexity and interaction of processes
- c) Competence of employees.

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

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ISO 9001 Clause	Requirement of the standard	Compliant Yes/No	Evidence
4.4-8	Does the organization determine performance indicators, how to monitor and measure effective operation and control of its processes?		
4.4-9			
4.4-10	Did the organization assign the responsibilities and authorities for its processes?		
4.4-11			
4.4-12			
4.4-13	Does the organization improve the processes and the Quality Management System?		
4.4-14			
5.1.1-1	Does the top management demonstrate leadership and commitment to the QMS?		
5.1.1-2			
5.1.1-3	Does the top management ensure that the Quality Policy and quality objectives are established for the QMS?		
5.1.1-4			
5.1.1-5	Does the top management ensure integration of the QMS requirements into the organization's business processes?		
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?		

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ISO 9001 Clause	Requirement of the standard	Compliant Yes/No	Evidence
5.1.1-10	Does the top management ensure that QMS objectives are consistent with the requirements of the ISO 9001:2015 standard?		
5.1.1-11	Does the top management promote QMS improvement?		
5.1.1-12	Does the top management support other relevant management systems to demonstrate their conformity to applicable requirements?		
5.1.2-1	Does the top management demonstrate leadership and commitment with respect to customer focus?		
5.1.2-2	Does the top management ensure that customer requirements are determined, understood, and addressed?		
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	Does the top management ensure that the focus on enhancing customer satisfaction is addressed?		
5.2.1-1	Did the top management establish, implement, and maintain the Quality Policy?		
5.2.1-2	Does the top management ensure that the Quality Policy is applicable to the context and scope of the organization and supports its strategic direction?		
5.2.1-3	Does the top management ensure that the Quality Policy includes a commitment to satisfy applicable requirements?		
5.2.1-4	Did the top management ensure that the Quality Policy includes a commitment to satisfy applicable requirements?		
5.2.1-5	Does the top management ensure that the Quality Policy includes a commitment to continual improvement of the QMS?		
5.2.2-1	Does the top management ensure that the Quality Policy is communicated, understood, and applied within the organization?		
5.2.2-2	Did the top management ensure that the Quality Policy is communicated, understood, and applied within the organization?		

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ISO 9001 Clause	Requirement of the standard	Compliant Yes/No	Evidence
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 and authority to ensure reporting on the performance of the QMS and on opportunities for improvement, in particular to top management?		
5.3-5			
5.3-6			
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			
6.1.1-3	Does the organization enhance desirable effects?		
6.1.1-4			
6.1.1-5	Does the organization achieve improvement?		
6.1.2-1	Does the organization plan actions to address risks and opportunities?		
6.1.2-2			
6.1.2-3	Does the organization plan how to evaluate the effectiveness of these actions?		
6.1.2-4			

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ISO 9001 Clause	Requirement of the standard	Compliant Yes/No	Evidence
6.2.1-1	Are quality objectives consistent with the Quality Policy?		
6.2.1-2	When setting quality objectives, did the organization take into account applicable requirements?		
6.2.1-3	Does the organization monitor its quality objectives?		
6.2.1-4	Does the organization update its quality objectives, as appropriate?		
6.2.1-5	When planning how to achieve its quality objectives, did the organization determine what will be done?		
6.2.1-6	When planning how to achieve its quality objectives, did the organization determine completion date?		
6.2.1-7	When planning how to achieve its quality objectives, did the organization determine completion date?		
6.2.1-8	When planning how to achieve its quality objectives, did the organization determine completion date?		
6.2.1-9	When planning how to achieve its quality objectives, did the organization determine completion date?		
6.2.2-1	When planning how to achieve its quality objectives, did the organization determine completion date?		
6.2.2-2	When planning how to achieve its quality objectives, did the organization determine completion date?		
6.2.2-3	When planning how to achieve its quality objectives, did the organization determine completion date?		
6.2.2-4	When planning how to achieve its quality objectives, did the organization determine completion date?		
6.3-1	Did the organization carry out needed changes in a planned manner?		
6.3-2	Does the organization consider the integrity of the QMS?		
6.3-3	Does the organization consider the integrity of the QMS?		
6.3-4	Does the organization consider the integrity of the QMS?		

