ISO 9001

Checklist

ISO 9001

Company Name

Authored By: Your Name

Online ISO

Do we comply?	Y/N
4.0 Context of the organization	
4.1 Understanding our organisation and its context	
1. Have you determined the goal(s) of the QMS?	
2. Have you identified the internal and external issues relevant to the purpose of the QMS?	
3. Have you determined how internal and external issues may impact the QMS's ability to achieve its intended results?	
4.2 Understanding the needs and expectations of interested parties	
4. Have you identified interested parties?	
5. Does the list of requirements from all interested parties exist?	
6. Is the scope documented with clearly defined boundaries and applicability?	
4.4 Quality management system and its processes	
7. Have you established, documented, implemented, maintained and continuously improved a Quality Management System management system according to ISO 9001 requirements?	
5.0 Leadership	
5.1 Leadership and Commitment	
8. Are the overall QMS objectives compatible with the strategic direction?	
9. Does management ensure that necessary QMS resources are available when needed?	
10. Does management ensure that QMS achieves the intended results?	
5.2 Policy	
11. Is there a quality management policy with included objectives or a framework for setting objectives?	
12. Is the quality management policy documented and communicated within the company and to other interested parties?	
5.3 Organizations Roles, Responsibilities & Authorities	
13. Are roles, responsibilities and authorities for quality management policies assigned and communicated?	
6.0 Planning	
6.1 Addressing risks and opportunities	
14. Are internal and external issues and stakeholder requirements taken into account when addressing risks and opportunities?	
15. Is there a documented process to identify quality management risks, including risk acceptance criteria and risk assessment criteria?	
16. Is the risk treatment process documented, including risk treatment options and how to prepare an applicability statement?	
6.2 Quality objectives and planning to achieve them	
17. Have quality management objectives been established for relevant functions of the organization, measured where practical and consistent with the quality management policy?	
18. Is there a plan or group of plans to achieve the quality management objectives, including the designated responsibility, evaluation method and resources and schedule for the plan(s)?	
7.0 Support	

Do we comply?	Y/N
7.1 Resources	
19. Are sufficient resources provided for all elements of the QMS?	
7.2 Competency, Awareness and Communication	
20. Is appropriate competency assessed and, where necessary, trained for staff carrying out tasks that may affect quality management? Is competency data kept?	
21. Are staff aware of the quality management policy, their role and the consequences of non-compliance?	
22. Is there a communication process regarding quality management, including responsibilities and what to communicate, with whom and when?	
7.5 Documentation and Records	
23. Does the QMS documentation include the quality management policies, objectives and goals, the scope of the QMS, its key elements and their interaction, documents and records of ISO 9001 and those identified by the company?	
24. Is management of documents and records ensured, including who reviews and approves documents, and where and how they are published, stored and protected?	
25. Is documented information of external origin checked?	
8.0 Operations	
26. Does the organization have the necessary documented information to ensure that its processes are carried out as planned?	
27. Are planned changes checked? Are the impacts of unplanned changes assessed to identify mitigation measures if necessary?	
28. Are outsourced processes identified and controlled?	
29. Have the risks, their owners, probability, consequences and risk level been identified? Are these results documented?	
30. Is there a risk treatment plan approved by the risk owners?	
31. Is there a documented list of all necessary controls, with appropriate justification and implementation status?	
9.0 Performance	
9.1 Monitoring, measurement, analysis and evaluation	
32. Has it been defined what should be measured, with what method, who is responsible, who will analyze and evaluate the results?	
33. Are the measurement results documented, analyzed and evaluated by responsible persons?	
9.2 Internal audit	
34. Is there an audit program that defines timing, responsibilities, reporting, audit criteria and scope?	
35. Are internal audits conducted according to an audit programme, results reported via an internal audit report and relevant corrective actions highlighted?	
36. Is the management review conducted regularly and are the results documented in the meeting minutes?	
37. Has management decided on all critical issues important to the success of the QMS?	
10.0 Improvement	

Do we comply?	Y/N
10.1 Non-conformity and corrective action	
38. Does the organization respond to every deviation?	
39. Is the organization considering eliminating the cause of the deviation and taking corrective action if necessary?	
40. Are all deviations recorded, along with corrective actions?	
10.2 Continual improvement	
41. Is the QMS continuously updated to maintain its suitability, adequacy and effectiveness?	