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ISO 9001 Clause	Requirement of the standard	Compliant Yes/No	Evidence
9.1.1	Does the organization ensure proper allocation or redistribution of responsibilities and authorities?		
9.1.2	Does the organization determine and provide the resources needed for the establishment, implementation, maintenance, and continual improvement of its QMS?		
9.1.3	Does the organization consider the capabilities of, and constraints on, existing internal resources?		
9.1.4	Does the organization determine and provide the generic resources for the effective implementation of its QMS?		
9.1.5	Does the organization determine and provide the generic resources for the effective operation and control of its processes?		
9.1.6	Does the organization determine, provide, and maintain the environment necessary for the operation of its processes?		
9.1.7	Does the organization determine, provide, and maintain the environment necessary for achieving operation and control of its processes?		
9.1.8	Does the organization determine, provide, and maintain the environment necessary for achieving operation and conformity of its processes?		
9.1.9	Does the organization determine and provide the resources needed to ensure valid and reliable results when monitoring and measuring is used to verify the conformity of products and services?		
9.1.10	Does the organization ensure that the provided resources are suitable for the specific type of monitoring and measurement activities?		
9.1.11	Does the organization ensure that the provided resources are maintained to ensure that continuing fitness for their purpose?		
9.1.12	Does the organization retain appropriate documented information as evidence of the fitness for purpose of the monitoring and measurement resources?		
9.1.13	Does the organization calibrate or verify measuring equipment?		
9.1.14	Does the organization calibrate or verify measuring equipment against measurement		

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ISO 9001 Clause	Requirement of the standard	Compliant Yes/No	Evidence
7.1.5.1	Does the organization determine the measurement standards?		
7.1.5.2	Does the organization implement measuring equipment from adjustments, damage, or deterioration that would invalidate the calibration status and subsequent measurement results?		
7.1.5.3	Does the organization take appropriate action when measuring equipment is found to be unfit for its intended purpose?		
7.1.6	Has the organization determined knowledge necessary for the operation of its processes and to achieve conformity of products and services?		
7.1.6.1	Does the organization assess current knowledge when determining necessity of additional knowledge?		
7.1.6.2	Does the organization determine necessary competencies of its employees?		
7.1.6.3	Does the organization ensure that employees are competent on the basis of appropriate education, training, or experience?		
7.1.6.4	Does the organization take action to support the necessary competencies, and evaluate the effectiveness of the action taken?		
7.1.6.5	Does the organization retain appropriate documented information as evidence of competence?		
7.1.7	Are employees aware of the 'Quality Policy'?		
7.1.8	Are employees aware of relevant quality objectives?		
7.1.9	Are employees aware of their contribution to the effectiveness of the QMS?		
7.1.10	Are employees aware of the implications of non-conforming to the QMS requirements?		
7.2.1	Does the organization determine what it will communicate?		
7.2.2	How does the organization determine what to communicate?		
7.2.3	How does the organization determine with whom to communicate?		
7.2.4	How does the organization determine when to communicate?		

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ISO 9001 Clause	Requirement of the standard	Compliant Yes/No	Evidence
7.1.1	Does the organization's QMS include documented information required by the ISO 9001:2015 standard?		
7.1.2	Does the organization's QMS include documented information determined by the organization as being necessary for the effectiveness of the QMS?		
7.1.3	Does the organization ensure appropriate identification and description when creating and updating documented information?		
7.1.4	Does the organization ensure appropriate format when creating and updating documented information?		
7.1.5	Does the organization ensure appropriate review and approval for suitability and adequacy?		
7.1.6	Does the organization ensure that its documented information is available and suitable for use, when and where it is needed?		
7.1.7	Does the organization ensure that its documented information is adequately protected?		
7.1.8	Does the organization address distribution, access, retrieval, and use of its documented information in order to control it?		
7.1.9	Does the organization address storage and preservation, including preservation of legibility, of its documented information in order to control it?		
7.1.10	Does the organization address control of changes of its documented information in order to control it?		
7.1.11	Does the organization address retention and disposition of its documented information in order to control it?		
7.1.12	Does the organization control and identify documented information of external origin that is necessary for the planning and operation of the QMS?		
7.1.13	Does the organization protect documented information from unintended alterations?		
8.1	Does the organization plan, implement, and control its processes needed to meet the requirements for the provision of products and services?		

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ISO 9001 Clause	Requirement of the standard	Compliant Yes/No	Evidence
8.1.1	Does the organization determine the requirements for its products and services?		
8.1.2	Does the organization establish criteria for the processes?		
8.1.3	Does the organization establish criteria for competence of products and services?		
8.1.4	Does the organization determine the resources needed to achieve conformity to the product and service requirements?		
8.1.5	Does the organization implement control of the processes in accordance with the criteria?		
8.1.7	Does the organization determine and keep documented information to the extent necessary to have confidence that the processes have been carried out as planned?		
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	Does the organization control planned changes and assess the consequences of unintended changes?		
8.1.10	Does the organization ensure that outsourced processes are controlled?		
8.2.1.1	Does the communication with customers include providing information relating to products and services?		
8.2.1.2	Does the communication with customers include handling inquiries, contracts, or orders, including changes?		
8.2.1.3	Does the communication with customers include obtaining customer feedback related to product and services, including complaints?		
8.2.1.4	Does the communication with customers include handling or controlling customer property?		
8.2.1.5	Does the communication with customers include establishing specific requirements for contingency actions, when relevant?		
8.2.1.6	Does the organization ensure that the requirements for the products and services are defined?		
8.2.1.7	Do the requirements for the products and services include any applicable statutory and regulatory requirements?		

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ISO 9001 Clause	Requirement of the standard	Compliant Yes/No	Evidence
9.1.1	Do the requirements for the products and services include those considered necessary by the organization?		
9.1.2	Can the organization meet the claims for the products and services it offers?		
9.1.3	Does the organization ensure that it has the ability to meet the requirements for products and services to be offered to customers?		
9.1.4	Does the organization conduct a review of requirements specified by the customer, before committing to supply products and services to a customer?		
9.1.5	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?		
9.1.6	Does the organization conduct a review of requirements specified by the organization, before committing to supply products and services to a customer?		
9.1.7	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?		
9.1.8	Does the organization conduct a review of contract or order requirements to determine whether they differ from those previously approved?		
9.1.9	Does the organization ensure that contract or order requirements differing from those previously approved are resolved?		
9.1.10	Does the organization confirm the customer's requirements before acceptance, when the customer does not provide a documented statement of their requirements?		
9.1.11	Does the organization retain documented information on any new requirements for the products and services?		
9.1.12	Does the organization retain documented information about recalls of the order?		
9.1	When the requirements for products and services are changed, does the organization ensure that relevant documented information is		

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ISO 9001 Clause	Requirement of the standard	Compliant Yes/No	Evidence
8.1	Does the organization consider the needs and wishes of its customers and other interested parties?		
8.1.1	Does the organization consider the requirements for the design and development process that is appropriate to ensure the subsequent production of products and services?		
8.1.1.1	Does the organization consider the nature, duration, and complexity of the design and development activities?		
8.1.1.2	Does the organization consider the required process steps, including applicable design and development control?		
8.1.1.3	Does the organization consider required design and development verification and validation activities?		
8.1.1.4	Does the organization consider responsibilities and authorities involved in the design and development process?		
8.1.1.5	Does the organization consider internal and external resources used for the design and development process?		
8.1.1.6	Does the organization consider the need for involvement of customers and users in the design and development process?		
8.1.1.7	Does the organization consider requirements for subsequent production of products and services?		
8.1.1.8	Does the organization consider the level of control required for the design and development process by customers and other relevant interested parties?		
8.1.1.9	Does the organization consider the documented information needed to demonstrate that design and development requirements have been met in determining the design and control for design and development?		
8.1.1.10	Does the organization determine requirements essential for the specific types of products and services to be designed and developed?		
8.1.1.11	Does the organization consider functional and performance requirements?		
8.1.1.12	Does the organization consider information derived from previous similar design and development activities?		

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8.1.1	Does the organization consider customer and regulatory requirements?		
8.1.2	Does the organization consider standards or codes of practice that the organization has committed to implement?		
8.1.3	Does the organization consider potential consequences of failure due to the nature of the products and services?		
8.1.4	Does the organization use adequate inputs for design and development?		
8.1.5	Does the organization resolve conflicting design and development, when discovered?		
8.1.6	Does the organization apply controls to the design and development process to ensure that the needs to be achieved are defined?		
8.1.7	Does the organization apply controls to the design and development process to ensure that reviews are conducted, to evaluate the ability of the results of design and development?		
8.1.8	Does the organization apply controls to the design and development process to ensure that verification activities are conducted, to ensure that the design and development outputs meet the requirements?		
8.1.9	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?		
8.1.10	Does organization apply controls to the design and development process to ensure that any necessary actions are taken on problems discovered during the review, or verification and validation activities?		
8.1.11	Does the organization document information about applied controls to the design and development process?		
8.1.12	Does the organization ensure that design and development outputs meet the legal requirements?		
8.1.13	Does the organization ensure that design and development outputs are adequate for the subsequent processes for the provision of products and services?		

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8.1001	Does the organization ensure that design and development outputs include or reference monitoring and measuring requirements, as applicable, and acceptance criteria?		
8.1002	Does the organization ensure that design and development outputs specify the characteristics of the products and services that are essential for their intended purposes and their safe and proper use?		
8.1003	Does the organization retain documented information on design and development output?		
8.1004	Does the organization identify, review, and control changes made during design and development of products and services?		
8.1005	Does the organization retain documented information on design and development changes?		
8.1006	Does the organization retain documented information on the results of review?		
8.1007	Does the organization retain documented information about the authorization of the changes?		
8.1008	Does the organization retain documented information about the actions taken to prevent adverse impact?		
8.1009	Does the organization ensure that externally provided processes, products, and services conform to requirements?		
8.1010	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?		
8.1011	Does the organization apply controls to externally provided processes, services, or products when provided directly to the customer by external providers on behalf of the organization?		
8.1012	Does the organization apply controls to externally provided processes, services, or products when necessary, or its parts, is provided by an external provider as a result of a decision by the organization?		

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9.1.1	Does the organization determine and apply criteria for the evaluation, selection, monitoring of performance and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with the requirements?		
9.1.2	Does the organization retain documented information of those activities and any necessary actions arising from the evaluation?		
9.1.3	Does the organization ensure the adequacy of requirements prior to their communication to the external provider?		
9.1.4	Does the organization communicate to external providers its requirements for the processes, products, and services to be provided?		
9.1.5	Does the organization communicate to external providers its requirements for the approval of products and services?		
9.1.6	Does the organization communicate to external providers its requirements for the approval of methods, processes, and equipment?		
9.1.7	Does the organization communicate to external providers its requirements for the approval of the release of products and services?		
9.1.8	Does the organization communicate to external providers its requirements for the competence of persons, including any required qualifications?		
9.1.9	Does the organization communicate to external providers its requirements for the external provider's interaction with the organization?		
9.1.10	Does the organization communicate to external providers its requirements for the control and monitoring of the external provider's performance to be applied by the organization?		
9.1.11	Does the organization communicate to external providers its requirements for the verification of customer activities that the organization, or its customer, intends to perform at the external provider's premises?		
9.1.12	Does the organization ensure the adequacy of requirements prior to their communication to the external provider?		

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9.1.1	Has the organization communicated to the external provider its requirements for the processes, products, and services to be provided?		
9.1.2	Has the organization communicated to the external provider its requirements for the approval of products and services, methods, processes and measurements, and the release of products and services?		
9.1.3	Has the organization communicated to the external provider its requirements for competence, including any required qualifications of persons?		
9.1.4	Has the organization communicated to the external provider its requirements for the external provider's interaction with the organization?		
9.1.5	Has the organization communicated to the external provider its requirements for control and monitoring of the external provider's performance to be applied by the organization?		
9.1.6	Has the organization communicated to the external provider its requirements for verification or validation activities that the organization, or its customer, intends to perform at the external provider's premises?		
9.1.7	Does the organization implement production and service processes under controlled conditions?		
9.1.8	Do the organization's controlled conditions include the availability of documented information that defines the characteristics of the products to be produced, the services to be provided, or the activities to be performed?		
9.1.9	Do the organization's controlled conditions include the availability of documented information that defines the results to be achieved?		
9.1.10	Do the organization's controlled conditions include the availability and use of suitable monitoring and measuring resources?		
9.1.11	Do the organization's controlled conditions include the implementation of monitoring and measurement activities at appropriate stages of work that confirm the control of processes at		

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[organization name]

ISO 9001 Clause	Requirement of the standard	Compliant Yes/No	Evidence
8.5.1	Do the organization's controlled conditions include the use of suitable infrastructure and environment for the operation of processes?		
8.5.2	Do the organization's controlled conditions include the appointment of competent persons, including any required qualifications?		
8.5.3	Do the organization's controlled conditions include the selection and periodic re-evaluation of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified subsequent monitoring or measurement?		
8.5.4	Do the organization's controlled conditions include the implementation of actions to prevent human error?		
8.5.5	Do the organization's controlled conditions include implementation of release, delivery, and post-delivery activities?		
8.5.6	Does the organization use suitable means to identify outputs when it is necessary to ensure the conformity of products and services?		
8.5.7	Does the organization identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision?		
8.5.8	Does the organization control the output identification of the outputs when traceability is a requirement?		
8.5.9	Does the organization retain the documented information necessary to enable traceability?		
8.5.10	Does the organization ensure use with property belonging to customers or external providers?		
8.5.11	Does the organization identify, verify, protect, and safeguard customers' or external provider property provided for use or incorporation into the products and services?		
8.5.12	Does the organization report to the customer or external provider when their property is lost, damaged, or otherwise found to be unsuitable for use?		

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[organization name]

ISO 9001 Clause	Requirement of the standard	Compliant Yes/No	Evidence
8.5.3.1	Does the organization retain documented information on what occurred after a customer's or customer provider's property is lost, damaged, or otherwise found to be unavailable for use?		
8.5.3.2	Does the organization preserve the customer during production and service processes, to the extent necessary to ensure conformity to requirements?		
8.5.3.3	Does the organization retain requirements for post-delivery activities associated with the products and services?		
8.5.3.4	Does the organization consider customer and regulatory requirements in determining the extent of post-delivery activities that are required?		
8.5.3.5	Does the organization consider the potential customer consequences associated with its products and services in determining the extent of post-delivery activities that are required?		
8.5.3.6	Does the organization consider the nature, use, and intended lifetime of its products and services in determining the extent of post-delivery activities that are required?		
8.5.3.7	Does the organization consider customer requirements in determining the extent of post-delivery activities that are required?		
8.5.3.8	Does the organization consider customer feedback in determining the extent of post-delivery activities that are required?		
8.5.3.9	Does the organization monitor and control changes to production or service processes to the extent necessary to ensure continuing conformity with requirements?		
8.5.3.10	Does the organization retain documented information describing the results of the control of changes, the person authorizing the changes, and any necessary actions arising from the review?		
8.5.3.11	Does the organization implement planned arrangements, at appropriate stages, to verify that the product and service requirements have been met?		
8.5.3.12	Does the organization proceed with the release of products and services before delivery?		

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[organization name]

ISO 9001 Clause	Requirement of the standard	Compliant Yes/No	Evidence
8.2.1	Are requirements for each activity identified?		
8.2.2	Does the organization retain documented information on the release of products and services?		
8.2.3	Does the documented information on the release of products and services include evidence of conformity with the acceptance criteria?		
8.2.4	Does the documented information on the release of products and services include traceability to the person authorizing the release?		
8.2.5.1	Does the organization ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery?		
8.2.5.2	Does the organization take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services?		
8.2.5.3	Does the organization take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services directed after delivery of products, starting after the process?		
8.2.5.4	Does the organization deal with nonconforming outputs by correction?		
8.2.5.5	Does the organization deal with nonconforming outputs by segregation, containment, block or suspension of provision of products and services?		
8.2.5.6	Does the organization deal with nonconforming outputs by informing the customer?		
8.2.5.7	Does the organization deal with nonconforming outputs by obtaining authorization for acceptance under concession?		
8.2.5.8	Does the organization verify conformity to the requirements after nonconforming outputs are corrected?		
8.2.5.9	Does the organization retain documented information that describes the nonconformity?		
8.2.5.10	Does the organization retain documented information that describes the action taken?		
8.2.5.11	Does the organization retain documented information that describes any concessions obtained?		

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[organization name]

ISO 9001 Clause	Requirement of the standard	Compliant Yes/No	Evidence
8.2.1	Does the organization retain documented information that identifies the authority granting the order with respect to the nonconformity?		
8.2.2	Does the organization determine what needs to be monitored and measured?		
8.2.3	Does the organization determine the methods for monitoring, measurement, analysis, and evaluation needed to ensure conformity?		
8.2.4	Does the organization determine when the monitoring and measuring is performed?		
8.2.5	Does the organization determine when the results from monitoring and measurement shall be analyzed and evaluated?		
8.2.6	Does the organization evaluate the performance and effectiveness of its QMS?		
8.2.7	Does the organization retain appropriate documented information as evidence of the results?		
8.2.8	Does the organization monitor customer perception of the degree to which their needs and expectations have been fulfilled?		
8.2.9	Does the organization determine the methods for obtaining, monitoring, and reviewing customer satisfaction information?		
8.2.10	Does the organization analyze and evaluate appropriate data and information arising from monitoring and measurement?		
8.2.11	Does the organization use results of analysis to evaluate conformity of products and services?		
8.2.12	Does the organization use results of analysis to evaluate the degree of customer satisfaction?		
8.2.13	Does the organization use results of analysis to evaluate the performance and effectiveness of its QMS?		
8.2.14	Does the organization use results of analysis to evaluate if planning has been implemented effectively?		
8.2.15	Does the organization use results of analysis to evaluate the effectiveness of actions taken to address risks and opportunities?		
8.2.16	Does the organization use results of analysis to evaluate the performance of external providers?		
8.2.17	Does the organization use results of analysis to evaluate the need for improvements to its QMS?		

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[organization name]

ISO 9001 Clause	Requirement of the standard	Compliant Yes/No	Evidence
9.1.1	Does the organization establish, implement, and maintain an internal audit program?		
9.1.2	Does the organization determine the frequency, methods, responsibilities, planning requirements, and reporting of its internal audits?		
9.1.3	When establishing the internal audit program, does the organization take into account the results of previous audits?		
9.1.4	When establishing the internal audit program, does the organization take into account the importance of the processes concerned?		
9.1.5	Does the organization define the audit criteria and scope of each audit?		
9.1.6	Does the organization ensure the objectivity of the audit process?		
9.1.7	Does the organization communicate audit results to the relevant management?		
9.1.8	Does the organization document information about audits and audit results?		
9.1.9	Does the top management review the organization's QMS, at planned intervals, to ensure its continuing suitability, effectiveness, and alignment with the strategic direction of the organization?		
9.1.10	When planning and carrying out management review, does the organization take into consideration the status of actions from previous management review?		
9.1.11	When planning and carrying out management review, does the organization take into consideration changes in external and internal issues that are relevant to the QMS?		
9.1.12	When planning and carrying out management review, does the organization take into consideration information on the performance and effectiveness of the QMS?		
9.1.13	When planning and carrying out management review, does the organization take into consideration information on customer satisfaction and feedback from relevant interested parties?		
9.1.14	When planning and carrying out management review, does the organization take into		

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ISO 9001 Clause	Requirement of the standard	Compliant Yes/No	Evidence
9.1.1	When planning and carrying out management review, does the organization take into consideration information on the extent to which quality objectives have been met?		
9.1.2	When planning and carrying out management review, does the organization take into consideration information on process performance and conformity of products and services?		
9.1.3	When planning and carrying out management review, does the organization take into consideration information on nonconformities and corrective actions?		
9.1.4	When planning and carrying out management review, does the organization take into consideration information on monitoring and measurement results?		
9.1.5	When planning and carrying out management review, does the organization take into consideration information on audit results?		
9.1.6	When planning and carrying out management review, does the organization take into consideration information on the performance of external providers?		
9.1.7	When planning and carrying out management review, does the organization take into consideration information on the status of internal audits?		
9.1.8	When planning and carrying out management review, does the organization take into consideration information on the effectiveness of actions taken to address risks and opportunities?		
9.1.9	When planning and carrying out management review, does the organization take into consideration information on opportunities for improvement?		
9.1.10	Do management review outputs include decisions and actions related to opportunities for improvement?		
9.1.11	Do management review outputs include decisions and actions related to any needed changes to the QMS?		
9.1.12	Do management review outputs include decisions and actions related to resources needed?		

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ISO 9001 Clause	Requirement of the standard	Compliant Yes/No	Evidence
9.1.1	Does the organization retain documented information as evidence of the results of management review?		
9.1.2	Does the organization determine and select opportunities for improvement?		
9.1.3	Does the organization implement any necessary actions to meet customer requirements and enhance customer satisfaction?		
9.1.4	Does the organization improve products and services to meet requirements, as well as to address future needs and expectations?		
9.1.5	Does the organization correct, prevent, or reduce customer effects?		
9.1.6	Does the organization improve the performance and effectiveness of its QMS?		
9.2.1	Does the organization take action to control and correct any existing nonconformity?		
9.2.2	Does the organization evaluate the need for action to eliminate the causes of the nonconformity in order to prevent its recurrence?		
9.2.3	Does the organization review and analyze the nonconformity?		
9.2.4	Does the organization determine the cause of the nonconformity?		
9.2.5	Does the organization determine if similar nonconformities exist, or could potentially occur?		
9.2.6	When a nonconformity occurs, does the organization implement any action needed?		
9.2.7	When a nonconformity occurs, does the organization review the effectiveness of any corrective action taken?		
9.2.8	When a nonconformity occurs, does the organization utilize risk and opportunity determined during planning of resources?		
9.2.9	When a nonconformity occurs, does the organization make changes to the QMS if necessary?		
9.2.10	Does the organization undertake corrective action appropriate to the effects of the nonconformity concerned?		
9.2.11	Does the organization retain documented information as evidence of the nature of the nonconformity?		

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ISO 9001 Clause	Requirement of the standard	Compliant Yes/No	Evidence
9.1.1	Does the organization retain documented information as evidence of the achievement of its intended results?		
9.1.2	Does the organization retain documented information as evidence of the results of its corrective action?		
9.1.3	Does the organization continually improve the suitability, adequacy, and effectiveness of the SMS?		
9.1.4	Does the organization consider the results of audits and evaluations, and the outputs from management review, to determine if there are needs or opportunities that should be addressed as part of continual improvement?		

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